A description of practices of analgesia administration by Advanced Life Support paramedics in the City of Cape Town

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A Research Dissertation (60 credits)
Submitted to the University of Cape Town
In partial fulfillment of the requirements for the degree
Master of Philosophy in Clinical Emergency Medicine

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I, Ryan Ernest Matthews, hereby declare that the work contained in this submission is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree. No part of this work has been published prior to my registration for the abovementioned degree.

DECLARATION

Name: Ryan Matthews

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3. This dissertation is my own work.

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DEDICATION

This mini dissertation is dedicated to my wife, Lindie, for putting up with my continuous absence, and who sacrificed more for this degree than I did.

CONTENTS

DEFINITIONS AND TERMS

Advanced Life Support	A person registered on the 'ANT', 'ECT' or 'ECP' register of the Professional Board for Emergency Care Practitioners (PBEC) of the Health Professions Council of South Africa (HPCSA) and rendering care to their relevant scope of practice.
Analgesia	"*Absence of pain in response to stimulation which would normally be painful*" (1)
Critical Care Assistant (CCA)	A person holding the Critical Care Assistant certificate and eligible to register on the 'ANT' register of the Health Professions Council of South Africa (HPCSA) and rendering care to the 'ANT' scope of practice.
Emergency Care Practitioner	A person holding a 4 year Bachelor's degree in Emergency Medical Care and registered on the Emergency Care Practitioner's (ECP) roll of the Health Professions Council of South Africa and rendering care to the ECP scope of practice.
Emergency Care Technician	A person holding a 2 year certificate in Emergency Medical Care and registered on the Emergency Care Technicians' (ECT) roll of the of the Health Professions Council of South Africa and rendering care to the ECT scope of practice.
Emergency Centre	A portion of a healthcare facility designated for the exclusive provision of acute care. (2)
National Diploma Paramedic (NDip)	A person holding a 3 year National Diploma in Emergency Medical Care and eligible to register on the 'ANT' register of the Health Professions Council of South Africa (HPCSA) and rendering care to the 'ANT' scope of practice.

Pain	"*An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage"* (3)
Pain Relief	Reduction of pain intensity, determined by patient self-report, as a result of a clinical intervention. (3)
Paramedic	An emergency services worker registered with the Professional Board of Emergency Care (PBEC) of the Health Professions Council of South Africa (HPCSA) on the 'ANT' registration roll. Also known as 'Advanced Life Support'
Oligoanalgesia	Insufficient analgesia.

ACKNOWLEDGEMENTS

To Mr Michael McCaul of the Centre for Evidence-based Health Care, Stellenbosch University, for your kind assistance with the statistical interpretation and representation of the findings a very big thank you.

PART A: PROTOCOL

1. INTRODUCTION

Pain is a ubiquitous and important symptom in medicine (4) and one of the commonest reasons for seeking healthcare. (5) To quote one text, [it] *"stands preeminent among all the sensory experiences by which humans judge the existence of disease within themselves*". (4)

Pain has a distinct emotional component (4), acknowledged in the International Association for the Study of Pain's (IASP) definition of pain; "*An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage*" (3)

Acute pain adds to patient discomfort, is physiologically detrimental (6) and results in stress and suffering. (7) Unrelieved acute pain may precipitate chronic pain disorders (8) and lead to psychological disorders such as post-traumatic stress disorder (PTSD). (9)

Pain management is opined to be one of the few prehospital procedures to consistently show utility and benefit (10) and possibly one of the few tasks where Emergency Medical Services (EMS) can be truly effective (11).

Prehospital Emergency Care (PEC) is typically provided by EMS, which are mostly staffed by Paramedics and Emergency Medical Technicians (EMT).Physicians frequently staff ambulances, notably in Europe as well as in aeromedical services.

In both PEC and the Emergency Centre (EC) a lack of knowledge regarding acute pain management as well as fear of adverse drug events act lead to lack of analgesic use or use of lower than effective doses. Poor interdisciplinary communication acts as a barrier to analgesic use and access to limited pain management options is seen as a barrier especially in the prehospital environment.(12) Practitioners often doubt patient sincerity and honesty when describing pain intensity and practitioners frequently rely on clinical condition and patient demeanour when evaluating pain. (12,13). Pain management is frequently seen as secondary to management of life threatening injuries (12,14) Patient cooperation, cognition and combativeness also elevate the difficulties of acute pain management. (13) The use of a pain protocol acts as a facilitator of effective analgesic use. (12,15)

EMS are frequently characterised by protocol and procedure based practice which exerts influence on the type of and effectiveness of management provided. Protocols as well as training and capabilities of specifically non-physician providers (paramedics and EMTs) vary considerably throughout the world and sometimes also within individual services, making it difficult to generalise findings. The prehospital environment is very austere, dynamic and complex and 'life over limb' thinking often prevails.(14) Much of the knowledge applied in PEC stems from hospital based research brought into the prehospital environment in a 'best fit' approach. Given the disparities in resources, burden of disease and training, EMS and healthcare systems in general are not necessarily directly comparable. This strongly motivates for region specific descriptive prehospital research

In South Africa PEC is provided by tiered levels of EMTs and paramedics. The training system is in the process of transition from a vocational system to a Higher Education system. Currently practitioners from both training systems are found in the EMS. All healthcare providers in South Africa are required by law (16) to register with the Health Professions Council of South Africa (HPCSA) and follow national protocols as published by the Professional Board or Emergency Care (PBEC), a board of the HPCSA. In South Africa provision of ambulance services are a provincial competency and emergency services are administered and funded by the respective provincial government (reference needed). The training, scope of practice and capabilities are regulated by the HPCSA as described above, and not by the individual services. In addition an extensive network of private ambulance operators provide emergency services to clients, including extensive primary response and acute care. These operate as private enterprises and not under the auspices of the government. The personnel within all the private services however are still regulated by the HPCSA in exactly the same way as in all government services. Qualifications are completely portable between services and between provinces within the Republic.

The PBEC has not formally published a prehospital pain management protocol or guideline and no point of departure from which to gauge practice or measure compliance exists. As up to seven different qualifications may be active within South African EMS, each with a different scope of practice, potential for significant practice variation exists. Pain management would essentially be left to the training, judgement and possible biases, of the individual provider and actual prehospital acute pain management practices are unknown. A description of prehospital practices in the administration of prehospital analgesia was undertaken to sketch the landscape against which future studies could evaluate effectiveness.

Currently very little data is available to describe the South African PEC landscape and no published data is available regarding prehospital analgesia practices in the Western Cape.

2. AIM AND OBJECTIVES

The aim of this retrospective descriptive survey was to describe and document pre-hospital pharmacological analgesia administration practices by PEC providers in the City of Cape Town.

Specific objectives are:

1. To describe the type, dosage, dosage frequency and route of analgesic drugs administered by Advanced Life Support personnel when managing prehospital acute pain.
2. To determine the patient characteristics of patients receiving prehospital analgesic drugs in terms of gender and age.
3. To describe injury and disorder types for which prehospital analgesic drugs are administered.
4. To describe the qualifications and implied experience levels of paramedic providers of prehospital analgesia.

3. METHODS

Patient Care Records (PCR) containing an entry of analgesic administration were collected from the Medical Emergency Transport and Rescue Organisation (Metro), which is the ambulance and rescue emergency service of the Provincial Government of the Western Cape.

Twelve months' data was collected to allow for seasonal variation in injures and disorders. Only data from cases managed within the City of Cape Town was used. A pilot study was conducted, using data from the month of July 2013. Based on these findings changes were made to the data collection template. The main study examines data collected from the months August 2013 to June 2014.

