Levels of awareness of procedural sedation and analgesia among non-anaesthesiologists

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Declaration

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

Signature

[Signature]

Signed at Morningside, Johannesburg

On this date 1 June 2014
Abstract

Procedural sedation and analgesia (PSA) is performed by a variety of non-anaesthesiologists in numerous hospital settings. PSA guidelines have been formulated by a number of organisations in order to standardise practice and improve patient safety. Despite this it was uncertain whether PSA practitioners were aware of and used these guidelines, and whether the recommended equipment and drugs required for the safe delivery of PSA are available.

The purpose of this research was to assess the demographic profile of non-anaesthesiologist PSA providers at Chris Hani Baragwanath Academic Hospital (CHBAH), their awareness of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010 and their level of comfort when performing PSA. An audit of available equipment and drugs in PSA settings outside the operating theatre was also done.

The study revealed a gap in guideline knowledge, with respondents scoring a mean of 63.06%. The study also revealed that junior doctors performed better than consultants (p=0.008), but were more likely to feel uncomfortable administering PSA (0.031). A significant relationship between pharmacology knowledge and levels of comfort was also revealed, with those scoring higher in this section being more comfortable identifying and managing complications related to PSA (p=0.014).

The equipment and drug audit identified many deficiencies in some of the locations assessed. These locations will require major improvements in order to increase patient safety. The audit also identified locations that are well equipped that only require minor improvements.

PSA offers an alternative to general anaesthesia in a theatre environment; however, in order to ensure patient safety, practitioners need to adhere to recommended practice guidelines and the required equipment and drugs need to be readily available.
Acknowledgements

I would like to express my heartfelt gratitude to a number of people who were involved in this project.

To Juan Scribante and Helen Perrie: without your expertise, knowledge, support, guidance and sheer willpower, this project would not have grown and developed as smoothly as it did nor would it have reached its full potential. Your many long nights, patience and attention to detail are appreciated beyond measure.

To Paul, my Boo: Firstly, I would like to thank you for your technical expertise. Your help churning the data on Excel, constructing graphs and general IT aid saved me an immense amount of both time and frustration. Secondly, I would like to thank you for your support and encouragement throughout the project.

To Prof Lundgren: thank you for providing structured time to enable me to complete this project. Also thank you for helping to tackle issues when they arose.

To Prof Dickerson, Prof Smith, Prof Ally, Prof Nagdee, Prof Ramokgopa and Prof Huddle: thank you for allowing me to collect data in each of your departments.

To Dr Saffy: thank you for your assistance with distributing and collecting questionnaires in the Department of Emergency Medicine.

To the respondents: thank you for taking the time to complete the questionnaires.
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List of Abbreviations

1. PSA  Procedural sedation and analgesia
2. CHBAH  Chris Hani Baragwanath Academic Hospital
3. ASA  American Society for Anesthesiologists
4. SASA  South African Society of Anaesthesiologists
5. ESA  European Society of Anaesthesiology
6. EM  Emergency medicine
7. WFSA  World Federation of
8. ACEP  American College of Emergency Physicians
9. EMSSA  Emergency Medicine Society of South Africa
10. AGA  American Gastroenterology Association
11. IV  Intravenous
12. MAC  Monitored anaesthesia care
13. BLS  Basic life support
14. ACLS  Advanced cardiac life support
15. ATS  American Thoracic Society
16. RCA  Royal College of Anaesthesia
Chapter One  Overview of the research

1.1 Introduction

The assessment of procedural sedation and analgesia (PSA) practices at Chris Hani Baragwanath Academic Hospital (CHBAH) was performed in order to understand who is responsible for its administration, the level of awareness of PSA guidelines and the level of comfort felt by those administering PSA. This chapter provides an overview of the area that was studied and includes the background to the study; the problem statement; the aims and objectives; relevant definitions and a brief overview of methodology that was followed. The significance of this study for CHBAH will also be discussed.

1.2 Background

PSA has been widely used since its origin in dental anaesthesia in the 1970’s. Since that time, the advancement in the pharmaceutical industry has led to the evolution and discovery of many new short-acting drugs and refined knowledge of pharmacokinetic principles. This has led to PSA becoming a widely accepted and practised alternative to general anaesthesia but has simultaneously required the formulation of specific guidelines for the safe practice of PSA.

PSA aims to achieve levels of sedation for diagnostic and therapeutic interventions in which the patient is able to maintain cardiorespiratory function. The techniques also aim to provide appropriate analgesia and amnesia for procedures that are otherwise disagreeable to patients. Currently PSA is employed in both medical and surgical settings, including radiology, gastroenterology, plastic surgery, dermatology, cardiology and the emergency department (ED) setting.

PSA offers an attractive alternative to general anaesthesia as it reduces hospital stay and operating room time. Thus resources, both financial and human may be more efficiently utilised. The demand for health services is ever-growing and it is not a uniquely South African phenomenon that the demand for hospital beds and operating room time is increasing. The cost of performing a procedure with PSA rather than under general anaesthesia is also much reduced. The option, therefore, to perform certain procedures
under PSA offers an appealing alternative (5). Furthermore trained non-anaesthesiologists are able to provide PSA thereby reducing the workload on a diminishing number of anaesthesiologists (6).

The increasing use of PSA has also required professional bodies to provide guidelines to ensure consistent standards of care and patient safety. Sedation has traditionally formed part of the discipline of anaesthesia. International societies, such as the American Society for Anesthesiologists (ASA) and the European Society of Anaesthesiology (ESA) and national societies, such as the South African Society of Anaesthesiologists (SASA), have published guidelines for PSA (2, 3, 8, 9). Emergency medicine (EM) and gastroenterology are specialities that employ PSA commonly and therefore their governing bodies have also published speciality-specific guidelines (10-13). The guidelines provide direction with regard to personnel and their skills requirements, drugs and dosing, monitoring equipment, and detail patient selection and evaluation criteria.

The multiple guideline sources serve to emphasise the importance of following policies and protocols in order to avoid adverse patient outcomes. The incidence of adverse events is difficult to assess due to inconsistent findings in research conducted across the disciplines that employ PSA (14). ASA liability claims for 2009 show that procedures performed outside the operating room had a higher incidence of death compared to operating room procedures, with 50% of remote location deaths involving PSA. Respiratory dysfunction was found to be the most common complication. (15) Complication rates in South Africa show a mortality rate of 1 per 7500–11 000 endoscopic procedures and 0.03% of all procedures using PSA (16). These figures may appear low but are of concern as they are higher than those for general anaesthesia for outpatient procedures (1). Anecdotally it is also known that adverse events are under-reported.

1.3 Problem statement

The doctors of CHBAH make use of PSA techniques in a number of departments; however, it has been observed that the regulations formulated by SASA to ensure the safe performance of PSA are unfamiliar to some health care professionals involved. Furthermore, there is no record that anyone has ascertained whether the recommended equipment and drugs required for the safe delivery of PSA are available.
The perceived consequences of these inadequacies are that PSA is being provided by personnel who may lack the necessary knowledge and skill to offer a safe procedure by being ill-equipped to deal with possible complications that may arise. In addition, procedural and emergency equipment and drugs may not be available. This places patients at an increased risk of adverse events.

1.4 Purpose

The purpose of this research was to describe the profile of non-anaesthesiologist PSA providers at CHBAH, their awareness of the SASA Sedation Guidelines 2010 and their level of comfort when performing PSA. The available equipment and drugs in PSA settings outside the operating theatre complexes was also assessed.

1.5 Objectives

The objectives of the study were to:

- describe the professional level of respondents
- describe respondent PSA and resuscitation training
- describe the locations and procedures for which PSA is performed
- assess the level of awareness of PSA guidelines (SASA)
- describe the comfort level of practitioners when performing PSA
- compare the level of PSA knowledge by professional level
- compare the level of PSA knowledge by clinical department
- compare the level of comfort by professional level
- audit the availability of recommended drugs and equipment.

1.6 Research definitions

The following definitions will be used in the study.

**PSA**: procedural sedation and analgesia is the use of pharmacological and non-pharmacological methods to reduce patients’ discomfort or pain and anxiety associated with a procedure.
ASA physical status classification: the American Society of Anesthesiologist’s risk assessment for patients undergoing anaesthesia. The classification is detailed in Table 1.1.

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A normal healthy patient</td>
</tr>
<tr>
<td>II</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>III</td>
<td>A patient with severe systemic disease</td>
</tr>
<tr>
<td>IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>V</td>
<td>A moribund patient who is not expected to survive without the operation</td>
</tr>
</tbody>
</table>

Emergency medicine department/casualty: the department responsible for the initial assessment, triage and management of patients. Patients will either be treated and discharged or triaged to one of the following areas for further management.

Internal medicine casualty: the area that is responsible for assessment and management of patients with medical complaints;

Surgical casualty: the area that is responsible for assessment and management of patients with general surgical complaints;

Orthopaedic casualty: the area that is responsible for assessment and management of patients with orthopaedic complaints;

Trauma casualty: the area that is responsible for assessment and management of patients with trauma.

Intern: a doctor who has graduated from university and is completing further supervised training for a period of two years. This category of doctors is not registered by the HPCSA for independent practice.

Community service doctor: a doctor who is completing his/her community service as prescribed by the HPCSA prior to being granted full registration for independent practice. This
doctor has usually completed two years internship which is acknowledged as an extended period of training following graduation with a medical degree.

**Medical officer:** a doctor employed by the provincial government in a designated medical officer post. This doctor may have no formal postgraduate training in the discipline in which he/she may practice.

**Registrar:** is a doctor who is in the process of acquiring a specialist qualification endorsed by the HPCSA for specialist practice.

**Consultant:** a doctor who has a specialist qualification for a specified field endorsed by the HPCSA.

**Anaesthesiologist:** a doctor who has a specialist qualification endorsed by the HPCSA for specialist anaesthesiology practice. This status may be conferred on doctors who have obtained the Fellowship of the College of Anaesthesia or a MMed (Anaesthesia) from a university.

**Non-anaesthesiologist:** a medical doctor or nurse who does not have specialist anaesthesia training but may be involved in administering anaesthesia and related services such as PSA.

**Observer:** a medical professional (doctor or nurse) responsible for monitoring a patient during and after the administration of PSA.

**Operator:** a medical doctor responsible for performing a procedure in which PSA is required.

**Sedation practitioner/sedationist:** a medical professional responsible for administering sedation and/or analgesia drugs, and monitors the clinical effects of these drugs.
1.7 Demarcation of study field

The study was conducted at CHBAH and involved the departments of general surgery, trauma, radiology, emergency medicine, orthopaedic surgery and internal medicine. The physical locations audited were:

- radiology computed tomography (CT) scanner suite
- medical casualty
- endoscopy suites - upper and lower endoscopy suites
- endoscopic retrograde cholangiopancreatography (ERCP) suite
- emergency medicine department
- surgery casualty
- trauma casualty and resuscitation area
- orthopaedics casualty procedure room.

In the study these departments will be referred to as “the departments”.

1.8 Ethical considerations

Verbal assent was obtained from the heads of departments of general surgery, trauma, radiology, emergency medicine and orthopaedic surgery prior to the proposal being submitted to the Human Research Ethics Committee (Medical) of the University of the Witwatersrand.

Ethics approval was obtained from the Human Research Ethics Committee (Medical) (Appendix 1) and permission was granted by the Post-Graduate Committee of the University of the Witwatersrand (Appendix 2), the CHBAH Medical Advisory Committee (Appendix 3) and from the Heads of Departments of general surgery, trauma, radiology, emergency medicine and orthopaedic surgery (Appendix 4).

Upon assent from the listed departments, a self-administered questionnaire was distributed to potential participants. The questionnaire contained an information letter (Appendix 5) detailing the purpose of the study, ethics and CHBAH approval and the rights of participants to anonymity and withdrawal. The agreement to complete the questionnaire (Appendix 6) implied consent. Anonymity of participants and questionnaires was ensured by not recording
participants’ names on the questionnaires. Furthermore, confidentiality was ensured as the researcher and supervisors were the only people who had access to the raw data.

The study was conducted in adherence to the principles of the Declaration of Helsinki (18).

1.9 Research methodology

1.9.1 Research design

A cross-sectional prospective, descriptive, contextual study design was used.

1.9.2 Study population

Doctors working in the general surgery, trauma, radiology, emergency medicine, orthopaedic surgery and internal medicine belonging to the professional levels second year intern, community service officer, medical officer, registrar and consultant formed the population group studied. All interns in their second year of internship were selected as they would have had sufficient exposure to PSA during their clinical rotations in their first year. It is acknowledged that some of these interns will have rotated through anaesthesia, and would have had some formal exposure to sedation practice. First year interns were thus excluded as their exposure to PSA would be limited.

1.9.3 Study sample

Sample size

All doctors in the departments were identified and eligible to participate. A sample was realised from the number of respondents.

Sampling method

All members within the departments were identified. A convenience sampling method was used for registrars as this group of doctors rotate amongst three academic hospitals affiliated to the University of the Witwatersrand. Registrars who were rotating through CHBAH at the time of the study were selected.
Inclusion and exclusion criteria

Inclusion criteria

- Medical doctors from the departments of general surgery, trauma, orthopaedic surgery, radiology, emergency medicine and internal medicine
- Professional levels second year intern, community service officer, medical officer, registrar and consultant.

Exclusion criteria

- Medical doctors who indicated that they were never involved in the administration of PSA at CHBAH
- Medical doctors who declined to participate.
- First year interns

1.9.4 Data collection

Questionnaire development

Data collection was done with the use of two tools: a self-administered questionnaire and an equipment and drugs audit checklist. The questionnaire was developed based on the 2010 SASA Guidelines for the provision of PSA to adults and was validated by an expert panel of anaesthesiologists, with sub-speciality in pain, to ensure content and face validity.

All medical doctors that fit the inclusion criteria were identified. The questionnaire was distributed to those who agreed to participate. Questionnaires were collected by the researcher and kept in a box to which only the researcher and supervisors had access.

Equipment and drugs audit

The PSA locations identified were audited according to the SASA Basic Equipment and Drugs for Procedural Sedation and Analgesia (PSA) (3) checklist (Appendix 7).

All data obtained from both the questionnaire and the audit was captured onto an Excel spread sheet for analysis. Quality control checks were done to ensure data was captured accurately.
1.9.5 Data analysis

Data was analysed using descriptive and inferential statistics with the assistance of a biostatistician. For descriptive analysis of data that are normally distributed, mean and standard deviation (SD) was used.

1.10 Significance of study

This study was the first to evaluate PSA practices at CHBAH and will provide a baseline understanding of PSA practices and the problems that surround its safe administration. Furthermore, it has laid a foundation for further studies to be conducted on this topic.

More specifically the information gathered has shed light onto who is responsible for PSA, their level of training, their awareness of SASA Sedation Guidelines and their level of comfort when administering PSA. In addition, deficits of equipment and drugs in PSA locations were ascertained. This information will assist in identifying areas for improvement, thus enabling directed measures to be taken to enhance patient safety when PSA is administered. The Department of Anaesthesiology is in the position to assist non-anaesthesiologists to make improvements by providing both knowledge and training to non-anaesthesiologists, and by directing suitable equipping of non-operating room settings with the required equipment and drugs.

1.11 Validity

Validity and reliability was ensured and will be detailed in chapter three.

1.12 Project outline

The study is presented as follows:

In chapter one an overview of the study was provided. A review of the relevant literature is presented in chapter two. Chapter three describes the research methodology in detail. The results and a discussion thereof are presented in chapter four. In chapter five a summary, limitations, recommendations and conclusions from the study is discussed.
In this chapter an overview of the study has been given. It has described the background; problem statement; aims and objectives; the research design and methodology; importance of the study and ethical considerations. In the next chapter a review of the literature related to the topic under research is presented.
Chapter Two  

Literature review

2.1 The concept of safe practice

An improvement in the standards of care in the conventional theatre setting has lead to a reduction in morbidity and mortality (19). This is due to the great emphasis being placed by anaesthesiology societies on patient safety and quality of care. The World Federation of Societies of Anaesthesiologists (WFSA) and the European Board of Medical Specialists have developed standards for safe anaesthesia practice in which mandatory requirements are detailed. These include pre, intra and post-anaesthesia assessment and monitoring guidelines. Standards for training, documentation and accreditation as well as professional and ethical conduct towards fellow health care providers and patients are discussed. (8, 20) While these standards are intended for anaesthesia professionals, and focus on requirements in an operating theatre, they also refer to the importance of training and assisting non-anaesthesiologists to provide safe anaesthesia care (20). PSA is provided by non-anaesthesiologists and hence these standards should be used to assist with its delivery.