3.1 Qualifications of interest

The EMS education and training system in South Africa is undergoing transition from a vocational, short course, to a National Qualifications Framework (NQF) aligned system. Both systems are training concurrently and practitioners from both systems are active in the EMS. Currently seven different qualifications are present and five of these are viewed by the HPCSA as being advanced level providers though protocols and scopes of practice differ between these qualifications (described in the definitions). The term “Paramedic” is protected under law (17) in South Africa and may only be used by Critical Care Assistants and National Diploma Emergency Medical Care graduates. For the sake of convenience persons of all advanced qualifications will be collectively termed “Advanced Life Support (ALS) providers” in this manuscript.

3.2 Sample selection and data collection

PCRs were obtained from the archive of Metro EMS located at Pinelands Ambulance Base. All PCRs were screened by trained research assistants for entries recording the administration of Nitrates, Morphine, Ketamine or 50% Nitrous Oxide/Oxygen gas (Entonox®). Nitrates were included as they may bring about reduction of chest pain in myocardial ischaemia and preclude administration of further analgesia. Each PCR was read and eligibility for inclusion in the population determined according to the inclusion and exclusion criteria below. The researcher was the only person to read and evaluate the documentation. PCRs were allocated an identifier number and captured in a spreadsheet (Microsoft Excel, Microsoft Corporation, Redmond, WA). 1530 PCRs met the screening inclusion criteria, a further 601 PCRs were excluded with reasons (see Annexure 8) leaving a sampling frame of 933 eligible PCRs. A simple random sample of 530 PCRs was sampled from the sampling frame using a random number generator (Excel) based on the prior sample size calculation Initially sample size was calculated based on the estimate that 80 drug administrations per month was taking place. The pilot study however revealed that far more administrations of Nitrates were being recorded than initially anticipated and the data collection template was altered to accommodate this. Sample size was calculated to determine the median dose of Morphine. A confidence interval of 3 mg was used, on the assumption that 5mg was the median dosage. The calculated sample size was 498 PCRs and an additional 7% was added to allow for missing data. Statistical significance was considered to be $p < 0.05$. Once all 11 months had been sampled the data was collated for statistical analysis..

3.3 Inclusion criteria

- All Patient Care Records (PCRs) recording administration of:
    - 50% Nitrous Oxide/Oxygen (Entonox®)
    - Morphine
    - Ketamine
    - Nitrates (Isosorbide Dinitrate 5 mg tablets and Glyceryl Trinitrate 0.4 mg metered dose spray).

- The presence of pain was determined if a pain score was present, the word “pain” or an equivalent such as “tenderness” was present. If these criteria were missing, presence of disorders likely to have resulted in pain, such as a fracture, resulted in inclusion.

3.4 Exclusion criteria

- PCRs of patients younger than 18 years of age. A separate ethics process for research in children is required and for the sake of expediency and simplicity the study was limited to adults.
- PCRs containing analgesia administered by a healthcare provider other than an ALS provider. For example patient report forms recording an inter-facility transfer in which the ALS provider continued with an infusion initiated in hospital.
- When doubt existed as to whether the ALS provider had made the decision to administer the drugs of interest this documentation was excluded. E.g. if the PCR alluded to a physician’s orders around treatment without clear recording of the orders.
- PCRs which may have contained the drugs of interest but did not appear to be in the context of acute pain. An example would be the use of nitrates in the treatment of pulmonary oedema where pain was not explicitly described.
- Patients who were intubated or in whom a Glasgow Coma Scale (GCS) of 3 was recorded.
- PCRs with missing data, which was directly related to the objectives of the study, were also excluded.

Data from selected PCRs was codified according to Part D: Annexure 6: Amended Data Collection codes. Injury and disorder types are classified according to the primary diagnosis

recorded by the treating ALS provider in the relevant data field on the PCR. Where no specific diagnosis was recorded the researcher categorized the case by reading the clinical notes.

Information on total dosage of drug as well as number of administrations per case was recorded. Other variables captured were gender and age of patients, type of case (primary response or inter-facility transfer) and qualification of ALS provider. Qualifications were codified as categorical variables. Experience levels of prehospital care providers were estimated by cross referencing the ALS provider's HPCSA registration number present on the PCR with registration information available on the iRegister of the HPCSA, available to the public on the HPCSA website. ALS providers were allocated a study number which was used in the main data table. Identifying data was captured in a separate password protected spreadsheet (Microsoft Excel, Microsoft Corporation, Redmond, WA) and stored securely. An example is contained in Part D: Annexure 6: Practitioner study number and experience.

The PCR did not contain a field for pain intensity score and a pain intensity scores are not required. Scores were recorded only as being present or absent. Vital signs as well as treatment times were not recorded. The resource limited and uncontrolled prehospital environment does not always allow documentation to be completed immediately and PCRs are frequently completed after EC handover or on return to the ambulance base. This introduces the risk of recall errors. It was decided to omit this data as accuracy of times and vital signs could not be determined and it was not essential to the objectives.

3.5 Statistical Considerations

Data was analysed using Statistica version 12 (2014) and descriptive statistics were used. Tests for normality were done qualitatively using bar charts and histograms and data that was not normally distributed reported as medians and interquartile ranges. Normally distributed continuous variables (e.g. Age and experience [in years]) were described using means and standard deviations. Population parameters were estimated using 95% confidence intervals. Categorical data (such as type of injury) was analysed using frequency distributions indicating absolute and relative counts and for binary proportions 95% confidence intervals were used to estimate population parameters. Results are summarized in tables. Some comparison of variables was conducted. Spearman rank order correlation was used to compare not normally distributed continuous data and Pearson's correlation coefficient for normally distributed continuous data. ANOVA was used to compare normally

distributed continuous and categorical variables and Kruskal-Wallis ANOVA for non-normally distributed data. A p-value of <0.05 represents statistical significance.

Ethics approval for this study was granted by the Human Research Ethics Committee of the University of Cape Town (HREC Ref: 318/2014). Permission was granted by the Executive of the Medical Emergency Transport and Rescue Organization (Metro).

PART B: LITERATURE REVIEW

1. OBJECTIVES

The objectives of this literature review are to:

- Identify the background prevalence of acute pain.
- Determine known characteristics and methods of the assessment and management of acute prehospital pain.
- Determine the background level of effectiveness of prehospital analgesia.
- Describe the management practices, perceptions, attitudes and beliefs of emergency care personnel.
- Determine if patterns or recurring themes and issues are prevalent in the literature and identify gaps in the knowledge base.

2. SEARCH STRATEGY

The following databases were searched:

- Medline, using the Pubmed search platform
- Scopus, using the standalone search platform
- African Index Medicus, using the standalone search platform

The following limiters were used in all searches, when available:

- English Language
- Adults (age >19 years)
- Human
- 2005 – 2015 (last 10 years)

Keywords were used for searches using various combinations of the terms below:

- Analgesia
- Emergency medical technician
- Paramedic
- Emergency medical services
- Drug therapy
- Pattern, professional practice
- Prehospital

Initial searches using keywords ‘pain’ and ’acute pain’ produced too many results to be useful and, after consultation with a university librarian, these were omitted.

The titles produced by each search were scanned and relevant the abstracts were read. Where abstracts met with the quality criteria the full article was obtained. The reference lists of articles were also studied for relevant publications. If the full text article could not be obtained the title was discarded.

The literature search was limited to the last ten years and is correct as of 31 March 2015.