Despite best efforts, there is often a large gap that exists between what evidence-based best practice advocates and reality (21). In order to bridge this gap, one needs to understand the contributing factors to its formation, and put structures in place to assist all involved with health care delivery to practise best practice (22). The field of PSA is but one area where such a gap may exist. A greater understanding of the problems with its delivery must be sought to improve patient safety.

2.2 PSA guideline development

The birth and subsequent growth of PSA occurred in the field of dentistry in the middle of the 20th century. Niels Jorgensen, Ed Driscoll and Norman Trieger were the first to combine general anaesthetic agents in sub-anaesthetic doses with local anaesthetic agents for dental procedures. This paved the road for Drs Harry Langa and Wayne Hiatt, who did pioneering work with nitrous oxide in oxygen for PSA. The American Dental Association’s Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry was drawn up in 1970, and served as the first guideline for PSA. (23)
The demand for PSA services has since grown rapidly, with an increase in procedures performed outside the operating theatre (24, 25). This trend, however, has been associated with a rise in morbidity and mortality when compared to procedures performed in the operating room (14, 26) thus necessitating the development of guidelines in order to standardise practice (1, 11) and to improve patient safety (2, 3). PSA has traditionally formed part of anaesthesia practice and therefore the SASA, ASA and ESA guidelines will be discussed in detail. The use of PSA has extended to multiple areas. As such the American College of Emergency Physicians (ACEP), the Emergency Medicine Society of South Africa (EMSSA) and the American Gastroenterology Association (AGA) represent some organisations that have formulated their own guidelines to suit their specific needs (10-12).

2.3 Understanding PSA

PSA encompasses a range of altered levels of consciousness and is a group of techniques employed for selected diagnostic and therapeutic procedures (3). The identified levels of sedation range from mild sedation or anxiolysis and progress to moderate sedation, deep sedation and finally general anaesthesia (2, 3). Each level is characterised by a specific response and cardiorespiratory parameters, as detailed in Table 2.1.

Table 2.1  Levels of sedation and physiological characteristics (2, 3)

<table>
<thead>
<tr>
<th></th>
<th>Mild Sedation/ anxiolysis</th>
<th>Moderate Sedation</th>
<th>Deep Sedation</th>
<th>General Anaesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsiveness</td>
<td>Responds to verbal stimuli</td>
<td>Purposeful response to verbal or tactile stimuli</td>
<td>Purposeful response to repeated or painful stimuli</td>
<td>Unable to rouse</td>
</tr>
<tr>
<td>Airway</td>
<td>Unaffected</td>
<td>No intervention required</td>
<td>Intervention may be required</td>
<td>Intervention often required</td>
</tr>
<tr>
<td>Spontaneous ventilation</td>
<td>Unaffected</td>
<td>Adequate</td>
<td>May be adequate</td>
<td>Frequently inadequate</td>
</tr>
<tr>
<td>Cardiovascular function</td>
<td>Unaffected</td>
<td>Usually maintained</td>
<td>Usually maintained</td>
<td>May be impaired</td>
</tr>
</tbody>
</table>
SASA also draws a distinction between simple and advanced sedation. Simple sedation is defined as sedation using only one of the following regimens:

- benzodiazepines via the oral, rectal or trans-mucosal route
- nitrous oxide in no less than 50% oxygen, inhaled
- intravenous (IV) midazolam, titrated to response but not exceeding 0.1mg/kg.

Advanced sedation is defined as:

- the use of a combination of drugs, via any route
- use of the IV route for drug administration (except IV midazolam)
- inhalational agents, except nitrous oxide in no less than 50% oxygen
- infusion techniques.(3)

The distinction is important due to the consequences for monitoring and fasting requirements. These will be discussed in their relevant sections.

2.4 Monitored anaesthesia care

The literature also refers to monitored anaesthesia care (MAC) in the context of sedation practice. It is often used interchangeably with moderate sedation but the distinction is important. The ASA defines MAC as the provision of sedation together with the ability to convert to general anaesthesia, and the ability to perform rescue measures should the level of sedation progress to deeper than anticipated levels. Thus it does not form part of the sedation continuum, but rather refers to PSA in which an anaesthesiologist is required. Moderate sedation, on the other hand, should never progress to the point of airway compromise and the need for general anaesthesia requirements. Additionally, a practitioner of MAC must be able to provide post-sedation care that extends beyond the requirements of moderate sedation. This includes ensuring a return to a normal level of consciousness, adequate levels of analgesia, and ensuring no adverse drug-related side-effects, for example postoperative nausea and vomiting. (27)

Interestingly, no reference is made to MAC in the ASA Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists (2), nor by SASA in the SASA Sedation Guidelines 2010 (3). This may be due to the fact that non-anaesthesiologists should not perform sedation at the MAC level as they do not possess the necessary knowledge or skill to do so (1).
A further distinction between MAC and sedation is made in the Basic Standards for Monitoring. Both the ASA and the WFSA reflect this (8, 28). MAC standards for basic anaesthetic monitoring are considered together with those for general and regional anaesthesia, thereby emphasising that MAC is an anaesthesiology-driven service (28). In contrast the PSA guidelines are intended for use by non-anaesthesiologists, and so a different set of standards has been drafted (2). The standards for monitoring for PSA performed by non-anaesthesiologists will be discussed in due course.

Despite the definitions provided some authors group moderate sedation and MAC together. For clarity this will be stated when reference is made to these articles.

2.5 Aims of PSA

The aims of PSA are worth consideration as these may assist with appropriate patient and procedure selection. SASA Guidelines state that PSA should aim to reduce patients’ discomfort or pain and anxiety associated with a procedure, ensuring patients’ safety and returning them to a state where they are eligible for discharge (3). Moreover, EMSSA states that PSA, while fulfilling these objectives, should minimise fluctuations in cardiorespiratory function and should not compromise the patient’s airway reflexes (11).

2.6 Adverse events associated with PSA

The growth in PSA has required investigation into the adverse events that occur during its use. This serves to assist medical professionals to be aware of pitfalls and take steps to improve patient safety. A number of studies examine the incidence and nature of adverse events that occur during PSA. These complications occur for a variety of reasons namely patient, sedationist, location and procedural factors. A pre-procedure assessment will alert the sedationist to potential problems and will determine ASA physiological status classification. (29) A classification of III or more is associated with a higher incidence of adverse events during PSA (30), thereby explaining the reason for the ASA and SASA recommendation to non-anaesthesiologists to avoid performing PSA in patients with this classification (2, 3). Other patient related risk factors are extremes of age, obesity, obstructive sleep apnoea and a known difficult airway. Sedationist factors relate to the level of knowledge and skills required for safe PSA practice. It is these factors that are discussed extensively in PSA guidelines (2, 3,
9-11, 13). Procedure related risk factors are those procedures in the facial or oral area, prone position and lengthy or complex procedures (26). Lastly, office-based PSA is associated with a higher complication rate (24), a reason potentially being the lack of support resources available in a hospital when complications do occur.

It must be noted that complication rates differ for a number of reasons, namely heterogeneity of study designs, drug protocols, procedures, definitions of adverse events, patient demographics and comorbidities, to name a few. The data presented does, however, provide some insight to common problems that arise during PSA.

Many of the studies examining adverse events are discipline specific; however, Pino (31) undertook to establish the overall complication rates associated with PSA at the Massachusetts General Hospital. Complications that occurred most frequently were respiratory in nature, with oxygen desaturation and apnoea in 0.12% of cases. Cardiovascular complications, most often hypotension, and nausea and vomiting occurred in 0.1% and 0.11% of cases respectively.

PSA is frequently used in the ED for a variety of surgical, medical and orthopaedic procedures. A number of studies have been done to establish complication rates such as A Canadian Community Effectiveness and Safety Study (ACCESS) (32) carried out in a Canadian community ED staffed by family physicians, specifically trained in PSA. The overall adverse incident rate was 18% with the most common event being apnoea in 10% of cases, followed by inadequate sedation (2.5%) and bradycardia (1.9%). There were no reports of serious adverse events such as cardiac arrest or respiratory depression requiring intubation. (32)

In contrast to the ACCESS study Campbell et al. (33) examined adverse events in a tertiary ED. Overall adverse events occurred in 1.7% of cases, with a 1% incidence of oxygen desaturation and 0.8% incidence of hypotension. Another recorded adverse event was a case of emergence agitation when ketamine was used. A further study that reviewed PSA practices from 14 ED’s showed an overall complication rate of 4.1%. This rate, however, did not vary with the presence of a dedicated sedationist. (33) Each of these studies took place in very different settings, with a variation in complication rates. This may be explained by the presence of added resources to train ED staff on PSA, and more stringent protocol adherence in a tertiary
environment. Despite the higher complication rate in the community ED setting, sedationists were able to identify and manage these problems with no serious consequences. (32)

Gastrointestinal tract (GIT) endoscopy is prolific in its research on PSA due to the growth in its use for endoscopic procedures. In 1995 Quine et al. (34) examined the incidence of both cardiac and pulmonary adverse events for upper GIT endoscopy and showed the incidence to be 0.5%. At that time PSA guidelines for endoscopy had not been developed, yet it was recognised that a lack of basic standards for monitoring and care may have contributed to the morbidity seen. (34) More recent studies chose to only look at respiratory adverse events. Rex et al. (35), in a study on trained nurse-administered sedation using propofol for endoscopic procedures, showed the incidence of respiratory adverse events to range between 1 per 500 cases to 1 per 1000 cases. A similar study showed respiratory adverse events, including apnoea, laryngospasm and aspiration, to occur in 0.7% of cases (36). While these studies provide a degree of insight to the nature and frequency of respiratory complications, they do not define the time period for apnoea nor do they comment on oxygen saturation, thereby underestimating these complications (31). Indeed, it is estimated that cardiopulmonary events account for 50% and 60% of endoscopy-related morbidity and mortality respectively (37).

ERCP is worth specific mention as it is a procedure commonly performed using PSA, with a large proportion of patients having an ASA classification of III or more. It is associated with the highest incidence of adverse events and has the highest incidence of sedation-related mortality, compared to general anaesthesia. (38)

While there is a great deal of international data available, there are few South African studies examining the incidence of PSA adverse events. Despite this it has been stated that while the complication rates are low, they are higher than those for general anaesthesia (1). Furthermore it is known that mortality occurs more frequently outside the operating theatre, with an estimated rate of one per 7500 – 11 000 endoscopic procedures and 0.03% of all procedures using PSA (16). Despite the paucity of South African data, anecdotally it is known that complications are under-reported, and so the incidence may indeed by higher. In keeping with the international literature however, cardiopulmonary complications occur with the greatest frequency (1).
The data discussed aims to shed light on adverse events associated with non-anaesthesiologist PSA but few studies compare anaesthesiologist to non-anaesthesiologist PSA adverse events (14). It is assumed that anaesthesiologists are better equipped to provide care given their training but only one study was found questioning this assumption. The study did show a reduced rate of cardiopulmonary complications when PSA is performed by an anaesthesiologist (30).

2.7 PSA Guidelines: Recommendations for Safe Practice

2.7.1 Personnel requirements for PSA

SASA Guidelines state that in order to provide safe PSA, a sedation team is required. The sedation practitioner is responsible for the pre-procedure assessment, administration of PSA and monitoring the patient until fully recovered and the operator is responsible for performing the procedure. The sedationist and operator may perform both duties for simple sedation techniques; however, a dedicated sedationist is required if advanced techniques are used. The observer is a second person responsible for monitoring the patient and should be able to assist with the management of complications. Recovery room personnel are also required. (3)

ASA Guidelines are not as clear on this topic. They echo the acceptability of the sedationist and operator performing a dual function and state that a dedicated observer is only required for deep sedation. For moderate sedation, the observer may be involved with other minor tasks once the patients’ vital signs have stabilised. (2)

Other: ESA Guidelines state that the sedationist and operator roles are performed by one practitioner, and that a dedicated observer must be present to monitor the patient during the procedure (9). EM Guidelines vary in personnel requirements. The ACEP states that an observer, who is able to monitor the patient, is only required for moderate and deep sedation, and that once again, the sedationist and operator may perform both tasks (10). AGA echoes the ASA Guidelines (13). In contrast the EMSSA states that only one person is needed to administer, monitor and manage potential PSA complications. The second member of the team is the operator, whose role is limited to the performance of the procedure (11).
2.7.2 Training requirements

**SASA** Guidelines state a sedationist must have a registered medical degree, and be able to demonstrate current knowledge and skill in PSA and its complications. This includes pharmacokinetic and pharmacodynamic knowledge on drugs used for PSA, different sedation techniques, and the ability to recognise and manage complications. Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) are required. The observer must have the equivalent to nursing training, be able to monitor the patient, and recognise and assist with the management of airway compromise. BLS training is required. (3)

**ASA** stipulates the need for training on drugs used, and the recognition and management of PSA complications. For moderate and deep sedation a BLS certified person should be present whereas an ACLS certified person should be available (one to five minutes away) for moderate sedation, and in the room for deep sedation. (2)

**Other:** ESA recommends that the sedationist/operator have specialised PSA knowledge that encompasses theory of PSA practice, pharmacology of drugs used, knowledge of and skills to manage complications, such as airway management and advanced life support. The observer must be trained to monitor patient and should have BLS skills. (9) ACEP does not discuss training requirements and EMSSA only recognises the importance of pharmacology knowledge and the ability to diagnose and treat complications (11). In contrast, AGA details specific requirements for both sedationists and observers. Competence in the relevant pharmacology, recognition and management of complications, ALS principles and airway management is required. The guidelines also discuss methods for training and accreditation. (13)

2.7.3 Patient selection for PSA by non-anaesthesiologists

**SASA** recommends that only ASA class I and II patients be eligible for PSA outside theatre as higher classes require greater levels of care (3).

**ASA** recommends that for patients with significant underlying medical conditions, an anaesthesiologist should be consulted prior to PSA but does not provide a definition of what this may mean, and hence is at the discretion of the sedationist (2).
Other: ESA states that class I, II and stable class III patients are eligible for non-anaesthesiologist PSA (9). The EMSSA states that ASA III and IV patients are not suitable for PSA (11). AGA also supports non-anaesthesiologist PSA for class I, II and III patients, but recommends anaesthesiologist PSA for ERCP, endoscopic ultrasound and patients with a prior PSA adverse event (13).

All guidelines advocate a directed patient assessment with focus on medical conditions, prior general anaesthesia or PSA adverse events, allergies and current medications. Physical examination should include vital signs, cardiopulmonary examination and airway assessment (2, 3, 9-11, 13). In addition it is important to establish the time of last oral intake. While fasting is recommended for simple sedation, it is not an absolute requirement. SASA and ASA, however, prescribe the same fasting guidelines as for elective surgery, for advanced sedation (2, 3).

The fasting guidelines developed by the EM societies are not as stringent, and state that the practitioner should consider the level and timing of sedation relative to the last oral intake (10, 11). Due to the busy nature of the ED, the fact that ASA fasting guidelines apply specifically to elective surgery and the lack of evidence supporting ASA fasting guidelines, EM does not support these fasting protocols (10, 11, 39). Aspiration pneumonitis is acknowledged as a serious complication however it is an exceedingly rare complication during PSA, hence the recommendation to take the circumstances mentioned into consideration (10, 39).

2.7.4 The Issue of informed consent

SASA dictates that written and verbal informed consent be obtained prior to the commencement of PSA, and should include information about the procedure and PSA technique, possible complications and alternatives (3).

ASA makes no specific mention of informed consent.

Other: ESA only states that patients must be able to give informed consent (9). ACEP argues that an additional consent form to that required when registering at an ED is unnecessary as it does not affect clinical outcome or patient satisfaction. They go on to say that patients requiring PSA are often either in a great deal of pain, anxious or of an altered state of
consciousness and in such cases, implied consent is sufficient. (10) This is another area in which the EM approach differs from other disciplines.

2.7.5 Monitoring requirements

In a review of the ASA closed claims database for claims outside the operating theatre (including MAC) researchers showed that more than 50% of respiratory complications could have been prevented with better monitoring (26). The value of monitoring is therefore demonstrated by its ability to reduce the incidence of adverse events by alerting PSA providers to physiological abnormalities (19).