3. PREVALENCE OF ACUTE PAIN

Pain in Prehospital Emergency Care is common. An Australian study found pain to be present in 34.5% of ambulance patients with trauma and medical aetiology making up 40.15% and 39.1% respectively and with 17% of acute pain cases of cardiac aetiology. (18) An earlier Australian study found 53% of patients transported by ambulance reported pain. (19)

Pain in a rural Polish EMS was reported in 43.83%(n=963) of cases, with trauma pain making up 41.32%, non-trauma related pain 47.66% and chest pain 11% of cases. Moderate to severe pain presented in 75% of cases. (20)

The prevalence of pain in a French metropolitan prehospital service was found to be 42% with two thirds of those showing moderate to severe pain. (21) A prospective study in a mixed ground and aeromedical service in Italy found pain prevalence to be 63.75% with trauma to be the most important contributor. Pain intensity was moderate to severe in 41.75% of cases. Caution should be exercised in this study as the collection of data appeared to be on provider discretion, with no defined inclusion or exclusion criteria. (22)

A regional retrospective Patient Care Record (PCR) review of prehospital trauma patients in the Netherlands found 70% (n=980) of patients to have pain though 28% (n=393) of cases had a missing report of pain. Considering only 2% of patients with a pain report explicitly indicated ‘no pain’ it is a possibility that the prevalence is somewhat higher and that pain assessments were either not performed or not recorded. (23)

A study of post-surgical military patients transported by air shows troops were subject to significant post-operative pain during transport. Higher level of anxiety, distress and worry

during transport correlated with higher pain intensity scores. (24) This study may overestimate pain intensity as it relied on recalled pain scores up to 5 days post arrival at the final destination. Recalled pain scores have been shown to be unreliable in as little as 2 days post trauma. (25)

The MEDLINE literature search did not produce prevalence studies of acute pain in adults in the African context. The search of the African Index Medicus, using the keywords related to emergency services produced no relevant articles. The keyword “Pain”, revealed only four research articles examining pain in adults in the out of hospital or acute contexts and none relating to the EC or PEC. This lack of data regarding acute pain in the African prehospital and emergency medicine environments represents a major gap in the literature.

The Global Burden of Disease study might offer insight into acute pain in Africa and South Africa. Conditions associated with pain, such as road traffic accidents, are well represented both globally and in Sub-Saharan Africa and contribute significantly to Disability Adjusted Life Years (DALYs). (26)

South Africa has a high prevalence of HIV positive patients and at least half of patients on highly active antiretroviral therapy (HAART) experience pain on a routine basis, many of whom are outpatients. (27) In Kwa-Zulu Natal pain prevalence amongst HIV out patients has been determined to be 91%, with 83% of these experiencing severe pain levels and only 34% were considered to have adequate pain management. (28). Research places the prevalence of chronic pain in South Africa at 41% (CI 37.2-45.6) with back pain and joint pain being the largest contributors, 30.8% and 23.48% respectively. (29)Though published data is scarce, chronic and malignant pain in South Africa appears significant and South Africans suffer from similar pain pathologies to the developed world with the added burden of high rates of trauma, violence (30), poverty and HIV/Aids. (31)

Pain was the direct cause of 74.6% (95% CI: 63.2-81.4%) visits to two separate rural and peri-urban primary care clinics in the Eastern Cape province of South Africa. Median pain score was 8 out of 10 on the Numerical Rating Scale (NRS) and pain had lasted less than 3 months in 71.1% of cases. (32) This was a non-emergency setting and duplication and generalisability to the EC and PEC may be difficult. While no definitive data is available for the exposure of South African EMS to acute pain the background prevalence of out of hospital pain is relevant; anecdotally EMS, especially rural EMS often act as purely transport services and frequently encounters and transports non-emergency cases to primary care centres, potentially exposing them to these cases.

Casting some doubt on the assumption of high pain prevalence in South Africa is data on pain prevalence from a Cape Town paediatric trauma unit. The incidence of moderate to severe pain was found to be 13.3% (33), much lower than in the adult populations described above and lower than in a French paediatric study which found pain prevalence at 37%, with 67% of those cases showing moderate to severe pain. (34)

4. PAIN ASSESSMENT AND MANAGEMENT PRACTICES

The management of pain is rooted in the assessment of pain. Clinician assessment of pain has been found to differ significantly from patients' assessments (35); nurses and physicians have both been shown to perceive patient's pain at a lower intensity level than the patients themselves do. (36) Physiological measurements cannot be used to measure pain. Vital signs have shown poor correlation with pain severity in patients treated by paramedics (37) and changes in heart rate have shown poor correlation with changes in pain intensity in the EC. (38)

The experience of pain is specific to an individual and is influenced by personality and culture, making expression of pain variable between patients. (4) Patient self-report is considered the most effective method of pain assessment, making objective measures of pain important. (10,39)

4.1 Pain Assessment Tools

Unidimensional tools measure only a single aspect of the pain experience. Multidimensional tools measure more than one aspect of pain. Dimensions may include sensory, affective and evaluative aspects such as pain intensity, quality and associated disability as well as evaluating pain as a dimension of overall health status and the impact on patient's daily lives. Multidimensional pain tools evaluate the pain experience far more thoroughly and completely than the unidimensional scales, but are often time consuming and complex to administer and interpret. (40)

Expert opinion has identified three pain measurement tools as appropriate for use in the prehospital environment (10):

The Visual Analogue Scale (VAS) comprises a 100 millimetre (mm) horizontal line drawn on a piece of paper with a verbal descriptor at each end. The patient makes a mark along the

line between the ends which they feel best represents the intensity of their pain and the distance in millimetres from the “no pain” mark is measured. Easy to administer, it requires little or no training however cognitive, visual acuity and motor skill impairment limit usefulness. (40) In the EC it has been found to be valid (41) and reliable, though it seems to be more so at the extremes of pain. (42) It is accepted that a change of 13mm on the VAS is required to denote a clinically significant change in pain intensity (43,44)

A numeric variant of the VAS the Numerical Rating Scale (NRS) is verbally administered. The patient is asked to rate the intensity of their pain by giving an integer value in between two extremes, usually “0” being no pain and “10” denoting severest pain. The NRS is acceptable and suitable for use in the prehospital setting and unlike the VAS does not require any equipment and can be rapidly administered simultaneously with other actions. It is also more suitable in difficult conditions, such as in the dark, and does not require motor skills or visual acuity though language skills and cognition are needed. (10)

The Adjective Rating Scale (ARS) uses word descriptors, which are ranked, such as “no pain”, “mild”, “moderate”, “severe” and “excruciating” to describe pain intensity. These are clinically useful descriptions however lack sensitivity as there is only a few levels between no pain and severe pain. Language and culture act as barriers to the ARS. (10)

Use of the NRS and an ARS has been found to be feasible in EMS operations though significantly lower rates of pain assessment were conducted in the cognitively impaired. (45) Cognitive impairment appears to be a risk factor for pain assessment and acute pain literature frequently excludes cognitively impaired or comatose patients from data sets. Most of what is known about pain assessment stems from conscious, stable patients. This represents a gap in the literature in that discomfort and pain in cognitively impaired, unstable, unconscious and intubated patients in the prehospital environment has not been studied. A systematic search for pain assessment tools validated for use in cognitively impaired adults revealed no tools specifically developed for use by paramedics and those in use for chronic pain were probably inappropriate for prehospital use. While some behaviourally based tools have been recommended in guidelines they are probably a ‘best fit’ solution rather than a validated and accurate method. (46) Language barriers frequently act as exclusion criteria and participants need to speak the language of the researcher to be included.

4.2 Management of Prehospital Pain

An American retrospective analysis of prehospital management showed only 29% (n=279) of patients with isolated extremity fractures received Morphine. Severe initial pain and time spent under EMS care were significant predictors of analgesic administration with time spent under care a very strong predictor. Times greater than 40 minutes showed an Odds Ratio (OR) of 2.56 (95% CI 1.73-3.79), compared to durations shorter than 20 minutes an OR of 0.19 (95% CI0.08-0.46) for receiving analgesia. The study doesn't determine whether the longer time allows for administration of analgesia or if administration of analgesia adds to scene time. High rates of pain assessment and scoring were present in this service, measuring 95%. (47)

A retrospective review of records evaluating the safety and efficacy of Fentanyl in the aeromedical environment in the United States of America (USA) found 112 (87%) of non-intubated patients had a recorded pain assessment. Of these 88(78.6%) were in pain and 74 were offered analgesia with seven refusing. Of the analgesic administrations 92.5% (62/65) contained a follow up pain assessment and in 5 of the other cases repeat administration was documented. (48)

A comparison of two aeromedical services, also in the USA, found even in the presence of high analgesic treatment rates [80% (95% CI, 75.6%-86.2%)], absence of pain documentation showed a relationship with lower analgesic administration [OR 0.31 (95% CI 0.15-0.60)]. In this study 70.3% (n=147) of patients were administered analgesia and 10.5% (n=22) declined when offered. The low rate of refusal may show patient's desire for relief of discomfort and the high levels of pain present in transport services. Clear differences in dose and frequency of administration were reported between the two services, pointing perhaps to the effect of procedural or protocol differences in the organisations. (49)

In France physician staffed ambulances achieved a 73% [95%CI 69-76] rate of analgesia administration though only 51% of patients experienced pain relief. Paracetamol was used in 44% of cases and Morphine in only 29%, with Morphine being chiefly administered to trauma patients. Trauma patients experienced the highest chance of receiving treatment OR 9.1(95%CI, 4.2-20.0) but experienced lower rates of pain relief. While the mean total dose of Morphine was 0.12 mg/kg ± 0.07mg/kg the initial Morphine dosages may have been too low, with a mean first dose of 4mg. This study reported a mean EMS contact time of 52 minutes. (21)

In The Netherlands analgesia was administered to 42% of prehospital trauma patients in pain with 87% of these receiving a single drug. Pain intensity was reported in 31% of cases. Fentanyl was most frequently used as a first line agent, contrary to protocol in this service which calls for initial administration of a 50% Nitrous Oxide/Oxygen mixture (Entonox®). This shows paramedics may be basing management decisions on factors other than protocol. (23)

In a metropolitan EMS pain reduction was achieved in 60.4% of patients with a median 2 unit reduction on NRS. Half of patients (51%) received analgesia, with 20.3% receiving opioids. The total EMS contact time was 39.7 minutes. While this Australian study did not show clinically significant pain reduction, a high rate of pain assessment was present. Initial and final pain scores were available in 86% of cases, with a median NRS score of 5, or moderate pain. (18) A second article, resulting from the same study, showed an initial pain score of moderate to severe to be a strong predictor of clinically significant reductions in pain after management. (50)

An analysis of blunt trauma cases in the United States of America (N=6398) showed only 8% (n=516) received Morphine. 23% of patients had a score recorded and these patients were administered Morphine at a rate of 23%, much higher than the population as a whole. Within this group higher pain scores predicted analgesic administration. Total prehospital time also predicted Morphine administration with the proportion increasing from 2% in contacts lasting less than 25 minutes to 17% in contacts longer than 35 minutes. (51)

A case-control study in patients presenting to an urban EC with fractured neck of femur compared both prehospital and EC management of 44 cognitively impaired patients with 65 patients without cognitive impairment. Individual pain scores were recorded on the medical record of 75% of the cognitively intact cohort compared to just 45% of the impaired cohort. Just over half (55%) of patients with impairment were administered pain management in the ambulance compared with 92% of cognitively-intact patients. Impaired patients were administered opiates in 20% of cases compared with 32% of cognitively intact cases, similarly use of Entonox® showed a bias in favour of cognitively intact patients (37% administration rate vs 9%) (It must be noted that as a self-administered drug Entonox® requires a cooperative patient). In the EC cognitively impaired patients waited an hour longer for analgesia and cognitive-intact patients were administered opiates at a higher rate than impaired patients (69% receiving Morphine compared to 37% of impaired patients). (52)

In prehospital patients with falls, 43.33% of patients had a pain assessment. Of these patients 92 (8.18%) were administered an analgesic. Patients who received pain medication had a mean score of 9.11 NRS units (95%CI 8.69-9.53) compared with the average NRS score of 6.29 units for the population. Extremity and hip injuries were associated with better odds of receiving pain medication (OR 11.51 and 9.82 respectively) than head or neck injury. When a pain score was present the OR for pain medication was 4.41 (95% CI, 2.71-7.18; p=0.001). Race was also associated with changed odds of receiving pain medication, with black patients having odds of 0.19 (95% CI, 0.08-0.45; P, 0.001). (53)

A retrospective chart review conducted in a European physician staffed helicopter EMS reported oligoanalgesia to be present in 43% of patients. They were more likely to be male and more seriously injured. Non delivery of analgesics was associated with higher proportions of oligoanalgesia than those receiving analgesics (66% vs 39% p<0.001), though 75% of patients to whom analgesics were administered still did not experience analgesia. Greater pain severity resulted in higher Fentanyl doses, but there was little variation in dosage between achieved and unachieved analgesia. Percentage of oligoanalgesia was larger with greater pain intensity on scene and patients who did not achieve a significant reduction in pain (NRS<3) were more likely to be male. (54)

A Polish retrospective chart review found only half of patients displaying pain symptoms had an objective pain assessment completed. This study was characterised by low rates of analgesic administration. Moderate to severe pain (NRS >4) was present in 38% (n=367) however the analgesic administration rate was 19.2% (n=185). Non-pharmacological pain management was performed in 180 patients and additional medications such as nitroglycerine, which may have influenced pain, were administered in a further 82 patients. Overall 42.3% (n=407) of patients of patients with pain received pain management. Only 6 patients were recorded as having refused analgesia. (20)

4.3 Influence of Patient Characteristics on Analgesia Administration

Female gender has been shown to be a risk factor for oligoanalgesia. In management of extremity fractures a higher proportion of men versus women received Morphine (32.8% vs 26.7%) with men showing an OR of 1.65 for administration of intravenous Morphine. (47)

This finding differs slightly with findings of an Australian study. While no significant gender difference was found in rate of administration of analgesia, type of analgesia varied. These

differences remained when controlled for age, pain severity and pain type (OR 0.61; 95% CI, 0.44-0.84). (55)

While French physician staffed ambulances achieved high rates of analgesia administration overall, gynaecologic/obstetric emergencies were treated at a lower rate (OR 0.2 [95% CI 0.1–0.6]; p = 0.003) and showed lower rates of pain relief OR 0.3 (95%CI, 0.1–0.7). It is unclear whether the lower analgesia rates relate to the conditions themselves or to female gender (21)

The variable interaction between patient characteristics and pain management is illustrated in a large retrospective survey conducted in North Carolina (N=407 763). In the mild and moderate pain categories women were less likely to receive pain treatment, with age showing an inverse relationship with likelihood of receiving analgesia. This relationship reversed when the pain was assessed as 'severe', with receipt of analgesia increasing with increasing age. Younger men were more likely to receive analgesics than older men for NRS pain scores of 9 or lower and for those with pain scores of 10, older men were only marginally more likely than younger men to receive analgesics. Once again, patients with a recorded pain score were more likely to have received analgesics than those without recorded scores. (56)

Michael *et al* found neither income nor ethnicity to have a statistically significant effect on analgesia administration. The study was limited by low numbers of African-American patients as well as the fact that income was estimated based on the location of the patient's address, rather than actual income. (47)

Elsewhere analgesia administration in blunt trauma was found to be more common in Caucasians, with 10% of this population receiving analgesia and only 4% of African-Americans, 4% of Asians and 5% of Hispanics. Recorded pain scores and more severe pain were predictors of analgesia administration. Even in these subgroups Caucasians were more likely to receive Morphine. It must be noted that patient race was determined by paramedic impression rather than patient self-report. This specific study did not find a significant gender bias in the administration of analgesia. (51)

In older prehospital populations initial and final pain scores were documented in 67% and 51% of cases respectively. 107 (62%) achieved clinically significant pain reduction. The analgesia administration rate was 60%, with hip fracture being treated more often than other

fracture sites (OR 2.7, 95% CI 1.17-6.32; p=0.02) and analgesia administration being more likely when a pain score was recorded. Only 16 patients refused analgesia and 13 denied having pain. Most (80%) were administered opiates (IV Morphine or IN Fentanyl). While rates of pain assessment and effectiveness of management in this study seems much higher than in other studies two things need to be taken note of; paramedics had a broad range of options available (Morphine, Fentanyl, Paracetamol, Paracetamol with Codeine and Methoxyflurane as well as Ibuprofen). Secondly, while they were not aware of the exact aim of the study, they were aware they were being studied and the improved analgesia management may be as a result of the Hawthorne effect. Volunteer bias was a risk as paramedics could choose to participate or not. (57)