**SASA:** monitoring requirements will vary according to the level of sedation planned and the physiological profile of the patient; nevertheless SASA recommends basic clinical monitoring for all PSA. Monitoring of level of consciousness, pain and anxiety is done by maintaining verbal contact with the patient or by tactile stimulation. Other mandatory clinical monitoring includes ventilation, via observation or auscultation, and oxygenation, heart rate and rhythm with the aid of pulse oximetry. For deeper levels of sedation, blood pressure monitoring at five minute intervals should be added. Furthermore, electrocardiogram (ECG) monitoring is advised for patients with cardiovascular disease. (3)

**ASA Guidelines** are similar to those of SASA but add that if the procedure precludes verbal contact for monitoring level of consciousness, a non-verbal signal should be discussed with the patient prior to commencement of PSA (2).

**Other:** ESA recommends the use of pulse oximetry, blood pressure measurement, ECG recording and visual observation of respiration (9). ACEP guidelines recommend the use of pulse oximetry only in patients with a high risk of hypoxaemia and state that in otherwise healthy patients in which verbal communication is possible, pulse oximetry may not be needed (10). AGA guidelines advocate the assessment of level of consciousness commencing prior to PSA but do not specify the tool to be used. In addition these guidelines state that the use of blood pressure and pulse oximetry devices is supplementary to observation of the patient. While it is acknowledged that these monitoring devices play an important role for IV PSA techniques, it implies that observation is the primary tool for patient monitoring. (13) This may be problematic as many studies have shown that observers do not detect
physiological abnormalities as quickly as monitoring devices (40, 41). EMSSA guidelines require the monitoring of level of consciousness, airway patency, respiration and oxygen saturation, ECG and blood pressure (11).

There is much debate about the value of pulse oximetry as studies have shown that its use does not reduce mortality (19). A Cochrane Review examining the effect of pulse oximetry on perioperative adverse events showed that while pulse oximetry did reduce the incidence of hypoxaemia, it did not reduce the incidence of postoperative cognitive dysfunction and respiratory, cardiovascular or neurologic complications (42). Conversely, others argue that it plays an important role in reducing the rate of adverse events (26). It thus becomes important to understand the information that pulse oximetry provides. The ASA highlights that it is not an indicator of ventilation, but rather an indicator of oxygenation and as such assists with the detection of hypoxaemia (2). Therefore significant alveolar hypoventilation and hypercarbia can still occur in the presence of normal oxygen saturation (40). If these limitations are understood then its value for detecting hypoxaemia, and potentially avoiding serious adverse events that may occur as a result (2), can be appreciated.

Supplemental oxygen may further obscure the detection of respiratory depression when pulse oximetry is used as a surrogate marker for ventilation (19, 43). This is because an increased oxygen reserve created with supplemental oxygen increases the time to desaturation, masking respiratory depression or apnoea (10, 40). Notwithstanding, supplemental oxygen will reduce hypoxaemia which is particularly desirable in certain patients, such as those with ischaemic heart disease (44).

A true indicator of ventilation and the current gold standard is capnography (3). It alerts the sedationist to hypoventilation and apnoea more rapidly than observation or oximetry (40, 41). Furthermore, its ability to detect respiratory compromise is not altered by supplemental oxygen – the amplitude of the graph is reduced but apnoea detection remains unaffected (41). It is not, however, a mandatory requirement for minimal and moderate sedation for any of the anaesthesia or EM societies but is advised for patients at risk of airway compromise (3), deep sedation or when direct visualisation of respiration is not possible, for example during magnetic resonance imaging (2).
Level of consciousness is an important component to monitor during PSA, with observation, verbal and tactile stimulation being the primary means of assessment. Bispectral Index Monitoring (BIS) is a recorded measurement that makes use of electroencephalographic parameters obtained by monitoring frontal cortex activity (10, 44). The BIS scale ranges from zero, which corresponds to no cortical activity or coma, to 100 or fully awake (44). It has been used to guide sedation in the ICU setting (45) and has been shown to reduce awareness under general anaesthesia (19) and so researchers have investigated its use in the setting of PSA. Chen et al. (45) showed that BIS was not useful during the initial and recovery phases of PSA using propofol due to a lag between clinical sedation assessment and the BIS. While sedationists felt that BIS was more useful during the maintenance phase of PSA, there was a wide range in the BIS score (45). Another study showed that BIS is more useful to distinguish deep sedation from general anaesthesia but is unable to differentiate along the deep to mild sedation spectrum (46) or to differentiate comfortable from agitated patients, and patients in pain (47). In contrast to these findings, Bower et al. (48) found that BIS was an accurate measure of sedation and that it could be used to titrate additional sedation requirements. Large variation in the BIS score was found at deeper levels of sedation and no link between BIS score and physiologic measures, such as blood pressure, heart rate and pulse oximetry, was found (48).

It can be seen that great variability in the BIS literature exists. Both SASA and the ASA do not make reference to BIS in their guidelines and the ACEP acknowledges the technology and its potential but concludes that the data is insufficient to recommend its routine use (10). Until more consistent data is available, clinical evaluation of level of consciousness will remain standard practice.

2.7.6 Documentation

SASA stipulates the need for documentation of all components surrounding PSA. Documentation prior to PSA should detail consent, information and instructions given to the patient about PSA and a medical history questionnaire. A pre-procedural checklist should also be completed, which includes information about prior sedation history, fasting, chronic medication, and physical examination. During the procedure a real-time record of events, drugs and vital signs must be recorded. This should extend into the recovery phase of the procedure, and patients should not be discharged until specific criteria are met. A Modified
Aldrete score of ≥ 9 is acceptable. Furthermore, the patient must be accompanied home by a responsible adult who is able to care for the patient and to contact medical services should any problems arise. (3)

ASA advocates documentation of vital signs pre, intra and post-procedure for moderate and deep sedation. This should continue until the patient is recovered and eligible for discharge. Principles for recovery and discharge guidelines are listed. (2)

Other: ESA documentation requirements are few. Frequent recording of vital signs and the level of consciousness is all that is discussed (9). ACEP does not discuss documentation requirements whereas the EMSSA guidelines are in keeping with the SASA intra-procedural requirements (11). AGA requires documentation of the pre-procedure assessment, informed consent, intra and post-procedural vital signs, administered drugs, level of consciousness, pain and adverse events (13).

### 2.7.7 Drugs and PSA techniques

There are numerous techniques that can be employed to deliver safe and effective PSA. Regardless of technique one should consider the safety guidelines put forward by the various professional societies.

SASA principles advocate the use of the smallest amount of drug necessary for the desired level of sedation and analgesia and individualised dose-titration to response. In order to do this effectively, the sedationist must have knowledge of the time to onset of action for the drugs being used (3). Furthermore, SASA cautions sedationists to avoid using the sedating properties of opioids for painless procedures (16). ASA and ACEP discuss drugs according to category and make recommendations accordingly, however, the same principles of titration and minimal dosing, particularly with reference to sedatives and opioids, apply (2, 10).

It is at the discretion of the sedationist to choose a drug regimen. This choice should be governed by patient and procedural factors and his/her pharmacology knowledge and training (3).

[32]
Sedatives and opioids: these groups of drugs are used most commonly for PSA. They do have synergistic action and thus increase the risk of respiratory depression (2, 49). It is for this reason that the guidelines caution sedationists to administer each drug individually in order to better assess drug effect and to titrate as necessary (2, 3, 10, 11). Short-acting benzodiazepines used include midazolam and triazolam and opioids, which are also short-acting, include fentanyl, alfentanyl, sufentanyl and remifentanyl (3).

Ketamine is a dissociative agent that has sedative, hypnotic and analgesic properties (50). It may be used alone or in combination with other drugs, such as propofol or fentanyl. In contrast to benzodiazepines and opioids it has the advantage of preserving respiratory function. Its sialogogue effects, however, may negate this benefit (3). Another potential disadvantage is difficulty monitoring level of sedation due to the trance-like state that it produces (2).

As stated previously ketamine may be used in combination with benzodiazepines, and was shown to be safer than a benzodiazepine-opioid combination for paediatric PSA in the ED setting (51). In addition, Chudnovsky et al. (52) reported a 6% incidence in respiratory compromise and a 7.14% incidence of emergence reaction in adults with a ketamine-midazolam combination. These complications were transient, with respiratory depression attributable to midazolam, and had no further sequelae (52). Ketamine may also be used with propofol in a preparation called Ketofol, the rationale being that lower doses of propofol are required thereby avoiding its depressant effects on the respiratory and cardiovascular systems. The lower dose of ketamine still provides analgesia but reduces drug-induced delirium. (53) Despite these theoretical advantages an ED study found adverse events rates comparable to but not better than propofol or etomidate alone and there was no improvement in recovery times (54).

The use of propofol for PSA by non-anaesthesiologists is another debated subject. It offers a rapid onset to the desired level of sedation and then allows for maintenance of sedation by repeat boluses or a constant infusion titrated to effect. It also has the advantage of a rapid offset of action and has anti-emetic properties, all desirable features for PSA. (50)

SASA recommends that propofol and other induction agents be used only by anaesthesiologists, critical care specialists or those with extensive sedation and anaesthesia
experience (3). ASA is not as prescriptive but does state that sedationists using propofol should be able to manage complications that may arise as a result of its use, including rescuing the patient from general anaesthesia (2). This implies that the use of propofol falls into the realm of MAC and consequently should be used by anaesthesiologists or those with anaesthesia training (27). Non-anaesthesiologists argue that numerous studies show that propofol, whether alone or in combination with benzodiazepines or opioids, is safe in the hands of trained non-anaesthesiologists (10, 13).

The literature demonstrates the safety of trained non-anaesthesiologist administered propofol. Rex et al. (55) provides a synopsis of studies examining propofol use in the field of endoscopy. The cumulative data shows no deaths and one endotracheal intubation for a total of 220,000 procedures. The administration of propofol by appropriately trained nurses has also shown this practice to be safe (35, 36).

In order to address this issue the AGA has developed its own set of sedation guidelines with the aim of setting standards for propofol use amongst endoscopists. It states that propofol can be used alone or in combination with other drugs, by trained personnel provided that dosing protocols are followed and that patients are continuously monitored throughout the procedure until fully recovered. (13)

The field of EM has also investigated the use and safety of propofol in the ED. Studies have shown that general physicians and EM residents, who have received training on the use of propofol, are able to safely administer the drug for PSA in the ED (32, 56).

Notwithstanding cautious use of drugs, overdose does occur and so reversal agents, naloxone and flumazenil, must be readily available to treat patients with overdose of opioids and benzodiazepines respectively (2, 3, 10, 11, 13). Because the duration of action of opioids and benzodiazepines may exceed that of their reversal agents it is necessary to monitor patients with overdose for an extended period of time, and repeat reversal administration if overdose symptoms recur (3).
2.7.8 Equipment and emergency drugs

SASA provides a detailed checklist of equipment for PSA and for any emergency that may arise during the procedure (Appendix 7). This includes equipment for oxygen delivery, airway management, monitoring, establishing IV access, drug infusions and other equipment required for resuscitation. In addition emergency drugs that must be immediately available are listed. (3)

ASA has also included a checklist in its guidelines, but this list is focused on emergency equipment and drugs. Its requirements echo those of SASA except for cardiac defibrillators. ASA only deems it necessary to have a defibrillator immediately available for moderate sedation of patients with mild to severe cardiovascular disease, but should always be available for deep sedation. (2)

Furthermore, ASA has also published guidelines on the provision of anaesthesia outside the operating room. While these guidelines are intended for anaesthesia personnel, the principles should be borne in mind by all medical professionals involved in anaesthesia-related services outside the operating room. A reliable source of oxygen, as well as a supplemental source of oxygen sufficient for the duration of the procedure, must be available and be checked prior to commencing any procedure. Suction and all equipment and drugs for both the intended anaesthesia and possible emergencies must be available. Emergency equipment must be checked to be working. Other requirements deal with the availability of sufficient space, electrical outlets and trained personnel to assist during and after the procedure. (57)

Other: ESA does not discuss equipment requirements in detail and merely states that emergency and oxygen delivering equipment should be present and operational, and that personnel involved with PSA should be proficient with its use. Flumazenil and naloxone are stated as requirements (9). The ACEP recommends that equipment such as oxygen, suction, and equipment and drugs for advanced life support be available (10). No details about specific requirements are discussed. The AGA and EMSSA are more comprehensive in their guidelines, and follow the requirements set down by ASA (13).
2.8 Audit of equipment

The guidelines discussed include a list of equipment and drugs that should be available for safe PSA. Most focus on emergency equipment; however, SASA provides a comprehensive list of drugs and equipment for PSA as well as emergency situations. Despite the importance of these requirements, particularly emergency equipment and drugs, few studies have performed an audit of equipment availability at sites where PSA is performed. In a Dutch national survey, Leroy et al. (58) included availability of emergency equipment as part of a study on guideline adherence. Results showed that only 41.1% of respondents indicated full adherence in this area. This may not be truly indicative of reality as figures were based on respondent perception. It does, however, reveal a problem with provision of emergency equipment.

Pitetti et al. (59) allude to such an audit in their study on the effect on PSA practice after implementation of the Joint Commission on Accreditation of Healthcare Organization’s Guidelines but do not provide any results for this audit.

2.9 Guideline adherence

2.9.1 The role of guidelines in healthcare delivery

The formulation of guidelines is directed by a need to improve healthcare safety, standards of care and treatment and costs (60-63). It is a tool that is used by many medical and surgical specialities, with PSA being no exception. A unifying purpose to the multiple PSA guidelines is standardised and safe care, while simultaneously addressing speciality-specific circumstances. (2, 3, 10, 11, 13)

History has demonstrated the positive impact of such an intervention. Quine et al. (34) found in his 1995 study that high doses of midazolam, which may be indicative of limited pharmacology knowledge, and poor monitoring contributed to the high incidence of adverse events seen in endoscopic procedures. Similarly a 1994 study by Aslam et al. (64) identified a need for guidelines after demonstrating deficits in monitoring, drug knowledge and patient selection in the ED’s of England and Wales. The subsequent development and dissemination of guidelines have assisted to improve the PSA track record (44, 55, 59, 65), thereby illustrating their benefit.
2.9.2 Factors affecting guideline implementation

Despite the good intentions of various societies responsible for developing practice guidelines, studies across a wide range of clinical fields have shown that awareness, knowledge, attitudes and adherence to guidelines is poor. These variables are often studied individually (66), but form part of a composite whole that influence guideline adherence. They are not unique problems to the field of PSA, and hence studies from other fields will be discussed as they provide valuable insight.

Pathman et al. (60) suggest a model of awareness – agreement – adoption – adherence to explain the process to guideline adherence and was tested using vaccination guidelines. Findings supported the concept that the path to guideline adherence occurs in a sequential manner and that problems at any stage will negatively impact adherence (60). It is thus important to appreciate the complexity of adherence and the factors that impact guideline implementation.

Pathman et al. (60) model provides one framework for understanding a complex process. Other factors, such as knowledge and attitude also play a role. These, together with awareness and adherence are discussed.

Awareness

Awareness is understood to mean knowledge of a guideline’s existence (66), and is suggested to be the first step to guideline adherence. The study by Hagemeister et al. (63) focused on the management of arterial hypertension, and showed adequate guideline awareness, defined more broadly as knowledge and acceptance of guidelines, to be present in only 18.8% of general practitioners (GP), 25.6% of physicians (internists) and 37% of cardiologists. Amongst general practitioners and physicians, those with ≥ 20 years in private practice showed the lowest levels of awareness. Proposed explanations for these findings were a reduced level of interest in continuing medical education and poor transfer of information to those in the private sector (63).

Awareness and use of American Thoracic Society (ATS) and local guidelines for community acquired pneumonia was also studied. Once again, a low level of awareness of ATS guidelines
was found: 21% were not at all familiar with the guidelines, 29% had seen them, 30% had read them and only 20% used them. As with the hypertension study specialists, in this case pulmonologists and infectious disease specialists, were more likely to use the guidelines. This finding may highlight the influence of speciality affiliation and explain the reason for discipline-specific guideline development. This study also substantiates the concept that awareness does not necessarily translate into adherence. (62)

**Knowledge**

Knowledge is defined as the theoretical or practical understanding of a subject (67). A Canadian study focused on assessing PSA knowledge amongst radiology residents, with particular focus on pharmacology. The American College of Radiologists has published guidelines for radiologist-directed PSA, yet results showed that just over 50% of respondents knew the correct drug doses frequently used for PSA. Knowledge of onset of action and appropriate local anaesthetic doses was also poor. The study also emphasized that most respondents had not received PSA specific training, yet expressed the wish to have training incorporated into their curriculum. (68)

In a study at Johns Hopkins Hospital knowledge of adult and paediatric PSA guidelines amongst EM practitioners was assessed and compared to practitioners in other specialities. Findings demonstrated greater adult PSA knowledge amongst EM practitioners, and pointed out knowledge gaps in specific areas. Specific areas of weakness were drug routes of administration, ketamine dose, ECG evaluation, post-sedation discharge criteria and PSA nurse administration guidelines. Interestingly, the study also demonstrated that these deficiencies could be remedied with a PSA course, with post-course test scores showing significant improvement. (69) This lends some support to the proposal of including PSA training in speciality curricula.

**Attitude**

Attitude is defined as settled way of thinking or feeling about something (67) and is another factor that influences adherence. Breakey et al. (70) illustrated that the use of PSA amongst paediatric and EM residents for lumbar punctures in paediatric patients was influenced by their perception of the degree of pain felt, which varied with age, and their perception of the
degree of pain associated with the procedure. Other factors were adverse events experienced with a particular technique and whether respondents had received formal PSA training. The source of training was important as instruction received from a superior or colleague was subject to bias and personal experience rather than practice guidelines, thereby enabling propagation of misinformation and bad habits. Once again, of those residents who had no training in PSA, an overwhelming majority (85%) felt that a formal program would be useful. The authors concur that such a program would address the problems of “underuse and misuse” of PSA. (70)

Tunis et al. (71) further illustrate the impact of attitude on adherence. Their study revealed that specialists are more likely to have confidence in guidelines developed by their speciality societies (71), which is consistent with findings on guideline knowledge (62, 63). While most respondents agreed that guidelines have a positive impact on patient care, between 20% and 25% were of the opinion that guidelines are too rigid, limit practitioner autonomy, and seek to create a one-size-fits-all model for patient care (71). This was particularly evident amongst private practitioners.

**Adherence**

Guideline adherence is understood to mean the use of guidelines for appropriate situations most of the time. Fanning (72) conducted a study at a Dublin-based teaching hospital exploring adherence to recommended PSA guidelines across both medical and surgical disciplines, and across the different training grades. The questionnaire assessed the types and locations of procedures performed, protocol usage, the use of standards for pre-procedural assessment, monitoring, post-procedure care and resuscitation skills, and pharmacology knowledge. While adherence for each of these elements varied, the overall adherence was poor. (72) The Royal College of Anaesthesia (RCA) reports on safe sedation practice suggests that lack of PSA knowledge and training, and the failure of disciplines to recognise the need to incorporate PSA into their respective curricula may be a reason for the discouraging findings on guideline adherence. The report goes on to make specific recommendations to address the situation, such as the provision of resources to train and assess sedationists and the appointment of consultants from anaesthesia and other relevant specialities to oversee PSA practice. (61)
A Dutch study on PSA guideline adherence amongst general paediatricians found equally disappointing results with full adherence being less than 25% for history taking, risk assessment, blood pressure monitoring, monitoring during recovery and rescue competence during recovery. Despite full adherence being low, the study defined non-adherence as a “gradual deviation from full adherence” rather than “absence of full adherence”. Even with this modified definition, low levels of adherence, such that patient safety would be compromised, were found in 25% of respondents. Reasons cited for these findings once again are related to PSA not being a formalised subject and scarce training opportunities. (58)

**Understanding adherence**

These studies serve to illustrate that a large gap exists between guideline development and practitioner awareness, knowledge and adherence. As has been indicated the reasons for this gap focus mainly on the low status of PSA in speciality curricula and the consequent limited or non-existent training for non-anaesthesiology specialists on the subject (58, 68-70, 72). Thus formalised training offers one solution to the problem.

Tools, such as PSA forms, have also been shown to improve adherence to guidelines. While the study demonstrating this had limited power due to small numbers, the form served to prompt practitioners to fulfil PSA requirements (73). A similar approach was also shown to be effective for the ED management of asthma (74). While these options may partially address the problem, they only represent simplistic solutions to a multifaceted issue.

The National Institute for Clinical Excellence (NICE) is a program in the National Health Service in England and Wales that aims to improve access to and levels of healthcare. In a study examining the guidelines laid down by NICE, researchers sought evidence of guideline implementation. A number of different areas were targeted, each with differing degrees of implementation. More importantly the study explored the facilitators and barriers to guideline adoption and adherence. Guidelines that show distinct advantages to adherence are evidence-based and have professional endorsement. Procedures requiring a team approach were also shown to have higher rates of adherence due to a reduced allowance for autonomy. Organisational factors, such as an organisational culture of commitment to NICE, the degree to which administrators included healthcare institutions in the process of
implementation, the degree to which the program was prioritised at the point of care, funding needs, and consultant support, also influenced implementation. (75)

A systematic review by Cabana et al. (66) further enhances one’s understanding of practitioner adherence. All variables may be categorised into three central themes, these being knowledge, attitude and behaviour factors. Familiarity and awareness of guidelines were measures of knowledge, degree of agreement, outcome expectancy and self-efficacy and motivation were indicative of attitude, and external barriers namely patient, guideline and environmental factors were measures of behaviour. (66) While some of these variables are in common with the Awareness – to – Adherence model (60) the addition of environmental factors, such as lack of resources or patient preference, provides a more holistic view of adherence (66). The implication of this is that strategies to improve adherence can be appropriately tailored to address specific issues, rather than attempting to solve the problem blindly.

2.10 Summary

PSA offers a number of advantages as evidenced by its growth in use. This growth, however, has been accompanied by complication rates that are unacceptable thereby motivating the development of practice guidelines by anaesthesia and other specialities. These serve to assist practitioners to provide safe care; however, the literature has revealed a gap between guideline development and adherence. The factors affecting adherence are many due to the complexity of the issue, but assist in our understanding of the problems around PSA. With this insight, guided solutions may be better applied.

In this chapter the literature pertaining to PSA, its safe administration and the factors influencing PSA guideline adherence have been discussed. In the following chapter the study methodology is presented.
Chapter Three  

Research Methodology

3.1 Introduction

This chapter consists of the problem statement, aims and objectives, ethical considerations, research design and methodology that was followed and a discussion of validity and reliability of the study.

3.2 Problem statement

The doctors at CHBAH make use of PSA techniques in a number of departments; however, it has been observed that the regulations formulated by SASA to ensure the safe performance of PSA are unfamiliar to some health care professionals involved. Furthermore, it is doubted that anyone has ascertained whether the recommended drugs and equipment required for the safe delivery of PSA are available.

The perceived consequences of these inadequacies are that PSA is being provided by personnel not qualified in PSA, and may lack the necessary knowledge and skill to offer a safe procedure by being ill-equipped to deal with possible complications that may arise. In addition, procedural and emergency drugs and equipment may not be available. This places patients at an increased risk of adverse events.

3.3 Purpose

The purpose of this research is to assess the profile of non-anaesthesiologist PSA providers at CHBAH, their awareness of the SASA Sedation Guidelines 2010 and their level of comfort when performing PSA. The available equipment and drugs in PSA settings outside the operating theatre complexes was also assessed.
3.4 Objectives

The objectives of the study were to:

- describe the professional level of respondents
- describe respondent PSA and resuscitation training
- describe the locations and procedures for which PSA is performed
- assess the level of awareness of PSA guidelines (SASA)
- describe the comfort level of practitioners when performing PSA
- compare the level of PSA knowledge by professional level
- compare the level of PSA knowledge by clinical department
- compare the level of comfort by professional level
- audit the availability of recommended drugs and equipment.

3.5 Ethical considerations

Verbal assent was obtained from the heads of departments of general surgery, trauma, radiology, emergency medicine, orthopaedic surgery prior to the proposal being submitted to the Human Research Ethics Committee (Medical) of the University of the Witwatersrand. This was done in order to gauge whether the study would be acceptable to these departments. Assent from the department of Internal Medicine was obtained subsequent to ethics approval.

Ethics approval has been obtained from the Human Research Ethics Committee (Medical) (Appendix 1) and the Post-Graduate Committee of the University of the Witwatersrand (Appendix 2). Permission was also granted by the CHBAH Medical Advisory Committee (Appendix 3).

Subsequently, written assent was sought from the Heads of Departments of general surgery, trauma, radiology, emergency medicine, orthopaedic surgery and internal medicine (Appendix 4).

Upon assent from the listed departments, a self-administered questionnaire was distributed to potential participants. The questionnaire contained an information letter (Appendix 5) detailing the purpose of the study, ethics and CHBAH approval and the rights of participants to anonymity and withdrawal. The agreement to complete the questionnaire (Appendix 6)
implied consent. Anonymity of participants and questionnaires was ensured by not recording participants’ names on the questionnaires and once questionnaires were collected from the various departments, they were all placed together for data collection. Furthermore, confidentiality was ensured as the researcher and supervisors were the only people who had access to the raw data.

The study was conducted in adherence to the principles of the Declaration of Helsinki (18).

3.6 Research methodology

3.6.1 Research design

A prospective, descriptive, contextual study design was used.

A prospective study is defined as a study in which the variables will be measured at the time in which the study takes place (76). This study was prospective in that a group of doctors was identified for study and the data was collected from them during the course of the study.

A descriptive study aims to describe a situation or identify problems through observation, description or classification without manipulating variables (76, 77). No treatment or intervention is tested (77). This study was descriptive in design in that it planned to provide new information on the study variables defined in the objectives.

A contextual study is one that takes place in a specific location (77). This study was contextual as it was conducted at one hospital only, namely CHBAH. This may impact the validity of the study by limiting one’s ability to generalise results.

3.6.2 Study population

Doctors working in the general surgery, trauma, radiology, emergency medicine, orthopaedic surgery and internal medicine departments belonging to the professional levels second year intern, community service officer, medical officer, registrar and consultant formed the population group studied. All interns in their second year of internship were selected as they would have had sufficient exposure to PSA during their clinical rotations in their first year. It is acknowledged that some of these interns will have rotated through anaesthesia, and would
have had some formal exposure to sedation practice. First year interns were thus identified prior to distribution of questionnaires and were excluded as their exposure to PSA would be limited.

3.6.3 Study sample

Sample size

All doctors in the departments were identified and eligible to participate. A sample was realised from the number of respondents.

Sampling method

All professional levels within the departments were identified with the assistance of the departmental secretaries. A list with all the names of the members of that department was provided. A convenience sampling method was used for registrars as this group of doctors rotate amongst three academic hospitals affiliated to the University of the Witwatersrand. Registrars who were rotating through CHBAH at the time of the study were selected. Thus, a convenience sampling method was used for this professional level as only the registrars who were rotating through CHBAH at the time of the study were identified and were eligible to participate in the study.

Inclusion and exclusion criteria

Inclusion criteria

- Medical doctors from the departments of general surgery, trauma, radiology, emergency medicine, orthopaedic surgery and internal medicine
- Professional levels intern, community service officer, medical officer, registrar and consultant.

Exclusion criteria

- Medical doctors who indicated that they have never been involved in the administration of PSA at CHBAH.
- First year interns
- Medical doctors who declined to participate.
3.6.4 Data collection

Data collection was done with the use of two tools: a self-administered questionnaire and an equipment and drugs audit checklist.

Self-administered questionnaire (Appendix 6)

Questionnaire development

In order to develop a questionnaire that would accurately assess awareness of procedural sedation guidelines amongst doctors a review of the literature was done. The questionnaire used by Fanning (72) for her study: Monitoring during sedation given by non-anaesthetic doctors, served as a foundation for the questionnaire. Furthermore, search terms such as “awareness”, “knowledge” and “comfort” were included in the search. A few of the studies reviewed included their questionnaires and these served as a guide. Other studies did not include their questionnaires but the questions could be inferred from the results provided.

In addition a detailed review of the 2010 SASA Guidelines for the provision of PSA to adults was done as these would form the reference point for assessing PSA guideline awareness. The reasons for choosing the SASA Guidelines were that these guidelines were the most comprehensive guidelines available at the time of questionnaire development, they have been specifically developed for use by non-anaesthesiologists and the researcher is specialising in anaesthesiology, and thus follows the guidelines set by the speciality. It is however recognised, that guidelines have been developed by other specialities that perform PSA, and that the use of these speciality-specific guidelines supersedes those developed by SASA. After reviewing many of the guidelines, it was found that a great deal of common ground exists between them, but that the SASA guidelines are indeed, the most comprehensive.
With the study objectives in mind the questionnaire assessed the following items:

- professional level
- locations where PSA was performed
- procedures for which PSA was performed
- awareness of PSA guidelines
- PSA practices
- PSA-specific pharmacology knowledge
- comfort levels when performing PSA

The questionnaire was validated by four experts, with a special interest in pain, from the department of Anaesthesiology, University of the Witwatersrand. This was done in order to ensure content and face validity.

Scores for questions assessing guideline knowledge or awareness were awarded one score for a correct answer and a zero score for an incorrect answer. Unanswered questions will also be awarded a zero score.

**Questionnaire distribution**

Once approval to conduct the study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand the Heads of Departments of general surgery, trauma, radiology, emergency medicine, orthopaedic surgery and internal medicine were approached for written assent to conduct data collection in their respective departments.

Once assent as well as consent from the CHBAH Medical Advisory Committee was obtained, all medical doctors that fit the inclusion criteria within the departments were identified with the assistance of the departmental secretary. A list with all the names of the members of that department was provided and an indication of appropriate times to approach these medical doctors was sought, e.g. departmental meetings.

The questionnaires, contained within a box, were distributed during departmental meetings to those medical doctors who agreed to participate in the study. Furthermore, visits to the wards and theatre were made in order to offer as many doctors as possible the opportunity to
participate. Upon collection of a questionnaire, that participant was marked off the list that the departmental secretary had supplied and kept in a box to which only the researcher and supervisors had access. This was not possible in all cases, where questionnaires were completed and returned to a box placed in the secretary’s office.

**Equipment and drugs audit (Appendix 7)**

The assent and consent procedures have been outlined above and include the audit of PSA locations. These have been identified and suitable times to perform the audit were identified with the Heads of Department responsible for that location. Each of these areas was audited according to the SASA Basic Equipment and Drugs for Procedural Sedation and Analgesia (PSA) checklist (Appendix 7).

All data obtained from both the questionnaire and the audit was captured onto an Excel spread sheet for analysis. Quality control checks were performed to ensure accuracy.

The data collection process may be seen in Figure 3.1.
3.7 Data analysis

Data was analysed using descriptive and inferential statistics using Microsoft Excel. For descriptive analysis of data that were normally distributed, mean and standard deviation (SD) was used. After consultation with a bio-statistician the assumptions for ANOVA (equal variance and normality) were tested and met. Bonferroni testing and correction procedure was used for post-testing to identify where the significant differences lie. A p-value of less than 0.05 was considered to be statistically significant.

3.8 Validity and reliability

Validity of the study was ensured by:

- Representative sample size – all professional levels were approached to participate in the study. The results may thus be generalised.

[49]
• Selection bias was minimised by approaching all doctors involved in PSA at CHBAH. Convenience sampling was, however, applied to registrars, and thus those registrars at CHBAH at the time of the study were selected. This was not expected to reduce validity as these registrars are likely to be representative of this group of doctors.

• Consent and instrument validation processes. A panel of four anaesthesiologists, with a sub-speciality in pain, were involved in questionnaire development.

• Criterion-related validity. Instruments used in similar studies were used as a comparison for the development of the questionnaire.

A potential threat to validity was the possibility that Heads of Department may have tried to improve the equipping of PSA locations in anticipation of the study.

Reliability of the study was ensured by:

• Consistency has been ensured through a validation process by ensuring that items on the questionnaire measure the intended variables;

• The questionnaire was developed following a literature review. In addition the questionnaire was assessed by four consultant anaesthesiologists, with a special interest in pain. This ensured the reliability of the questionnaire.

3.9 Summary

This chapter has described the research methodology employed in this study. This includes: the research question; the aims and objectives of this study; the ethical considerations encountered in the conduct of this study; detailed the research design; the description of the population and samples used; discussed the data collection methods; data analysis used and reliability and validity

In the next chapter, the results of this study are presented.
Chapter Four Results

4.1 Introduction

This chapter contains the results of the data collected and are presented according to the objectives stated in chapter one.