In Australia persons in the 45-69 age group were less likely to achieve pain reduction when compared with persons both younger and older than them (OR 0.94, 95%CI 0.89-0.99. p<0.022). Patients younger than 15 years showed the greatest likelihood of experiencing clinically significant pain reduction (OR 1.60, 95%CI 1.43-1.78. p<0.001). (50)

In a separate Australian study (N=97705) increasing age was associated with increasing odds of receiving an opiate for analgesia (p<0.0001) when compared to paediatrics. Odds ratios for the age group 16-39 increased from 1.47 to 2.56 in those older than 60 and paediatric patients were less likely to receive opiate than inhaled Methoxyflurane (RR = 0.65; 95% CI, 0.63– 0.67; p < 0.0001). Females were less likely to receive an opiate than males (RR0.83; 95%CI, 0.82-0.84; p<0.0001). The use of intranasal (IN) Fentanyl showed an association with decreasing age, with patients younger than 15 more likely to receive Fentanyl than Morphine (RR1.69; 95%CI, 1.64-1.74; p<0.0001). When drug combinations were analysed single agent therapy was used 87% of the time. The fact that Methoxyflurane was mostly the analgesic and that IN Fentanyl was mostly used in paediatrics is probably a reflection of the pain management protocol and scope of practice of the participants. The most common combinations were Methoxyflurane and an opiate, with the combined use of Morphine and Fentanyl being uncommon and the combination of all three drugs rarer still. (58)

4.4 Variation in Practice and Provider Characteristics

In a European aeromedical service female physicians were almost twice as likely to be associated with unachieved analgesia and administered smaller Fentanyl doses overall with patients experiencing a smaller pain reduction. Analgesia was better achieved with

increasing levels of post graduate training and experience. The authors conclude that lower levels of experience resulted in less effective analgesia for physicians of either gender, however a gender breakdown of experience is not provided and experience as a confounder for gender differences is not explicitly ruled out. This study also had a very small number of female physicians and might have been too underpowered to draw the conclusion that females achieve poorer analgesia. (54)

Analysis of provider qualifications in Poland showed interesting differences in pain management behaviour between paramedics and physicians. Paramedics used an objective pain scale over twice as often as physicians (26% versus 11.3%, P<0.001) yet used analgesics half as often (16.5% versus 30.2%, P<0.001) and opiates 10 times less often than physicians (1% versus 12%, P<0.001). The NRS score obtained was similar with a mean of 5.03±2.11 for paramedics versus 6.38 ±2.57 (P<0.001). (20)

4.5 Type of Disorder or injury

A retrospective cross sectional study examining pain assessment and factors associated with pain management in both fracture and suspected acute myocardial infarction (AMI) found 38.7% of patients (n=1412) to have received analgesics. Single drug therapy was used in 32% (n=1168) and only 6.7% received 2 drugs. 61.4% (n=2242) patients received no analgesia. Only 32% (n=1168) of patients with fracture received Entonox® and 21.6% (n=790) of patients with either condition received opiates, with the 2 drug strategy being more effective. The majority of AMI patients, 79.6% (972), received Glyceryl Trinitrate, which could have alleviated pain and obviated the need for opiates. Alert patients were almost 4 times more likely to have pain assessed (OR 3.55, 95% CI 2.32-5.43) than those with reduced consciousness. Pain assessment was also more frequent in AMI than fracture, 85.1% versus 75%, with 22% of all patients having no pain assessment at all. AMI was twice as likely to have pain assessment as fracture (OR 2.05), and analgesics were more likely to be administered when pain assessment took place (OR 2.20 and 3.72 respectively). (59)

Another comparison of pain management in chest pain and traumatic extremity fracture in a Norway found Morphine administration in 21% of chest pain patients and 31% of trauma patients. NRS scores were present in 64% of chest pain patients and 55% of trauma patients. Chest pain patients had lower NRS scores than trauma cases [median 6 (IQR 4-7) versus 8 (IQR 6-9)] and 46% of trauma and 66% of chest pain patients achieved NRS score reductions to below 3 [median 4(IQR 2-6) versus 2 (IQR 0-4)]. Patients with higher

prehospital times (mean 90 minutes) experienced greater pain reduction overall (mean 3.4 vs. 2.8, P=0.016) than shorter times (mean 35 minutes). Morphine dosing was between 5mg and 9.9 mg and similar for both conditions. Glyceryl Trinitrate might act as a confounder when assessing pain reduction between the two conditions. The rate of analgesic administration in this study was very low. Adherence to protocol was greater in chest pain patients (60) Prehospital personnel in this study had a more liberal protocol, with up to 0.3mg/kg allowed before consultation was required, yet doses seldom reached above 10mg. (60)

5. ANALGESIC DRUGS USED IN EMERGENCY CARE

In South Africa 50% Nitrous Oxide/Oxygen (Entonox®) is on scope for all levels of personnel. Morphine is on scope for all ALS providers and Ketamine is available to Emergency Care Practitioners only. (61)

A 2004 systematic review of Entonox® analgesia showed overall occurrence of side effects to be low and none of the reported adverse events could be definitively attributed to Entonox®. Patients showed shorter recovery times after withdrawal of treatment and required fewer additional medications to achieve pain relief. None of the 12 incorporated systematic reviews or RCTs was conducted in the prehospital environment. (62)

A RCT trialling Entonox® analgesia in moderate traumatic pain showed the effectiveness of the drug in moderate intensity traumatic pain. 67% of patients in the trial arm achieved a reduction in pain to an NRS score of <3 at 15 minutes compared with only 27% in the control arm, breathing medical air. They also achieved much lower median pain scores 2 (IQR = 1 to 4) versus 5 (IQR = 3 to 6; $p < 0.0001$). Worth noting is that 27% of patients breathing Medical Air achieved pain reduction to below 3 on an NRS. (63)

In an effort to determine a single weight based dose for Morphine 119 patients presenting to an EC with a complaint of acute pain each received a 0.1mg/kg dose of Morphine and then pain intensity was measured 30 minutes later. Sixty seven percent (n=80) did not achieve a 50% reduction in pain intensity on this dosage and moderate pain levels remained. (64) It must be noted that the outcome measure of a reduction of 3 NRS units usually represents a clinically significant pain reduction. (65)

A RCT comparing an IV Morphine dose of 0.10mg/kg with a 0.15mg/kg dose found that the higher dose of Morphine was safe and provided statistically significant superior pain relief in

the EC. As the reduction was only 0.8 NRS units the higher dose probably does not provide clinically superior analgesia. Pain was measured at 0 minutes and again at 30 and 60 minutes (Morphine reaches peak effect in 20 minutes). (66) These time periods are probably inappropriate outcome measures in prehospital emergency contexts.

A RCT comparing 0.1mg/kg boluses of Morphine followed by 0.05mg.kg titrations with 0.05 mg/kg boluses followed by 0.025 mg.kg titrations in prehospital severe acute pain produced similar results at 30 minutes (77% of patients in the higher dose group achieved 50% pain intensity reduction compared with 66% in the lower dose group). Important for PEC, at 10 minutes 40% in the higher dose group achieved significant pain intensity reduction compared with only 17% in the lower dose group (OR, 3.4; 95% CI, 1.3-8.8; P < .01). The adverse event rates were low though the higher dose did result in a non-statistically significant increase in emesis. (67) This study should be read with caution; the randomisation process is not well described and there is no description of allocation concealment. The method used to prepare the drugs is vague, and it is unclear whether the syringes were prepared on scene by a team member or pre-filled in another location. This doubt is amplified by the finding that in patients achieving pain relief, in the lower dosing strategy pain relief was obtained at 0.1mg/kg and in the higher dosing strategy at 0.2mg/kg. Possibly these groups of patients were managed differently.

While not available to ALS providers in South Africa Fentanyl is prominent in PEC worldwide and compares well with Morphine. A RCT comparing IV Morphine (0.1mg/kg) with IV Fentanyl (1µg/kg) showed the two drugs to be safe for prehospital use and comparable in performance. While both achieved similar pain reductions at 30 minutes Fentanyl achieved a greater pain reduction at 10 and 20 minutes than Morphine. Patients in the Fentanyl group were also more satisfied with treatment. There were few adverse events in both groups. This RCT was relatively small (n=60) and randomisation procedures were not adequately described. The report does not make it clear exactly how and where the blinded syringes were prepared and bias cannot be ruled out. (68)

A blinded comparison of Morphine and Fentanyl in a physician staffed aeromedical service found that both drugs reduced the median final pain score to 5 NRS units, from a median initial score of 8 with a significant change in 61.5% of patients who received Morphine and 69% of patients who received Fentanyl. Neither group displayed any adverse events. This study produced significant changes in pain scores with lower doses of drug, 0.05mg/kg for Morphine and 0.71mg/kg in Fentanyl. All data was collected by study authors and bias in

management cannot be ruled out. (69) The fact that in this study analgesia was achieved with lower doses of drug than is reported elsewhere (70) should be viewed with caution.

A prospective open label out of hospital study in Scandinavia evaluated the addition of Ketamine to a loading dose of Morphine. Patients with extremity fractures and a pain score greater than 4 were randomly assigned to receive a 0.2mg/kg dose of Ketamine or additional doses of Morphine up to a total dose of 0.2mg/kg. All patients received an initial dose of 0.1mg.kg of Morphine. The Morphine only group received higher doses of Morphine than the Ketamine group (13.5±3.2mg vs 7.0±1.5mg) with the Ketamine group achieving significantly lower NRS scores at hospital admission (3.1 vs 5.4 $p<0.05$) with a low rate of adverse events. The Ketamine group experienced higher rates of nausea and vomiting. (71) The Morphine only group did not meet Swedish Association of Anaesthesia and Intensive Care (SFAI) targets of NRS<4 and thus by definition showed oligoanalgesia, a finding consistent with an earlier study showing that 0.1 mg/kg dosing of Morphine was inadequate for patient presenting with acute severe pain. (64)

An open label RCT comparing prehospital pain management with Morphine alone and a multi-drug regimen of Morphine and Ketamine showed a mean numerical pain score reduction of 5.6 points (95% CI 6.2 to 5.0) in the multi drug group compared with 3.2 (95% CI 3.7 to 2.7) points in the group that received Morphine only. The combination regimen achieved a quicker reduction in pain score, with 6.5 points per minute (7.2 to 5.4) reduction in for the Ketamine group compared with 3.9 pain points /minute (95% CI 4.4 to 3.1) reduction for Morphine alone. Another notable finding was the reduction in opioid administration with the addition of Ketamine. While both arms of the trial received 5 mg of Morphine initially, the Morphine alone arm went on to receive a mean of 14.4 mg of Morphine, for a smaller pain reduction. Adverse events recorded were slightly higher in the Ketamine group, but they were mild and no patients required withdrawal from the study. All patients received a dose of Methoxyflurane prior to IV access (72) In an interesting long term (6-12 month) follow up of patients enrolled in this trial, identical rates of persistent pain was found in the two groups, showing that there is a high prevalence of long term pain associated with injury, 45% of patients in this case. (73).

6. SUMMARY AND INTERPRETATION

The prevalence of prehospital acute pain is between 34.5% and 70% of patients transported by ambulance. No literature is published regarding the prevalence of prehospital acute pain in Africa, South Africa or the Western Cape.

Objective pain assessment scales are an important tool as the pain experience differs between patients and is influenced by dimensions such as personality, culture, state of mind and context. Three pain assessment tools are generally used in PEC; the Visual Analogue Scale, the Numeric Response Scale and the Adjective Descriptor Scale. These scales require patient participation and cognitively impaired and unconscious patients are a risk factor for no acute pain assessment. Physiological methods of pain assessment are unreliable.

Pain assessment forms a vital part of acute pain management and there might be a positive correlation between frequency of pain assessment and frequency of analgesic administration, though some studies showing high pain assessment rates also show low analgesic administration rates. Rate of prehospital analgesic administration to patients in acute pain is between 8% and 84% however; mostly less than half of patients in pain are administered analgesics. There may be correlation between provider qualification and rates of pain assessment and analgesic administration, with higher qualifications more likely to assess and manage pain. A major gap in literature is pain assessment and management in cognitively impaired, comatose and unstable patients. Most studies exclude these cases from the data. There may be correlations between patient characteristics such as gender, race and age and administration of analgesics, though this is variable in the literature
In general high rates of assessment, analgesic administration or level of provider qualification and experience as well as patient characteristics do not necessarily positively correlate with high rates of pain relief for patients.

Barriers to effective pain management may include provider ignorance around pain assessment and management techniques, as well as fear of adverse events, inter disciplinary communication and restrictions around drug options and protocols. PEC providers seem hesitant to use drugs and despite drugs being shown to be safe and effective administered dosages are frequently lower than required. The prehospital environment may not lend itself to detailed and complex assessments and treatments and the influence of the environment on pain management has not yet been adequately explored.

EMS operations are frequently protocol based and these, along with qualifications, scopes of practice and burdens of disease vary around the world. This might explain some of the variation in the literature. Local research is required to describe local practices.

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PART C: JOURNAL ARTICLE

COVER PAGE

Title:

A description of practices of analgesia administration by Advanced Life Support paramedics in the City of Cape Town

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Words: **2988**
Tables: **4 Tables**
Figures: **1 Figure**

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ABSTRACT

Introduction

Emergency Medical Services (EMS) are ideally placed to provide relief of acute pain and discomfort. EMS frequently follow locally prescribed guidelines and have a variety of qualifications each with differing capabilities and scopes of practice. The objectives of this study are to describe prehospital pain management practices by EMS in the Western Cape, South Africa.

Methods

A retrospective descriptive survey was undertaken of analgesic drug administration by advanced life support (ALS) paramedics. Patient care records (PCRs) generated in the City of Cape Town during an 11 month period containing administrations of Morphine, Ketamine, Nitrates and 50% Nitrous Oxide/Oxygen were randomly sampled. Variables studied were drug dose, dose frequency, and route of administration, patient age, gender, disorder and call type as well as qualification and experience level of the provider.

Results

A total of 530 PCRs were included (N=530). Morphine was administered in 70% (95% CI 66-74, n=371) of cases, Nitrates in 37 %(95% CI 33-41, n=197) and Ketamine in 1.7% (95% CI 1-3, n=9) of cases. A total of 5mg or less of Morphine was administered in 75% (95% CI 70-79, n=278), with the mean dose being 4mg (IQR 3-6). Single doses were administered in 72.2% (95% CI, 67-77, n=268) of Morphine administrations, 56% (95% CI, 21-86, n=5) of Ketamine administrations and 82% (95% CI, 76-87, n=161) of Nitrate administrations. Chest pain was the reason for pain management in 43% (n=226) of cases. ALS providers have a median experience level of 2 years (IQR2-4).

Conclusion

ALS providers in the Western Cape appear to use low doses of Morphine, with most analgesia administered as a single dose. Chest pain is an important reason for drug administration in acute prehospital pain. Paramedics do not appear to be using a weight based nor a titration based strategy.