The objectives of the study were to:

- describe the professional level of respondents
- describe respondent PSA and resuscitation training
- describe the locations and procedures for which PSA is performed
- assess the level of awareness of PSA guidelines (SASA)
- describe the comfort level of practitioners when performing PSA
- compare the level of PSA knowledge by professional level
- compare the level of PSA knowledge by clinical department
- compare the level of comfort by professional level
- audit the availability of prescribed drugs and equipment.

4.2 Sample realisation

The study was conducted from October 2012 to January 2013. All professional levels were eligible to participate with the exception of first year interns. Doctors were identified with lists provided by departmental secretaries and interns were excluded prior to questionnaire distribution. Questionnaires were distributed to the departments of general surgery and trauma, radiology, emergency medicine, orthopaedic surgery and internal medicine. This was done at departmental meetings. The researcher attended one meeting in the departments of emergency medicine and general surgery and trauma. Doctors who were not present at the meetings were then sought out to offer them an opportunity to participate. Numerous meetings needed to be attended in the Department of Orthopaedic Surgery in order to ensure that most doctors within this department had an opportunity to participate.

The attendance of departmental meetings was not possible in two departments. In one of these departments a box containing the questionnaires was placed in the administration office. The departmental secretary distributed and collected questionnaires from the doctors who came into her office. In the second department, academic meetings were held at the
Charlotte Maxeke Johannesburg Academic Hospital. This made administration of the questionnaires to the CHBAH doctors alone very difficult. For this reason the researcher went to the department during tea-times to explain and distribute the questionnaires. Doctors were also sought out in order to offer as many as possible the opportunity to participate. Electronic questionnaires were emailed to members of that department upon their request. A box containing questionnaires was also placed in the administration office for collection.

Questionnaires were distributed to the interns within the above-mentioned departments. Those rotating through other departments at the time of collection were individually sought. In addition questionnaires were emailed to those interns placed at peripheral clinics at the time of data collection.

A total of 359 doctors worked for the departments, as identified by the lists provided by departmental secretaries. It is uncertain how many of these doctors were approached, however, a total of 160 doctors agreed to participate and completed questionnaires. Of the questionnaires returned, one questionnaire was excluded as the respondent indicated that he did not perform PSA. The total number of respondents was thus 159.

4.3 Results

The results of the questionnaires collected and the equipment and drug audit are presented below. Descriptive and inferential statistics are used to analyse the data and percentages will be rounded off to two decimal places. One point was awarded for a correct answer and no point was awarded for an incorrect or unanswered question.

4.3.1 Demographics

Of the 159 respondents, 65 (40.88%) were female and 93 (58.49%) were male. One respondent did not complete this question.

The departmental breakdown of the number of people who chose to respond is shown in Figure 4.1. Thirty seven (23.27%) respondents were from the department of general surgery and trauma. Nineteen (11.95%) respondents were from the department of orthopaedic surgery. Twenty (12.58%) respondents were from the department of emergency medicine.
Fourteen (8.81%) respondents were from the department of radiology. Twenty two (13.84%) respondents were from the department of internal medicine. Forty seven (29.56%) respondents did not answer this question (blank), 46 of whom were interns who do not belong to any one department. This question was not applicable to 46 respondents as they were second year interns. They constitute 46 of the 47 respondents who did not complete this question. One other respondent did not complete this question.

**Figure 4.1 Departmental breakdown of respondents**

There were 37 completed questionnaires from the department of general surgery and trauma. This constituted 77.08% of this department. The department of orthopaedic surgery returned 19 (41.30%) completed questionnaires, emergency medicine returned 20 (100%), radiology returned 14 (37.84%) and internal medicine returned 22 (18.33%) completed questionnaires.

The results relating to the objectives outlined above will now be discussed. For continuity the relevant questions from the questionnaire will be placed in the results.
4.3.2 Professional level of PSA practitioners

The first objective of the study was to describe the professional level of respondents. Thirtyeight (23.90%) consultants, 52 (32.70%) registrars, 21 (13.21%) medical officers, one (0.63%) community service doctor and 46 (28.93%) interns participated in the study (Figure 4.2).

**Figure 4.2 Professional levels of respondents**

4.3.3 Describe respondent PSA and resuscitation training

The second objective of the study was to describe the training of respondents after attainment of their medical degrees. One hundred and thirteen (70.63%) respondents indicated they had completed BLS, 97 (60.63%) respondents ACLS, 25 (15.63%) PSA training/lectures/workshops and 40 (25%) indicated they had done other forms of training.

In addition, respondents were asked whether they thought they would benefit from PSA training, the results of which are shown in Figure 4.3. One hundred and twenty seven (79.87%) respondents indicated that they would benefit from PSA training, 6 (3.77%) indicated that they would not benefit and 20 (12.58%) responded that they didn’t know. Six (3.77%) respondents did not answer this question.
Describe the locations and procedures for which PSA is performed

The third objective of the study was to describe the locations and procedures for which PSA is performed. PSA locations are displayed in Figure 4.4. “Other” was an option on the questionnaire and this was indicated by six (3.77%) respondents.
The procedures for which PSA are performed was also assessed. Sixty nine (43.43%) respondents indicated they use PSA for incision and drainage procedures, 73 (45.91%) for suturing, 71 (44.65%) for orthopaedic procedures, 49 (30.82%) for radiological procedures, 46 (28.93%) for endoscopy, 84 (52.83%) for the insertion of intercostal drains, 40 (25.16%) for cardioversion and 36 (22.64%) indicated “other”. “Other” procedures specified by respondents included bone marrow aspirate and trephine (12), central venous access (4), lumbar puncture (4), and endotracheal intubation (3), Quinton line insertion (2), pleural tap (2). Procedures listed by no more than one respondent included dressing changes, Tenckhoff catheter insertion, percutaneous endoscopic gastrostomy tube insertion, liver biopsy, fine needle aspirates, minor theatre.

4.3.5 Level of awareness of PSA guidelines (SASA)

The fourth objective of the study, levels of awareness of PSA guidelines, was assessed in two sections.
Section 1

The first section assessed guideline awareness with specific focus on knowledge and use of guidelines, permitted scope of PSA practice and PSA monitoring requirements.

Respondents were asked about the presence of a protocol for sedation practices in their departments. As shown in Figure 4.5, 117 (73.59%) respondents indicated that they were not at all aware of a protocol for sedation practices in their departments, 16 (10.06%) indicated that they had heard about them, 9 (5.66%) were familiar with their content and 15 (9.43%) use them when performing PSA. Two (1.26%) respondents did not answer this question.

Respondents were also asked if they were aware of which PSA protocol was in use in their departments. Thirteen (8.18%) indicated that SASA Guidelines were used, seven (4.40%) indicated Emergency Medicine Society of South Africa, Procedural sedation in the emergency centre were in use, four (2.52%) indicated AGA and eight (5.03%) indicated that other guidelines were in use. One respondent stated that he was aware that a protocol was in use but was unsure which one.

Respondents were then asked questions to assess detailed knowledge of the SASA Guidelines.

[57]
The number of medical personnel required for minimal sedation/anxiolysis was answered correctly by 109 (68.55%) respondents and incorrectly by 50 (31.45%).

Pre-sedation recommendations were assessed by providing a number of options to respondents. Fourteen (8.81%) respondents correctly marked all three of the appropriate options. Thirty nine (24.53%) correctly marked two and 81 (50.94%) marked one option correctly. Twenty five respondents (15.72%) did not mark anything for this question.

A non-anaesthesiologist is permitted to give PSA to ASA grades I and II. This was correctly indicated by 82 (51.57%) respondents. Forty nine (30.82%) respondents correctly indicated one correct option and 28 (17.61%) did not answer this question. No one indicated an ASA level of III or more.

Respondents were asked to indicate the appropriate monitoring required for PSA. Fifty eight (36.48%) respondents correctly indicated all five PSA monitoring requirements. Fifty four (33.96%) respondents correctly indicated 4 of 5 correct answers, 27 (16.98%) correctly indicated 3 of 5 correct answers, 16 (10.06%) correctly indicated 2 of 5 correct answers, 1 (0.63%) correctly indicated 1 of 5 correct answers and 3 (1.89%) did not mark anything correctly for this question.

Respondents were asked to indicate the required PSA Emergency equipment. Ninety six (60.38%) respondents correctly indicated all five emergency equipment requirements, 43 (27.04%) respondents correctly indicated 4 of 5 correct answers, 8 (5.03%) correctly indicated 3 of 5 correct answers, 7 (4.40%) correctly indicated 2 of 5 correct answers, 2 (1.26%) correctly indicated 1 of 5 correct answers and 3 (1.89%) did not mark anything correctly for this question.

The mean score for guideline knowledge was 11.54 (72.13%), with a standard deviation of 2.58 (16.13%).

**Section 2**

The second section assessed guideline awareness with specific focus on the pharmacology for PSA. Respondents were asked to indicate the drugs they use for PSA. This is illustrated in
Figure 4.6. “Other” refers to other drugs that respondents may use and was an option on the questionnaire and this was indicated by five (3.14%) respondents.

One hundred and thirty nine (87.42%) respondents correctly answered that when using more than one class of drug for PSA one should administer the medication in divided doses titrated to effect. Twenty (12.58%) respondents did not answer this question correctly.

The dose of midazolam was correctly answered by 59 (37.11%) respondents, and incorrectly answered by 100 (62.89%) respondents.

The side effects of midazolam were assessed with five true/false/don’t know statements. Eleven (6.92%) respondents correctly answered all 5 statements. Thirty two (20.13%) answered 4 of 5 correctly, 46 (28.93%) answered 3 of 5 correctly, 41 (25.79%) answered 2 of 5 correctly, 17 (10.69%) answered 1 of 5 correctly and 12 (7.55%) left this question blank.

The side effects of ketamine were assessed in a similar way. Twenty six (16.35%) respondents answered all 5 statements correctly, 25 (15.72%) answered 4 of 5 correctly, 31 (19.50%) answered 3 of 5 correctly, 33 (20.75%) answered 2 of 5 correctly, 15 (9.43%) answered 1 of 5
correctly and 29 (18.24%) did not answer anything correctly for this question. One respondent wrote that he does not know about ketamine and for this reason does not use it.

One hundred and twenty one (76.10%) respondents correctly stated that opioid induced respiratory depression is dose dependent, while 38 (23.90%) incorrectly answered this question.

The correct dose of naloxone was indicated by 38 (23.90%) respondents, while 121 (76.10) incorrectly answered this question.

Ninety one (57.23%) respondents correctly answered “false” for the use of opioids for their sedative effect for painless procedures and 68 (42.77%) incorrectly answered this question.

The mean score for pharmacology knowledge was 8.01 (53.40%) with a standard deviation of 3.14 (20.93%).

The mean score for both guideline knowledge and pharmacology was 19.55 (63.06%) with a standard deviation of 4.75 (15.32%).

4.3.6 Levels of comfort of PSA practitioners

The fifth objective of the study was to describe the level of comfort of practitioners when performing PSA, and is illustrated in Figure 4.7

When administering PSA, seven (4.40%) respondents indicated they feel very comfortable when administering PSA, 44 (27.67%) feel comfortable, 61 (38.36%) neutral, 42 (26.42%) uncomfortable and three (1.89%) feel very uncomfortable. Two (1.26%) respondents did not answer this question.

With regard to identifying complications related to PSA eight (5.03%) respondents indicated they feel very comfortable, 71 (44.65%) feel comfortable, 45 (28.30%) feel neutral, 27 (16.98%) feel uncomfortable and 6 (3.77%) feel very uncomfortable. Two (1.26%) respondents did not answer this question.
With regards to managing complications related to PSA nine (5.66%) respondents indicated they feel very comfortable, 50 (31.45%) respondents feel comfortable, 57 (35.85%) feel neutral, 32 (20.13%) feel uncomfortable and 9 (5.66%) feel very uncomfortable. Two (1.26%) respondents did not answer this question.

Figure 4.7 Levels of comfort performing PSA

It was found that 110 (69.18%) respondents feel that they are able to object to administering PSA if they feel uncomfortable. 29 (18.24%) respondents indicated they were not able to object, 17 (10.69%) were unsure and three (1.89%) did not answer this question.

4.3.7 PSA knowledge by professional level

The sixth objective of the study was to compare the level of knowledge of PSA among the different professional levels.

After consultation with a bio-statistician the assumptions for ANOVA (equal variance and normality) were tested and met. Bonferroni testing and correction procedure was used for post-testing to identify where the significant differences lie.
For the purposes of comparison professional levels were divided into three groups. Consultants and registrars each formed one group and medical offices, community service doctors and interns (MO/CS/I) were combined to form the third group. These professional levels were combined as they are all pre-specialisation and are not part of a formal academic program.

Knowledge was assessed in two sections, namely guideline knowledge and pharmacology knowledge. For guideline knowledge a statistically significant difference was found between the groups ANOVA \(F[2, 155]=5.40, p=0.0054\). The MO/CS/I group performed better than the consultant group \((p=0.008)\) with mean scores of 12.26 (76.63%) and 10.71 (66.94%) respectively. Registrars achieved a mean score of 11.19 (69.94%) but no statistically significant difference was found between this group and consultants \((p=1.00)\) or the MO/CS/I group \((p=0.065)\).

For pharmacology knowledge, no statistically significant difference was found between the groups ANOVA \(F[2, 155]=1.67, p=0.19\). Consultants achieved a mean score of 7.21 (48.07%), registrars achieved a mean score of 8.33 (55.53%) and the MO/CS/I group achieved a mean score of 8.22 (54.80%).

A total knowledge score was also calculated and a statistically significant difference was found between the groups ANOVA \(F[2, 155]=3.67, p=0.027\). The MO/CS/I group once again performed better than the consultant group \((p=0.02)\), with mean scores of 20.50 (66.08%) and 17.92 (57.81%) respectively. Registrars achieved a mean score of 19.5 (62.97%) but no statistically significant difference was found between this group and consultants \((p=0.33)\) or the MO/CS/I group \((p=0.79)\). The performance of each professional level for guideline, pharmacology and total knowledge is shown in Figure 4.8.
4.3.8 PSA knowledge by clinical department

The seventh objective of the study was to compare the level of knowledge of PSA among the different clinical departments. For the purposes of departmental comparison interns were excluded from the analysis as they rotate through the departments for a period of four months only. The total number of respondents is thus reduced to 113.

Table 4.1 shows the mean, standard deviation and percentages for each department for guideline knowledge, pharmacology knowledge and a total of the two.
Table 4.1  Guideline and pharmacology knowledge per department

<table>
<thead>
<tr>
<th>Clinical departments</th>
<th>Knowledge (mean (SD) %)</th>
<th>Guideline</th>
<th>Pharmacology</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiology (n=14)</td>
<td>10.21 (2.55) 63.81</td>
<td>6.21 (3.36) 41.40</td>
<td>16.43 (4.80) 53.00</td>
<td></td>
</tr>
<tr>
<td>Orthopaedics (n=19)</td>
<td>9.89 (3.41) 61.81</td>
<td>6.58 (2.59) 43.87</td>
<td>16.47 (5.28) 53.13</td>
<td></td>
</tr>
<tr>
<td>General surgery/trauma (n=37)</td>
<td>11.05 (2.86) 69.06</td>
<td>8.19 (3.22) 54.60</td>
<td>19.24 (4.77) 62.06</td>
<td></td>
</tr>
<tr>
<td>Internal medicine (22)</td>
<td>11.45 (2.42) 71.56</td>
<td>7.86 (3.23) 52.40</td>
<td>19.32 (4.58) 62.32</td>
<td></td>
</tr>
<tr>
<td>Emergency medicine (20)</td>
<td>12.45 (1.50) 77.81</td>
<td>9.20 (3.37) 61.33</td>
<td>21.65 (4.25) 69.84</td>
<td></td>
</tr>
</tbody>
</table>

For guideline knowledge a statistically significant difference was found between the departments ANOVA (F [4, 107]=2.76, p=0.0314). The emergency medicine department performed better than the orthopaedic surgery department (p=0.03) with mean scores of 12.45 (77.81%) and 9.89 (61.81%) respectively.

For pharmacology knowledge, ANOVA testing suggested a statistically significant difference existed between the groups ANOVA (F [4, 107]=2.70, p=0.034); however, Bonferroni testing and correction procedure failed to show a difference between the departments. This is possible due to under-powering as the sample size was not calculated to find this difference.