INTRODUCTION

Acute pain is frequently encountered by Emergency Medical Services (EMS) (1–5) and the presentation is often early on following the occurrence of a painful injury or disorder. This positions the EMS well for expeditious relief of pain. EMS mostly follows protocol published by statutory regulators or the medical directors of services. Introduction of protocols in acute care has improved acute pain management. (6) Unfortunately prehospital management of acute pain is often ineffective, rates of analgesia administration are frequently low and oligoanalgesia is common. (7–10)

Specific patient and acute care provider factors are associated with oligoanalgesia; female gender (7) or gynaecological conditions (4), low rates of pain scale documentation (11,12), older age (13,14), race (15) and inexperience of acute care providers. (9) Factors associated with better acute pain management include longer scene time (7,10), and higher pain severity (13,16). The prehospital environment is dynamic and complex and may render some interventions difficult, impossible or undesirable. Pain management may be seen as secondary to stabilisation and rescue of patients and management of primary disorders. (17) The Health Professions Council of South Africa (HPCSA), which prescribes the South African EMS scope of practice and protocols nationally, has not published explicit recommendations or guidelines on the management of acute pain but does infer a titration based strategy for Morphine. Recommendations for chest pain are to administer sublingual Nitrates until pain relief is achieved or three doses have been administered. (18)

South African prehospital practice in respect of acute pain management is unknown. With the lack of a published EMS pain management guideline and as many as seven different EMS qualifications active in South Africa, the potential for practice variation is significant, making local descriptive research important.

The aim of this study is to describe pre-hospital pharmacological analgesia practices in the City of Cape Town. Specific objectives are to describe the age and gender profile of patients, the injury types for which providers are administering analgesics, the qualifications and experience levels of these providers as well as to document the type, dosage, dosage frequency and route of administration of analgesic drugs.

METHODS

Study Design and Setting

The study was a retrospective, descriptive survey of patient care records (PCRs) reporting analgesic drug administration by advanced life support paramedics The EMS education and training system in South Africa is undergoing transition from a vocational, short course, to a National Qualifications Framework (NQF) aligned system. Both systems are operating concurrently and practitioners from both systems are active in the EMS. Five of seven different qualifications are viewed by the HPCSA as being advanced level providers though protocols and scopes of practice differ between these qualifications (qualifications listed in Table 1). The term "Paramedic" is protected by law in (19) South Africa and may only be used by Critical Care Assistants and National Diploma Emergency Medical Care graduates. For convenience sake persons of all advanced qualifications will be collectively termed "Advanced Life Support (ALS) providers".

Data was collected from the EMS service of the Provincial Government of the Western Cape in the City of Cape Town. The city has a population of 3 740 026 people in an area of 2206 square kilometers. . Provincial EMS provides services to a substantial number of patients as just during the study period of August 2013 to July 2014, 347,844 primary responses and 174,843 inter-facility transfers were serviced. A pilot study was conducted in the July 2013 and appropriate adjustments made including the data collection tool

Ethics approval for this study was granted by the Human Research Ethics Committee of the University of Cape Town (HREC Ref: 318/2014). Permission was granted by the Executive of the Medical Emergency Transport and Rescue Organisation (Metro).

Inclusions

PCRs were included if Nitrates, Morphine or Ketamine were administered in the context of acute pain. Patients needed to be older than 18 years and the decision for the drug administration was made by the ALS provider. The presence of pain was determined if a pain score was present, the word "pain" or an equivalent such as "tenderness" appeared on the PCR or if a condition requiring clear pain intervention was present

Exclusions

PCRs from patients younger than 18 years of age, intubated or unconscious patients or where the ALS provider had not made the decision to administer the drugs, were excluded. If clear information was missing the PCR was excluded.

Data Collection and management

Trained research assistants screened all PCRs generated by ALS providers between August 2013 to July 2014 containing an entry of Nitrates, Morphine, Ketamine or 50% Nitrous Oxide/Oxygen gas (Entonox®).Sample size was calculated to determine the median dosage of Morphine, based on the results of the pilot study. A confidence interval of 3mg was used on the assumption that 5mg was the median dose. Sample size was calculated to be 498 and an additional 7% was added to allow for missing data. . Of the 1534 potential eligible PCRs, 601 were excluded with reasons. Of the 933 eligible PCRs, 530 were randomly sampled and included in the analysis. The primary researcher read each PCR and determined eligibility for inclusion in the study. Information on total dosage of drug, number of administrations per case, gender and age of patients, type of case (primary response or inter-facility transfer) and qualification of ALS provider. Qualifications were codified as categorical variables. Experience levels of prehospital care providers were estimated by cross referencing the ALS provider's HPCSA registration number, present on the PCR, with registration information available on the iRegister of the HPCSA which is available on their website. ALS providers were allocated a study number which was used in the main data table. Identifying data was captured in a separate password protected spreadsheet (Microsoft Excel, Microsoft Corporation, Redmond, WA) and stored securely. Pain intensity scores were recorded only as being present or absent

Statistical Considerations

Continuous data was described using means and standard deviations and medians and interquartile ranges depending on the distribution of data. Categorical data is described using proportions and 95% Confidence Intervals. Spearmans ranks correlation, Kruskal Wallis ANOVA and ANOVA was used where appropriate. Data was analysed using Statistica version 12 (2014).

RESULTS

Injuries, patients and ALS provider characteristics

A total of 530 PCRs were included, representing drug administrations by 117 individual providers. Trauma accounted for 49.4% (95% CI 45-54, n=262) of cases and non-traumatic acute pain for the remainder of cases. Figure 1 summarises the injury and disorder types in which pain is being treated. ALS provider qualifications and characteristics as well as patient demographics and are summarised in Table 1. Case characteristics are described in Table2.

Figure 1: Proportion of injuries by type.