Calculation of the total knowledge score showed a statistically significant difference between the departments ANOVA (F [4, 107]=3.97, p=0.0048). These differences were found between the departments of radiology and emergency medicine (p=0.02), with mean scores of 16.43 (53.00%) and 21.65 (69.84%) respectively. A statistically significant difference was also found between the departments of orthopaedic surgery and emergency medicine (p=0.009), with mean scores of 16.47 (53.13%) and 21.65 (69.84%) respectively.

4.3.9 Levels of comfort between the different professional levels

The eighth objective of the study was to compare the level of comfort when performing PSA among the different professional levels. The levels of comfort were grouped into three categories. Very comfortable and comfortable formed one category, neutral formed the second category and uncomfortable and very uncomfortable formed the third category. Table 4.2 shows the number of respondents per professional level and their respective levels of
comfort when administering drugs for PSA. Three respondents did not indicate their professional level and so they were excluded from the analysis.

### Table 4.2 Level of comfort per professional level when administering drugs for PSA

<table>
<thead>
<tr>
<th>Professional Level</th>
<th>Consultant (36)</th>
<th>Registrar (52)</th>
<th>MO/CS/I (68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levels of comfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable</td>
<td>19 (52.78%)</td>
<td>16 (30.77%)</td>
<td>16 (23.53%)</td>
</tr>
<tr>
<td>Neutral</td>
<td>10 (27.78%)</td>
<td>23 (44.23%)</td>
<td>27 (39.71%)</td>
</tr>
<tr>
<td>Uncomfortable</td>
<td>7 (19.44%)</td>
<td>13 (25.00%)</td>
<td>25 (36.76%)</td>
</tr>
</tbody>
</table>

A Pearson $\chi^2$ test was performed and showed a statistically significant difference ($p=0.031$) existed between the groups. This difference was found between the MO/CS/I group and the consultant group, where 36.76% of the MO/CS/I group, in contrast to 19.44% of the consultant group, indicated they felt uncomfortable administering PSA. No other statistically significant difference between the groups was found.

Table 4.3 shows the number of respondents per professional level and their respective levels of comfort when identifying complications related to PSA.

### Table 4.3 Level of comfort per professional level identifying PSA complications

<table>
<thead>
<tr>
<th>Professional Level</th>
<th>Consultant (36)</th>
<th>Registrar (52)</th>
<th>MO/CS/I (68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levels of comfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable</td>
<td>21 (58.33%)</td>
<td>29 (55.77%)</td>
<td>29 (42.65%)</td>
</tr>
<tr>
<td>Neutral</td>
<td>6 (16.67%)</td>
<td>15 (28.85%)</td>
<td>23 (33.82%)</td>
</tr>
<tr>
<td>Uncomfortable</td>
<td>9 (25.00%)</td>
<td>8 (15.38%)</td>
<td>16 (23.53%)</td>
</tr>
</tbody>
</table>

Analysis with a Pearson $\chi^2$ test showed no statistical significant difference between the groups for this question ($p=0.26$).
Table 4.4 shows the number of respondents per professional level and their respective levels of comfort managing complications related to PSA.

<table>
<thead>
<tr>
<th>Professional Level</th>
<th>Consultant (36)</th>
<th>Registrar (52)</th>
<th>MO/CS/I (68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levels of comfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comfortable</td>
<td>20 (55.56%)</td>
<td>24 (46.15%)</td>
<td>15 (22.06%)</td>
</tr>
<tr>
<td>Neutral</td>
<td>8 (22.22%)</td>
<td>17 (32.69%)</td>
<td>31 (45.59%)</td>
</tr>
<tr>
<td>Uncomfortable</td>
<td>8 (22.22%)</td>
<td>11 (21.15%)</td>
<td>22 (32.35%)</td>
</tr>
</tbody>
</table>

Analysis with a Pearson $\chi^2$ test showed a statistically significant difference ($p=0.008$) between the groups. Fifty five point five six percent of the consultant group, in contrast to 22.26% of the MO/CS/I group, indicated they felt comfortable managing complications related to PSA. In addition a larger proportion (45.59%) of the MO/CS/I group felt neutral compared to the consultant group (22.22%).

The greatest proportion of respondents felt they could object to the administration of PSA in all three groups. The largest proportion of respondents that felt they could not object was the MO/CS/I group (23.53%). This is in contrast to 16.67% in the consultant groups and 13.46% in the registrar group. Despite these findings, analysis with a Pearson $\chi^2$ test showed no statistical significant difference between the groups ($p=0.32$).

Lastly, a relationship between knowledge and level of comfort was examined. No statistically significant relationship was found between guideline knowledge ANOVA ($F [2, 154]=0.69$, $p=0.50$), pharmacology knowledge ANOVA ($F [2, 154]=0.84$, $p=0.44$), or overall knowledge ANOVA ($F [2, 154]=0.89$, $p=0.41$), and the level of comfort when administering drugs for PSA.

A statistically significant relationship was found between pharmacology knowledge and the level of comfort identifying complications related to PSA, with the comfortable group scoring 8.63 (57.55%) and the uncomfortable group scoring 7.03 (46.87%) ANOVA ($F [2,154]=3.40$, $p=0.036$).
In addition a statistically significant relationship was found between pharmacology knowledge and the level of comfort managing complications related to PSA ANOVA (F [2,154]=4.42, p=0.014). The comfortable group scored 8.97 (59.77%) and the uncomfortable group scored 7.27 (48.46%).

4.3.10 Audit of the availability of prescribed drugs and equipment

The ninth objective of the study assessed the equipment and drugs available in the locations in which PSA is performed. This audit was based upon the list provided in the SASA guidelines.

The following areas were assessed: CT scan rooms 1 and 2, medical casualty, endoscopy suites, ERCP suite, emergency medicine department, surgical casualty, trauma casualty and resuscitation area, and the orthopaedic casualty procedure room. The overall percentage of expected equipment and drugs available in these areas is shown in Figure 4.9.

![Figure 4.9 Equipment and drug availability in different PSA locations](image)

The checklist is divided into components. The availability of devices to administer oxygen and assist with ventilation was found to be 63.64% in CT scan room 1, 72.73% in CT room 2, 81.82% in the medical casualty, 81.82% in the endoscopy suites, 72.73% in the ERCP suite,
81.82% in the emergency medicine department, 18.18% in the surgical casualty, 81.82% in the trauma casualty and resuscitation area, and 0% in the orthopaedic casualty procedure room.

The availability of airway devices and equipment was found to be 63.64% in CT scan room 1, 72.73% in CT scan room 2, 81.25% in the medical casualty, 81.25% in the endoscopy suites, 72.73% in the ERCP suite, 81.25% in the emergency medicine department, 18.18% in the surgical casualty, 81.25% in the trauma casualty and resuscitation area, and nil in the orthopaedic casualty procedure room.

The availability of monitoring equipment was found to be 12.50% in CT scan room 1, 50.00% in CT scan room 2, 62.50% in the medical casualty, 50.00% in the endoscopy suites, 50.00% in the ERCP suite, 75.00% in the emergency medicine department, 37.50% in the surgical casualty, 75.00% in the trauma casualty and resuscitation area, and 0% in the orthopaedic casualty procedure room.

The availability of equipment with which to gain intravenous access was found to be 66.67% in CT scan room 1, 88.89% in CT scan room 2, 77.78% in the medical casualty, 77.78% in the endoscopy suites, 77.78% in the ERCP suite, 88.89% in the emergency medicine department, 88.89% in the surgical casualty, 88.89% in the trauma casualty and resuscitation area, and nil in the orthopaedic casualty procedure room.

The availability of equipment for the accurate infusion of drugs and fluids was found to be 50.00% in CT scan room 1, 2, the endoscopy suites and the ERCP suite. Availability in the medical casualty, emergency medicine department, surgical casualty and the trauma casualty and resuscitation area was found to be 66.67%, and 16.67% in the orthopaedic casualty procedure room.

The availability of hardware and miscellaneous equipment was found to be 45.45% in CT scan room 1, 2 and endoscopy suites, 63.64% in the medical casualty and surgical casualty, 54.55% in the ERCP suite, 81.82% in the emergency medicine department, 72.73% in the trauma casualty and resuscitation area, and 18.18% in the orthopaedic casualty procedure room.

The availability of the recommended drugs was found to be 53.85% in CT scan room 1 and 2, 84.62% in the medical casualty and trauma casualty and resuscitation area, 46.15% in the
endoscopy suites, 38.46% in the ERCP suite, 92.31% in the emergency medicine department, 38.46% in the surgical casualty and 0% in the orthopaedic casualty procedure room.

4.4 Discussion

The proportion of doctors for each professional level is a reflection of the level of hospital at which the study was performed. CHBAH is a teaching/academic hospital and for this reason, consultants, registrars and interns form the majority of the doctor workforce. Registrars constituted the greatest proportion of participants (32.70%). This mirrored the study by Fanning (72), which was conducted at the university teaching hospitals in Dublin, Ireland. Posts for community service doctors at CHBAH are limited or unavailable as these doctors are sent to secondary and peripheral hospitals, thereby explaining the single community service doctor who participated in the study.

According to the SASA Guidelines, sedationists are required to have a registered medical degree, BLS, ACLS training as well as current knowledge and skill in PSA and its complications (3). All respondents were presumed to have a registered medical degree as this forms part of the conditions for employment as a doctor at the hospital. Most respondents indicated that they had received BLS (70.63%) and ACLS (60.63%) training. It is not known, however, if this training is current as one is required to requalify every two years.

The proportion of doctors with PSA training was very low (15.63%). The RCA and Leroy et al. (58, 61) have suggested that PSA training within the specialist disciplines is overlooked but needs to be incorporated into specialist training in order to reduce PSA related adverse events.

Whilst the number of respondents with PSA training was low, the perceived benefit of PSA training was high (79.87%). Similar results were obtained in a Canadian study among radiologists (68). Studies have shown that the incorporation of formalised PSA teaching was thought to be useful and that training was indeed able to address PSA knowledge gaps among EM practitioners (69, 70). For this reason the introduction of formal PSA training within specialist departments has the potential to contribute to practitioners’ PSA knowledge.

[69]
PSA is performed in a number of locations, however the majority of PSA is conducted in the surgical and trauma casualties and emergency department. The procedures for which PSA is done may be linked to the location, with intercostal drain insertion, suturing and incision and drainage procedures being done mainly in these areas. These results are in contrast to those found by Fanning (72), where most PSA was conducted in the endoscopy suites (36.94%) and minor surgical theatre (34.23%). The difference may be as a result of the greater number of trauma-related cases seen at CHBAH and the need to perform procedures in the surgical, trauma and emergency departments to relieve pressure on theatre demand.

The development of guidelines was done in order to improve standards of care and safety however adherence to guidelines is a complex process. Most respondents (73.58%) indicated that they were not at all aware of a protocol for sedation practice in their department and only 9.43% used them when performing PSA. While these results are lower than those found in other studies (58, 62, 63, 72), the successful implementation of guidelines remains a challenging task across specialities. One of the reasons for this may be the tendency to follow guidelines developed by ones’ own speciality (62, 71). This was the reason for enquiring about the use of guidelines other than those developed by SASA. Specialist affiliation was, however, not observed in this study. Other reasons for poor guideline adherence are discussed in Pathman et al. (60) awareness – agreement - adoption model. The impact of these factors was not explored in this study, but may serve as a guide for future research.

Guideline knowledge was assessed with a number of questions concerning correct conduct of PSA and monitoring requirements. The low levels of awareness and use of PSA guidelines suggests that the mean score of 72.13% is based on knowledge acquired through means other than guideline use. When analysing the results further it was found that the MO/CS/I group performed better than the consultant group. This was a surprising result as consultants have completed their specialist training and would thus be expected to have greater knowledge. A possible explanation may be that once doctors have obtained their specialisation, the level of knowledge acquisition and retention declines as they are no longer in a structured teaching program. Another reason may be that the task of PSA may be assigned to more junior doctors, with the result being a decline in PSA knowledge and skill among consultants.

Guideline knowledge was also found to be greater among EM respondents, with a significant different existing between this group and the department and orthopaedic surgery.
The most frequently used drug for PSA, in both this study and by Fanning (72), was found to be midazolam, with rates of 80.50% and 98.20% respectively. This was followed by local anaesthetic agents (65.41%), morphine (64.15%) and ketamine (62.26%), which was in contrast to Fanning’s findings of a combination of sedation and local anaesthetic agent (82.88%) and sedation and opioid (25.23%) (72).

The use of propofol for PSA is a debated topic. The SASA guidelines state that only trained anaesthesiologists should be using this drug (3), ASA states that those who use it must be trained to identify and manage complications that may arise from its use (2), and AGA and the field of EM have demonstrated its safe use provided sedationists are adequately trained (13, 32, 56).

Twenty eight percent of respondents indicated that they use propofol for PSA yet only 15.63% indicated they had received PSA training. This raises safety concerns about the use of drugs for which sedationists are not adequately trained to use. While each speciality may follow its own guidelines, knowledge of drugs, their complications and management thereof is crucial.

Pharmacology knowledge was indeed assessed. The mean score was only 53.40%, which demonstrates the large pharmacology knowledge gap that exists. Comparison between professional levels and departments showed no statistically significant difference. Fanning (72) found similarly poor results with a mean pharmacology score of 48.75%. Furthermore, 19.82% of respondents reported the occurrence of adverse events while administering PSA.

Anecdotal evidence suggested that PSA practitioners did not feel comfortable performing PSA due to the lack of training in this area. The results were confounding as most respondents felt neutral with regard to levels of comfort when administering drugs for PSA and managing PSA related complications, yet felt comfortable identifying complications. An encouraging finding, however, was respondents’ perceived ability to object should they feel uncomfortable administering PSA.

Analysis of levels of comfort according to professional level revealed the MO/CS/I group to be the most uncomfortable when administering PSA, whereas the consultant group felt the most comfortable managing PSA related complications. Ones’ amount of experience would appear
to be a reasonable explanation for this result, with the MO/CS/I group having the least experience and years of training.

A relationship between levels of comfort and knowledge was also sought. It was postulated that those who felt more comfortable performing PSA would have greater knowledge. No such relationship was found between levels of comfort and guideline knowledge but a relationship between levels of comfort identifying and managing complications and pharmacology knowledge was found. Those respondents who indicated they felt comfortable scored higher than those who indicated they felt uncomfortable, thereby confirming the idea that levels of comfort are related to levels of knowledge.

The drugs and equipment checklist provided by the SASA Guidelines is extremely comprehensive. The results indicate many inadequacies, with items missing in each section of the checklist. For devices to administer oxygen and assist with ventilation, Venturi and nebuliser masks, peak end expiratory pressure (PEEP) valves and catheter mounts were the most commonly missing items. In the airway devices and equipment, laryngeal masks and nasopharyngeal airways were the most commonly missing items. Amongst monitoring equipment stethoscopes, thermometers and blood glucose devices were found to be missing most often. Equipment for IV access showed deficiencies in sterile gauze pads and tourniquets, equipment for drug infusion showed reduced availability of infusion pumps and syringe drivers. Amongst hardware and miscellaneous equipment operating tables that could be tilted, South African Resuscitation Council Algorithms, procedural documentation and a therapeutic heat source were found to be missing. Drugs most commonly missing were flumazenil, ephedrine or phenylephrine, nitroglycerine spray, aspirin, salbutamol and suxemethonium.

While the list of items missing appears to be long, some of these are acceptable as their absence does not preclude the safe administration of PSA e.g. the lack of stethoscopes is acceptable as most if not all practitioners will have one of their own. While the orthopaedic casualty was extremely poorly equipped and the surgical casualty moderately equipped, these areas are within close proximity to the trauma resuscitation area and may make use of its drugs and equipment if required. Equipment deficiencies that need to be addressed are the lack of Venturi and nebuliser masks and the availability of flumazenil, ephedrine or
phenylephrine, nitroglycerine spray, aspirin, salbutamol and suxemethonium. In light of the high usage of midazolam, flumazenil is of particular importance.

4.5 Summary

In this chapter the results of this study have been presented and discussed as per the research objectives.

In the final chapter a summary, the limitations, recommendations and conclusions of the study are presented.
Chapter Five  
Summary, limitations, recommendations and conclusions

5.1 Introduction

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

5.2 Summary of the study

5.2.1 Purpose of the study

The purpose of this research was to assess the profile of non-anaesthesiologist PSA providers at CHBAH, their awareness of the SASA Sedation Guidelines 2010 (3) and their level of comfort when performing PSA. The available equipment and drugs in PSA settings outside the operating theatre complexes was also assessed.

5.2.2 Objectives of the study

The objectives of the study were to:

- describe the professional level of respondents
- describe respondent PSA and resuscitation training
- describe the locations and procedures for which PSA is performed
- assess the level of awareness of PSA guidelines (SASA)
- describe the comfort level of practitioners when performing PSA
- compare the level of PSA knowledge by professional level
- compare the level of PSA knowledge by clinical department
- compare the level of comfort by professional level
- audit the availability of recommended drugs and equipment.

5.2.3 Summary of the methodology used in the study

A prospective, descriptive, contextual study design was used. Doctors working in general surgery, trauma, orthopaedic surgery, radiology, emergency medicine and internal medicine...
departments belonging to the professional levels consultant, registrar, medical officer, community service officer and second year intern formed the population group studied.

All doctors within the departments were identified. A convenience sampling method was used. The true sample was realised from the number of respondents.

Data collection was done with the use of two tools: a self-administered questionnaire (appendix 6) and the SASA Equipment and Drugs for Procedural Sedation and Analgesia (3) checklist (appendix 7). Approval from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, the heads of the departments and CHBAH Medical Advisory Committee was obtained. The questionnaire was distributed to those medical doctors who agreed to participate in the study. Questionnaires were collected by the researcher and kept in a box to which only the researcher and supervisors had access. The PSA locations were audited according to the above-mentioned checklist.

5.2.4 Results

The level of awareness of PSA among non-anaesthesiologists at CHBAH is disappointing, with a knowledge gap existing in both guideline and pharmacology knowledge. While certain professional levels and clinical departments demonstrate better knowledge than others, the need for PSA training is highlighted by these poor results and respondents’ indication that they would benefit from such training.

Assessment of levels of comfort among PSA practitioners showed that the MO/CS/I group experienced lower levels of comfort, and while the overwhelming majority felt they could object to administering PSA if they felt uncomfortable, these doctors, once again, formed the largest proportion of doctors who felt they could not object. A relationship between pharmacology knowledge and levels of comfort was also found, with higher scores being achieved by those with higher levels of comfort.

Drugs and equipment availability was extremely variable, with trauma, department and surgical casualty being reasonably well equipped, and endoscopy and orthopaedic casualty being poorly equipped. Steps need to be taken in order to address these deficiencies in order to improve patient safety.
5.3 Limitations of the study

The study design, sampling methodology and data collection process constitute the main limitations of the study. The study was contextual in nature. Specified departments at CHBAH were involved and thus the findings may not be generalised to other departments or academic hospitals in the province or country. Convenience sampling was used, particularly within the registrar group, and this may contribute to bias.

The questionnaires were distributed at departmental meetings where doctors had the opportunity to participate. Questionnaires were collected at the end of a meeting, at subsequent meetings or on an individual basis. It was thus possible for participants to discuss answers, or check for correctness before returning the questionnaires, thereby potentially giving an untrue reflection of guideline awareness. In two departments, the attendance of meetings by the researcher was not possible, and so equal opportunity to all doctors in these departments could not be assured. This may explain the poor response rates. Consequently, limited insight into PSA practice in these departments is available.

A self-administered questionnaire was used to assess SASA Sedation Guidelines 2010 (3) awareness and PSA specific knowledge. Correct answers to the questionnaire may not indicate awareness of the guidelines but may rather reflect a consistency between the guidelines and the respondents’ judgement and knowledge. Furthermore, awareness cannot be interpreted as use of or adherence to these guidelines.

The study focuses on awareness of the SASA Sedation Guidelines 2010 (3), however, these are not the only sedation guidelines in use. Despite a small number of respondents indicating use of other guidelines, EMSSA, AGA and other guidelines are used and may recommend alternative PSA practices.

The use of multiple-choice questions in the questionnaire may increase the measured levels of awareness by offering options to which respondents may have been previously unaware.

Department heads were timeously approached for permission to conduct the study in their departments and were thus aware of the upcoming questionnaire and audit. This may have
resulted in an effort to improve guideline awareness and equipment and drug availability in their respective departments in anticipation of the study, and hence may not reflect reality.

ASA practice guidelines for sedation and analgesia by non-anaesthesiologist were last updated in 2006. The review of these guidelines may thus be out-dated and no longer evidence-based practice. Despite this they have been extensively discussed in the literature review.

5.4 Recommendations

5.4.1 Recommendations for clinical practice

The study may have identified a specific knowledge deficit within the departments involved and for this reason, may be of value to these departments and CHBAH management. The Department of Anaesthesiology may be in the position to assist departments in constructing a formal PSA training programme or may be able to offer PSA training directly. This would require regular review to ensure that such training has a positive impact.

The study has also identified areas deficient of equipment and drugs required for PSA. This will assist departments to order the required items, and hence improve patient safety.

5.4.2 Recommendations for further research

Guideline adherence is a complex process, one that was not assessed in the study. Future research may focus on understanding the issues around this subject.

One of the main benefits to guideline use is the positive impact on patient safety. This study did not explore the occurrence of PSA-related adverse events but future research may explore this area. Furthermore, should PSA training be instituted, reassessment of guideline knowledge, levels of comfort among PSA practitioners and the potential impact on patient safety may be conducted. This will assist with understanding the impact of training on PSA practitioners as well as patients.

Once departments have been given an opportunity to improve equipment and drug availability, a repeat audit may be performed in order to assess the adequacy of measures taken.
5.5 Conclusion

The levels of awareness of PSA among non-anaesthesiologists are lacking. While guideline knowledge was substantially better than pharmacology knowledge, an opportunity to address these deficiencies exists in the form of PSA specific training.

The equipment and drugs audit also provides detailed information about areas that need to be addressed in each of the PSA locations assessed. Targeted measures may thus be instituted in order to improve equipment and drug availability and hence patient safety.
References


[82]


Appendices

Appendix 1: Permission from the Human Research Ethics Committee (Medical)

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

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Karin-Ann Ben-Israel

CLEARANCE CERTIFICATE M120112
PROJECT
Levels of Awareness and Comfort for
Procedural Sedation and Analgesia among
Non-Anaesthesiologists

INVESTIGATORS Dr Karin-Ann Ben-Israel.
DEPARTMENT Department of Anaesthesiology
DATE CONSIDERED 27/01/2012

DECISION OF THE COMMITTEE* Approved unconditionally

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

DATE 07/08/2012 CHAIRPERSON

(Professor PE Cleaton-Jones)

*Guidelines for written ‘informed consent’ attached where applicable
cc: Supervisor: Mrs Juan Scribante

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...
Appendix 2: Permission from the University of the Witwatersrand Post-graduate Committee

Faculty of Health Sciences
Medical School, 7 York Road, Parktown, 2193
Fax: (011) 717-2119
Tel: (011)717-2075/6

Reference: Ms Salamina Segole
E-mail: Salamina.segole@wits.ac.za
12 April 2012
0103514Y
PAG

Dr K Ben-Israel
P. O. Box 4937
Rivonia
2128
South Africa

Dear Dr Ben-Israel

Master of Medicine (in the specialty Anaesthesia): Approval of Title

We have pleasure in advising that your proposal entitled “Levels of awareness for procedural sedation and analgesia among non-anaesthesiologists” has been approved. Please note that any amendments to this title have to be endorsed by the Faculty’s higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences
Appendix 3: Permission from the CHBAH Medical Advisory Committee

Gauteng Province

Health
Republic of South Africa

Medical Advisory Committee
Chris Hani Baragwanath Academic Hospital

Permission to Conduct Research

Date: 20 September 2012

Title of Project: levels of awareness of procedural sedation and analgesia among non-anaesthesiologists

University: Witwatersrand

Principal Investigator: Dr K-A Ben-Israel

Department: Anaesthesiology

Supervisor (If relevant): Dr H Perie/Ms J Scribante

Permission Head Department (where research conducted):

Date of start of proposed study: October 2012

Date of completion of data collection: December 2012

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO/management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- The hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee approval.

Recommended
(On behalf of the MAC)
Date: 20 September 2012

Approved/Not Approved
Hospital Management
Date: 28/9/12
Appendix 4: Letter of assent from Heads of Departments

Dear Professor Smith,

My name is Karin-Ann Ben-Israel and I am an anaesthesiology registrar on the Wits anaesthesiology registrar circuit.

I would like to request your assent to conduct a research study that will be handed in to the Wits University Department of Health Sciences as part of my MMED degree.

The study has been approved by the Human Research Ethics Committee (Medical) (Number R14/49). Furthermore, permission to conduct the study has been granted by the Chris Hani Baragwanath Academic Hospital (CHBAH) Research Board.

The study involves the assessment of procedural sedation and analgesia (PSA) practices at CHBAH and will entail the distribution of a self-administered questionnaire to the medical officers, registrars and consultants in your department, as well as the second year interns that have rotated through your department during the course of last year. The questionnaire aims to evaluate the doctors responsible for administering PSA, the locations and procedures that use PSA, levels of awareness of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010 and their level of comfort when performing PSA. It will also entail an audit of the areas in which PSA is administered to evaluate if the equipment and drugs required for the provision of PSA are available. This will be based on the checklist provided by SASA in the Sedation Guidelines 2010.

I would like to request permission to conduct my study in your department.

I, [Signature], grant permission to Karin-Ann Ben-Israel to perform data collection for her MMED study on PSA practices at CHBAH in the department of surgery.

Date: 21st October 2013
Dear Professor Dickerson,

My name is Karin-Ann Ben-Israel and I am an anaesthesiology registrar on the Wits anaesthesiology registrar circuit.

I would like to request your assent to conduct a research study that will be handed in to the Wits University Department of Health Sciences as part of my MMED degree.

The study has been approved by the Human Research Ethics Committee (Medical) (Number R14/49). Furthermore, permission to conduct the study has been granted by the Chris Hani Baragwanath Academic Hospital (CHBAH) Research Board.

The study involves the assessment of procedural sedation and analgesia (PSA) practices at (CHBAH) and will entail the distribution of a self-administered questionnaire to the medical officers, registrars and consultants in your department, as well as the second year interns that have rotated through your department during the course of last year. The questionnaire aims to evaluate the doctors responsible for administering PSA, the locations and procedures that use PSA, levels of awareness of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010 and their level of comfort when performing PSA. It will also entail an audit of the areas in which PSA is administered to evaluate if the equipment and drugs required for the provision of PSA are available. This will be based on the checklist provided by SASA in the Sedation Guidelines 2010.

I would like to request permission to conduct my study in your department.

\[ \text{Signature} \]

Published: 02/10/2012

I, \text{Roger Dickerson}, grant permission to Karin-Ann Ben-Israel to perform data collection for her MMED study on PSA practices at CHBAH in the department of emergency medicine.
Dear Professor Ramokgopa,

My name is Karin-Ann Ben-Israel and I am an anaesthesiology registrar on the Wits anaesthesiology registrar circuit.

I would like to request your assent to conduct a research study that will be handed in to the Wits University Department of Health Sciences as part of my MMED degree.

The study has been approved by the Human Research Ethics Committee (Medical) (Number R14/49). Furthermore, permission to conduct the study has been granted by the Chris Hani Baragwanath Academic Hospital (CHBAH) Research Board.

The study involves the assessment of procedural sedation and analgesia (PSA) practices at (CHBAH) and will entail the distribution of a self-administered questionnaire to the medical officers, registrars and consultants in your department, as well as the second year interns that have rotated through your department during the course of last year. The questionnaire aims to evaluate the doctors responsible for administering PSA, the locations and procedures that use PSA, levels of awareness of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010 and their level of comfort when performing PSA. It will also entail an audit of the areas in which PSA is administered to evaluate if the equipment and drugs required for the provision of PSA are available. This will be based on the checklist provided by SASA in the Sedation Guidelines 2010.

I would like to request permission to conduct my study in your department.

I, Prof M.T.Ramokgopa grant permission to Karin-Ann Ben-Israel to perform data collection for her MMED study on PSA practices at CHBAH in the department of orthopaedics.

Signature:

Date: 02/10/2012.
Dear Professor Ally,

My name is Karin-Ann Ben-Israel and I am an anaesthesiology registrar on the Wits anaesthesiology registrar circuit.

I would like to request your assent to conduct a research study that will be handed in to the Wits University Department of Health Sciences as part of my MMED degree.

The study has been approved by the Human Research Ethics Committee (Medical) (Number R14/49). Furthermore, permission to conduct the study has been granted by the Chris Hani Baragwanath Academic Hospital (CHBAH) Research Board.

The study involves the assessment of procedural sedation and analgesia (PSA) practices at (CHBAH) and will entail the distribution of a self-administered questionnaire to the medical officers, registrars and consultants in your department, as well as the second year interns that have rotated through your department during the course of last year. The questionnaire aims to evaluate the doctors responsible for administering PSA, the locations and procedures that use PSA, levels of awareness of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010 and their level of comfort when performing PSA. It will also entail an audit of the areas in which PSA is administered to evaluate if the equipment and drugs required for the provision of PSA are available. This will be based on the checklist provided by SASA in the Sedation Guidelines 2010.

I would like to request permission to conduct my study in your department.

I, ....................................................., grant permission to Karin-Ann Ben-Israel to perform data collection for her MMED study on PSA practices at CHBAH in the gastrointestinal unit of the department of internal medicine.

Signature: .............................................

Date: .................................................
Dear Professor Huddle,

My name is Karin-Ann Ben-Israel and I am an anaesthesiology registrar on the Wits anaesthesiology registrar circuit.

I would like to request your assent to conduct a research study that will be handed in to the Wits University Department of Health Sciences as part of my MMED degree.

The study has been approved by the Human Research Ethics Committee (Medical) [Number R14/49]. Furthermore, permission to conduct the study has been granted by the Chris Hani Baragwanath Academic Hospital (CHBAH) Research Board.

The study involves the assessment of procedural sedation and analgesia (PSA) practices at [CHBAH] and will entail the distribution of a self-administered questionnaire to the medical officers, registrars and consultants in your department, as well as the second year interns that have rotated through your department during the course of last year. The questionnaire aims to evaluate the doctors responsible for administering PSA, the locations and procedures that use PSA, levels of awareness of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010 and their level of comfort when performing PSA. It will also entail an audit of the areas in which PSA is administered to evaluate if the equipment and drugs required for the provision of PSA are available. This will be based on the checklist provided by SASA in the Sedation Guidelines 2010.

I would like to request permission to conduct my study in your department.

I, ____________________________, grant permission to Karin-Ann Ben-Israel to perform data collection for her MMED study on PSA practices at CHBAH in the department of internal medicine.

Signature: __________________________

Date: __________________________
Dear Professor Nagdee,

My name is Karin-Ann Ben-Israel and I am an anaesthesiology registrar on the Wits anaesthesiology registrar circuit.

I would like to request your assent to conduct a research study that will be handed in to the Wits University Department of Health Sciences as part of my MMED degree.

The study has been approved by the Human Research Ethics Committee (Medical) (Number R14/49). Furthermore, permission to conduct the study has been granted by the Chris Hani Baragwanath Academic Hospital (CHBAH) Research Board.

The study involves the assessment of procedural sedation and analgesia (PSA) practices at (CHBAH) and will entail the distribution of a self-administered questionnaire to the medical officers, registrars and consultants in your department, as well as the second year interns that have rotated through your department during the course of last year. The questionnaire aims to evaluate the doctors responsible for administering PSA, the locations and procedures that use PSA, levels of awareness of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010 and their level of comfort when performing PSA. It will also entail an audit of the areas in which PSA is administered to evaluate if the equipment and drugs required for the provision of PSA are available. This will be based on the checklist provided by SASA in the Sedation Guidelines 2010.

I would like to request permission to conduct my study in your department.

I, Dr. A. Nagdee, hereby grant permission to Karin-Ann Ben-Israel to perform data collection for her MMED study on PSA practices at CHBAH in the department of radiology.

Signature:

Date: 22/11/2012
Appendix 5: Information letter, questionnaire

Dear colleague,

Hello, my name is Karin-Ann Ben-Israel and I am an anaesthesiology registrar on the University of the Witwatersrand’s anaesthesiology registrar circuit.

I would like to invite you to participate in a research study entitled: levels of awareness and comfort for procedural sedation and analgesia among non-anaesthesiologist. This will be handed in to the Wits University Department of Health Sciences as part of my MMED degree.

The study will involve the assessment of procedural sedation and analgesia (PSA) practices at Chris Hani Baragwanath Academic Hospital (CHBAH). It has been observed that the regulations formulated by the South African Society of Anaesthesiologists (SASA) for the administration of PSA in adults, which ensure the safe performance of PSA, are unfamiliar to some health care professionals. Thus the study wishes to assess:

- the professional levels of the doctors administering PSA
- the locations and types of procedures being done using PSA
- the levels of awareness amongst non-anaesthesiologists of the South African Society of Anaesthesiologists (SASA) Sedation Guidelines 2010
- the levels of comfort when administering PSA.

The study has been approved by the Human Research Ethics Committee (HREC) (Medical) (Number R14/49) and the Post-graduate Committee of the University of the Witwatersrand. Furthermore, permission to conduct the study has been obtained from the CHBAH Research Board and the heads of departments involved.

Consent will be implied by agreeing to complete the questionnaire and is entirely voluntary. Questionnaires are not marked in any way for identification and no identifying data will be collected. The questionnaire should only take approximately 10 minutes to complete. Once completed questionnaires will be placed into a sealed box. The content of the completed questionnaires will only be viewed by myself and my research supervisors.

Results published will have no identifying data and will be made available to participants.

The study offers no benefit to participants but may result in positive changes for the future.

Thank you for taking the time to read this letter. If you have any questions or concerns with regard to the study, you may contact the following people with your queries:

- Professor Cleaton-Jones (chairperson of the HREC): 011 717 1234
- Karin-Ann Ben-Israel (researcher): 083 329 8655.

Please know that you are free to withdraw from the study at any time without having to provide a reason. The study is entirely voluntary and not taking part in it or withdrawing from it carries no penalty or repercussion of any sort.

Yours sincerely
Karin-Ann Ben-Israel
Appendix 6: Questionnaire

I would like to thank you for taking the time to complete the following questionnaire. The questionnaire consists of five sections, and has a total of 26 questions. It should take approximately 10 minutes to complete.

Instructions: Please will you complete the following questionnaire by marking the appropriate box with an “x”, and by filling in written responses in the space provided, where this is required.

Please note: All respondents will be kept anonymous and the information kept confidential.

Section 1: Demographics, professional level and training

1. Gender:

   Male
   Female

2. Professional level:

   Intern
   Community service
   Medical officer
   Registrar
   Consultant

3. Please answer questions 3.1 or 3.2 according to your professional level.

   3.1 If you are a community service/medical officer, registrar or consultant, to which discipline do you belong?

   General surgery/trauma
   Orthopaedic surgery
   Emergency medicine
   Internal medicine
   Radiology
3.2 If you are an **intern**, through which disciplines have you rotated?

<table>
<thead>
<tr>
<th>Discipline</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>General surgery/trauma</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic surgery</td>
<td></td>
</tr>
<tr>
<td>Emergency medicine</td>
<td></td>
</tr>
<tr>
<td>Internal medicine</td>
<td></td>
</tr>
<tr>
<td>Obstetrics and gynaecology</td>
<td></td>
</tr>
<tr>
<td>Paediatrics</td>
<td></td>
</tr>
<tr>
<td>Anaesthesiology</td>
<td></td>
</tr>
<tr>
<td>Family medicine</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

If you have marked “other” please write down through which other disciplines you have rotated...

4. Training post-medical degree: please mark all appropriate boxes

<table>
<thead>
<tr>
<th>Training</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Life Support</td>
<td></td>
</tr>
<tr>
<td>Advanced Cardiac Life Support</td>
<td></td>
</tr>
<tr>
<td>PSA training, lectures/tutorials/workshops</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

5. I would benefit from PSA training.

<table>
<thead>
<tr>
<th>Benefit from PSA training</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Don’t know</td>
<td></td>
</tr>
</tbody>
</table>
Section 2: PSA procedures and locations

1. In what locations do you perform PSA? Please mark all appropriate boxes.

<table>
<thead>
<tr>
<th>Location</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical casualty</td>
<td></td>
</tr>
<tr>
<td>Trauma casualty</td>
<td></td>
</tr>
<tr>
<td>Upper endoscopy suite</td>
<td></td>
</tr>
<tr>
<td>Lower endoscopy suite</td>
<td></td>
</tr>
<tr>
<td>ERCP suite</td>
<td></td>
</tr>
<tr>
<td>CT scan suite</td>
<td></td>
</tr>
<tr>
<td>Interventional radiology suite</td>
<td></td>
</tr>
<tr>
<td>Emergency department/casualty</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic casualty</td>
<td></td>
</tr>
<tr>
<td>Medical casualty (Short stay ward or ward 20)</td>
<td></td>
</tr>
<tr>
<td>General wards</td>
<td></td>
</tr>
</tbody>
</table>

2. For what procedures do you perform PSA? Please mark all appropriate boxes.

<table>
<thead>
<tr>
<th>Procedure</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision and drainage</td>
<td></td>
</tr>
<tr>
<td>Suturing</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic procedures</td>
<td></td>
</tr>
<tr>
<td>Radiological procedures</td>
<td></td>
</tr>
<tr>
<td>Endoscopy</td>
<td></td>
</tr>
<tr>
<td>Intercostal drain insertion</td>
<td></td>
</tr>
<tr>
<td>Cardioversion</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

If you have marked other, please specify the procedures for which you have used PSA.

..............................................................................................................................................
Section 3: Guideline awareness/knowledge

1. Is there a protocol for sedation practices in your department?

<table>
<thead>
<tr>
<th>I am not at all aware of them</th>
<th>I have heard about them</th>
<th>I am familiar with their content</th>
<th>I use them when performing PSA</th>
</tr>
</thead>
</table>

1.1 If you are aware of a PSA protocol in your department, please indicate which protocol is followed.

SASA Sedation Guidelines 2010

| Emergency Medicine Society of South Africa, Procedural sedation in the emergency centre |
| American Gastroenterology Association (AGA) |
| Other |

2. How many medical personnel are required when minimal sedation/anxiolysis is performed by the same doctor? Please indicate the total number of people required.

1
2
3

3. Which of the following are recommended by the SASA PSA guidelines before administering PSA? Please mark all appropriate boxes.

A pre-sedation assessment documented in the patient file
A pre-sedation assessment documented on a PSA assessment form
No pre-sedation assessment is required as PSA is not general anaesthesia
Baseline vital signs
Ensure the patient is fasted for 6 hours for solids and 2 hours for clear fluids
Ensure the patient is fasted for 4 hours for solids and 2 hours for clear fluids
Document last oral intake and fast patient according to planned level of sedation planned
4. A non-anaesthesiologist is permitted to administer PSA to patients with an ASA physiological classification: Please mark all the appropriate boxes

<table>
<thead>
<tr>
<th></th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>V</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. What monitoring is required when PSA is administered? Please mark all the appropriate boxes.

- Non-invasive blood pressure
- ECG
- Pulse oximetry
- Capnography
- Level of consciousness by clinically means
- Airway patency and respiration
- Level of consciousness with bispectral index monitoring
- Serial arterial blood gas measurements

6. Please indicate what emergency equipment and drugs that are required to be present in locations where PSA is administered. Please mark all appropriate boxes.

- Self-inflating resuscitation bag with reservoir
- Endotracheal tubes of various sizes
- Capnograph
- Naloxone
- Rocuronium
- N-acetyl cysteine
- Cardiac defibrillator
- Adrenaline
Section 4: Pharmacology

1. Please indicate which medications you use for PSA. Please mark all appropriate boxes.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Midazolam</td>
<td></td>
</tr>
<tr>
<td>Diazepam</td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td></td>
</tr>
<tr>
<td>Pethidine</td>
<td></td>
</tr>
<tr>
<td>Propofol</td>
<td></td>
</tr>
<tr>
<td>Ketamine</td>
<td></td>
</tr>
<tr>
<td>Local anaesthetic agents</td>
<td></td>
</tr>
<tr>
<td>Opiates in combination with benzodiazepines</td>
<td></td>
</tr>
<tr>
<td>Local anaesthesia agents in combination with sedation</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

If you have marked “other”, please specify which other medications you use for PSA.

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

2. When using more than one class of drug for PSA should one administer the medication in boluses or divided doses titrated to effect?

| Boluses                     |   |
|                            |   |
| Divided doses titrated to effect |   |

3. The dose of IV midazolam for PSA is:

<table>
<thead>
<tr>
<th>0.01-0.04mg/kg to a maximum bolus of 1mg</th>
<th>0.05-0.1mg/kg to a maximum bolus of 2mg</th>
<th>0.1-0.2mg/kg to a maximum bolus of 3mg</th>
<th>1-2mg boluses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Midazolam produces the following side effects: please tick all appropriate answers.

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>True</th>
<th>False</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of upper airway tone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agitation/excitement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tachycardia</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Ketamine produces the following side effects: please tick appropriate boxes.

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>True</th>
<th>False</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bradycardia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in intracranial pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased saliva production</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergence delirium</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Opioid-induced respiratory depression is dose-dependent.

<table>
<thead>
<tr>
<th>Opioid-induced respiratory depression</th>
<th>True</th>
<th>False</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>dose-dependent</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. The dose of naloxone is:

<table>
<thead>
<tr>
<th>Dose Range</th>
<th>True</th>
<th>False</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01-0.05mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.5-0.8mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.04-0.2mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No defined</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dose: titrate to effect</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. When performing PSA for painless procedures it is recommended to use opioids for their sedative effects.

<table>
<thead>
<tr>
<th>Opioid-induced respiratory depression</th>
<th>True</th>
<th>False</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>painless procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[104]
Section 5: Levels of comfort

Please indicate your level of comfort, from very uncomfortable to very comfortable.

1. Please rate your level of comfort when administering drugs for PSA.

<table>
<thead>
<tr>
<th>Very uncomfortable</th>
<th>Uncomfortable</th>
<th>Neutral</th>
<th>Comfortable</th>
<th>Very comfortable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Please rate your level of comfort at being able to identify complications related to PSA

<table>
<thead>
<tr>
<th>Very uncomfortable</th>
<th>Uncomfortable</th>
<th>Neutral</th>
<th>Comfortable</th>
<th>Very comfortable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Please rate your level of comfort at being able to manage complications related to PSA

<table>
<thead>
<tr>
<th>Very uncomfortable</th>
<th>Uncomfortable</th>
<th>Neutral</th>
<th>Comfortable</th>
<th>Very comfortable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Do you feel you can object to administering PSA if you feel uncomfortable?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 7: Equipment and drugs audit checklist, SASA Sedation Guidelines 2010 (3)

<table>
<thead>
<tr>
<th>Equipment and drugs for procedural sedation and analgesia (PSA), SASA Sedation Guidelines 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>All equipment should be checked regularly and stored in a mobile cupboard</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Devices to administer oxygen and assist with ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen and oxygen tubing</td>
</tr>
<tr>
<td>Oxygen source must be reliable and able to provide at least 90% oxygen via a self-inflating positive pressure delivery system at 15 l/min for at least 60 minutes</td>
</tr>
<tr>
<td>Oxygen flow regulator</td>
</tr>
<tr>
<td>Nasal prongs</td>
</tr>
<tr>
<td>Venturi masks</td>
</tr>
<tr>
<td>To deliver 40% oxygen</td>
</tr>
<tr>
<td>Nebuliser and mask</td>
</tr>
<tr>
<td>PEEP valve</td>
</tr>
<tr>
<td>Catheter mount</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Airway devices and equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face masks</td>
</tr>
<tr>
<td>Selection of sizes</td>
</tr>
<tr>
<td>Laryngeal mask airways or similar supraglottic devices</td>
</tr>
<tr>
<td>Sizes 3 – 5</td>
</tr>
<tr>
<td>Range of cuffed endotracheal tubes</td>
</tr>
<tr>
<td>Sizes 5 – 8</td>
</tr>
<tr>
<td>Laryngoscope set</td>
</tr>
<tr>
<td>Two handles with long and standard blades and spare batteries and bulbs</td>
</tr>
<tr>
<td>Water-soluble lubricant</td>
</tr>
<tr>
<td>10 ml syringe for inflation of pilot balloon</td>
</tr>
<tr>
<td>Tape or equivalent to secure endotracheal tube</td>
</tr>
<tr>
<td>Oropharyngeal airways</td>
</tr>
<tr>
<td>Sizes 3 – 5</td>
</tr>
<tr>
<td>Nasopharyngeal airways</td>
</tr>
<tr>
<td>Sizes 6 mm and 7 mm</td>
</tr>
<tr>
<td>Stylets/introducers</td>
</tr>
<tr>
<td>Appropriately sized for endotracheal tubes</td>
</tr>
<tr>
<td>Magill forceps</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG monitor and cardiac defibrillator</td>
</tr>
<tr>
<td>With conductive paste, chest paddles and razor</td>
</tr>
<tr>
<td>Pulse oximeter</td>
</tr>
<tr>
<td>Blood pressure monitoring device</td>
</tr>
<tr>
<td>Non-invasive with appropriately sized cuffs</td>
</tr>
<tr>
<td>Stethoscope</td>
</tr>
<tr>
<td>Thermometer</td>
</tr>
<tr>
<td>Blood glucose testing device</td>
</tr>
<tr>
<td>Selection of test tubes for blood biochemistry and full blood count</td>
</tr>
<tr>
<td>Capnograph</td>
</tr>
<tr>
<td>Nasal prongs with capnography line. Strongly recommended but not compulsory</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equipment with which to gain intravenous access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves</td>
</tr>
<tr>
<td>Tourniquet</td>
</tr>
<tr>
<td>Sterile gauze pads</td>
</tr>
<tr>
<td>Alcohol skin wipes</td>
</tr>
<tr>
<td>Intravenous cannulae</td>
</tr>
<tr>
<td>18 – 22 gauge</td>
</tr>
<tr>
<td>Sterile needles</td>
</tr>
<tr>
<td>Assortment of syringes</td>
</tr>
<tr>
<td>1 ml – 50 ml</td>
</tr>
<tr>
<td>Sharps container</td>
</tr>
<tr>
<td>Tape or equivalent to secure intravenous cannula</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equipment for the accurate infusion of drugs and fluids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion pumps</td>
</tr>
<tr>
<td>Intravenous fluid administration for simple sedation</td>
</tr>
<tr>
<td>Syringe drivers</td>
</tr>
<tr>
<td>Drug administration in advanced sedation</td>
</tr>
<tr>
<td>Intravenous administration sets</td>
</tr>
<tr>
<td>Must be compatible with infusion pumps</td>
</tr>
<tr>
<td>Stickers for labelling syringes</td>
</tr>
<tr>
<td>Drip stands</td>
</tr>
<tr>
<td>Intravenous fluids</td>
</tr>
<tr>
<td>Crystalloids and colloids</td>
</tr>
<tr>
<td>Hardware and miscellaneous equipment</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Source of suction</td>
</tr>
<tr>
<td>Including connection tubing</td>
</tr>
<tr>
<td>Suction catheters</td>
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<tr>
<td>Including catheters for suctioning endotracheal tubes,</td>
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<tr>
<td>and Yangkauer-type suction nozzles</td>
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<tr>
<td>Therapeutic heat source</td>
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<tr>
<td>Cardiac arrest board</td>
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<tr>
<td>Appropriate lighting</td>
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<tr>
<td>Operating surface that can be tilted</td>
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<tr>
<td>Urinary catheters</td>
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<tr>
<td>Nasogastric tubes</td>
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<tr>
<td>Means of summoning emergency assistance</td>
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<tr>
<td>South African Resuscitation Council algorithms</td>
</tr>
<tr>
<td>Basic and advanced life support</td>
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<tr>
<td>Procedural documentation</td>
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</tbody>
</table>

**Recommended emergency drugs**

- Naloxone
- Flumazenil
- Adrenaline (at least 10 ampoules)
- Atropine or glycopyrrolate
- Ephedrine or phenylephrine
  (or other alpha-agonist)
- Lignocaine
- Glucose 50%
- Hydrocortisone, methylprednisolone or dexamethasone
- Promethazine
  (or other H1-antagonist)
- Nitroglycerine spray
- Aspirin
- Salbutamol
- Suxamethonium