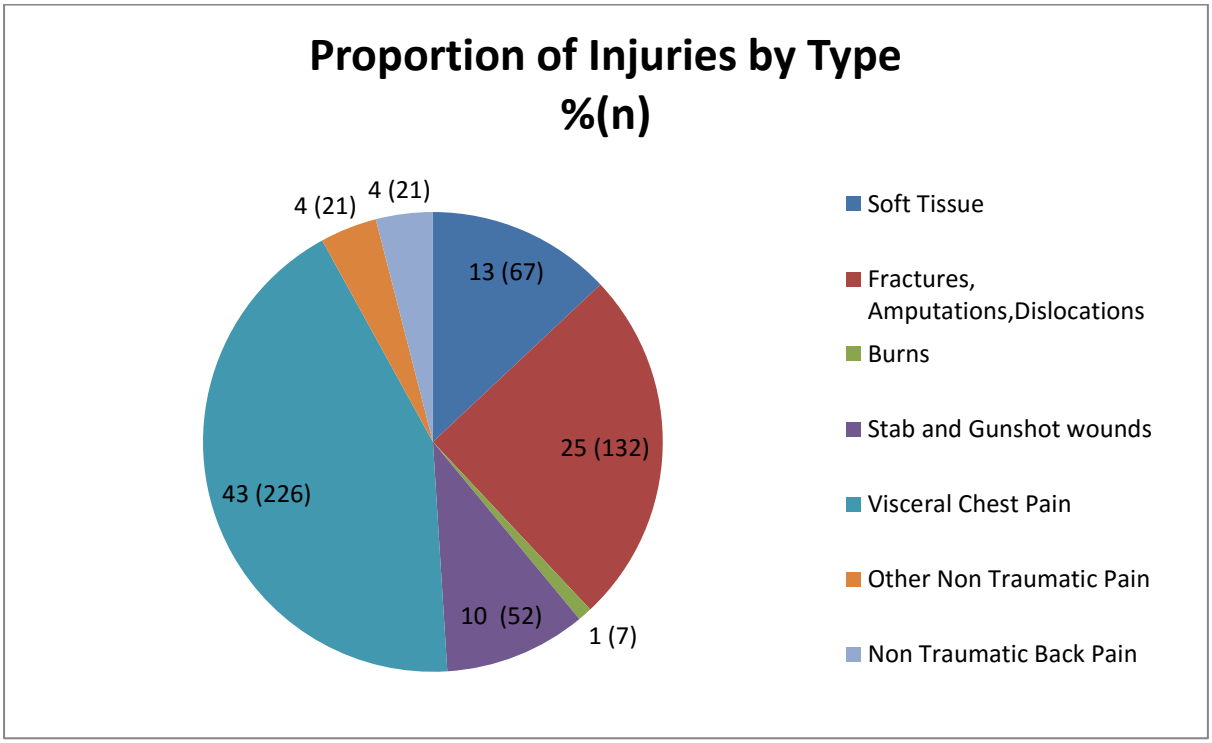

Table 1: Demographics of patients and providers

Provider Qualification (n)	**Years* in Advanced Qualification Median (IQR)**	**Years* in EMS Median (IQR)**
Critical Care Assistant (46)	3 (2-5)	10 (6-12)
Emergency Care Technician (21)	1 (1-2)	7 (6-12)
National Diploma Emergency Medical Care (34)	3 (2-3.75)	3.5 (2-7)
Emergency Care Practitioner[#] (16)	2.5 (2-4)	5 (3.75-10.25)
All (117)	2 (2-4)	7 (4-11)
Patients	**Proportion % (n)**	**Mean (SD)**
Gender (Male)	61.24(324)	-
Age	-	46.8 (18.2)

** Represents full years, or part thereof. Inferred level of experience by qualification of practitioner (Measured by date of registration with the HPCSA).*
[#] encompasses the qualifications Bachelor of Technology (BTech) as well as Bachelor of Emergency Medical Care (B.EMC). Only holders of the BTech were active in the Western Cape at the time of data collection.

Table 2: Case characteristics

	n (%)	*95% CI*
Primary Response	468(88)	(85-91)
Inter-facility transfer	61 (12)	(9-15)
Cases with recorded Pain Assessment	111(21)	(18-25)
Cases with second pain assessment	34(6.4)	(4-9)

Drug Administration

Morphine was administered in 70% (95% CI 66-74, n=371) of cases, Nitrates in 37 %(95% CI 33-41, n=197) and Ketamine in 1.7% (95% CI 1-3, n=9) of cases. No recorded administrations of Entonox® were found. Descriptive statistics for drug administrations are recorded in Table 3. All intravenous (IV) drug administrations were in the form of boluses and no evidence of ALS provider initiated infusions was found. Of the Morphine administrations a total of 5mg or less was administered in 75% (95% CI 70-79, n=278) of all cases. A single dose of Morphine was administered in 72.2% (95% CI, 67-77, n=268), two doses in 23% (95% CI, 19-28, n=86) and three doses in 5% (95% CI 3-8, n=18) of cases. Additional doses raised the total mean Morphine dose to 6 mg for 2 doses and 8 mg for 3 doses (p=<0.01).

Morphine was administered intra-muscularly in 1.4% (95% CI 1-3, n=6) of administrations and the sub-lingual route used for all Nitrate administrations. Morphine was co-administered in 24 %(95% CI 18-30,n=47) of Nitrate administrations and in 33% (95%CI 7-70, n=3) of Ketamine administrations.

Table 3: Characteristics of drug administrations

	Morphine	**Ketamine**	**Nitrates[&]**
Proportion of cases %(n)	70(371)	9(1.7)	37% (197)
Median Total Dose in mg (IQR)	4mg (3-6)	50 (50-100)	-
Only drug administered %(n)	87(322)	67 (6)	75(148)
Intravenous route % (n)	99 (366)	100 (9)	-
One dose %(n)	72(268)	56(5)	81(161)

[&] *describes both Isosorbide Dinitrate tablets (5mg) and Glyceryl Trinitrate spray (0.4mg)*

Qualifications and Drug Administration

The mean total dosages of Morphine are described in Table 3. There was no significant difference in mean number of Morphine doses between qualifications (p=0.69) Correlation between drug administrations, years of experience and qualification type are described in Table 4. For the different qualifications the mean total dosages of Morphine were Critical Care Assistants 4.4mg (95% CI, 3.99-4.8), Emergency Care Technicians 4.8mg (95% CI, 4.2-5.3), National Diplomas 5mg(95% CI, 4.6-5.5) and Emergency Care Practitioners 5.4mg (95% CI, 4.7-6.1) and these differing dosages were statistically significant (p=0.03).

Table 4: Comparisons

Comparison	Spearman's rho (p)
Qualification and number of Morphine doses	-0.01 (0.86)
Qualification and Total Morphine dose (mg)	0.21 (<0.001)
Years of experience in Qualification and number of Morphine Doses	-0.03 (0.51)
Years of Experience in Qualification and total Morphine (mg)	-0.01 (0.81)
Years of experience in Qualification and number of Ketamine* Doses	0.31 (0.39)
Years of Experience in Qualification and total Ketamine* (mg)	0.77 (0.01)

** Only Emergency Care Practitioners are authorised to use Ketamine.*

DISCUSSION

This study is the first to describe operational prehospital pain management practices in the Western Cape. Most Morphine administrations occur as a single bolus and as the only administered drug. Morphine was the most commonly administered drug and used in 5mg, or lower, doses. Elsewhere it has been found that while South African ALS providers are familiar with a weight based dosing most would never exceed 5mg as an initial bolus and definitely never exceed 10mg even if the patient's weight allowed for it (20), a finding supported by our study. This approach was adopted out of a fear for adverse events(20), which are commonly cited as a reason for withholding analgesia or using lower doses(20,21) even though adverse events they do not frequently occur and are mostly mild. (22)

Our study does not shed light on the actual dosing strategy or how ALS providers decide on the dose of Morphine to administer. Whether a single effective dose of Morphine exists is uncertain and descriptions of intra-venous Morphine dosing vary. Some texts advocate small boluses in an individual titration based manner (23) and others an initial weight based dose of 0.1mg/kg. (24) Research evaluating prehospital pain management report total Morphine

doses of between 5 mg (10) and 13.5mg ± 3 mg (4) with varying levels of pain reduction, higher than the mean dose found in our study. An initial weight based dose of 0.1mg/kg did not effectively control pain in the Emergency Centre (EC) 30 minutes after administration (25) while a dose of 0.15mg/kg provided statistically superior pain reductions than doses of 0.1mg/kg though it was not necessarily clinically superior in reducing pain intensity at 30 and 60 minutes. (26) A prehospital Randomised Controlled Trial (RCT) comparing a 0.05mg/kg bolus and subsequent 0.025mg/kg titrations with 0.1mg/kg boluses and 0.05mg/kg titrations found both regimens showing similar pain reduction at 30 minutes however the higher dose provided significantly better pain reduction at 10 minutes (27) which is potentially more desirable in the prehospital context.

We found use of an objective pain score in approximately a fifth of cases. This rate is consistent with some international findings (3), though others show much higher rates of assessment (2,10). The proportion of cases with a second documented objective pain assessment was only 6.4%. When one considers the use of single boluses together with the low rate of pain score recording, a titration based strategy seems unlikely; it is reasonable to expect multiple boluses together with multiple pain assessments in such a strategy. Use of an objective, self-reported pain assessment method, such as a Numerical Rating Scale (NRS), is best practice (28,29) as subjective and clinical pain assessments have been found to be unreliable and underestimate pain intensity. (30–33) Higher rates of objective pain assessment are associated with higher rates of analgesia administration. (11,15)

Our findings do not definitively indicate that pain assessments are not taking place. Scoring systems require cognition, hearing and numeracy on the part of the patient which we could not determine from the PCRs. Pain may have been assessed and not recorded or an adjective type scale may have been used rather than the NRS as “pain”, or pain equivalent words were frequently found on PCRs. Whether these constitute assessment or are merely case notes is unknown. Paramedics, both internationally and in South Africa , have indicated that they base pain assessment not just on a pain score but on clinical presentation, disorder type and own clinical experience(20,21,34), which is significant considering the median experience level of ALS providers is 2 years at advanced level.

Differing experience levels have been associated with differences in prescribing patterns in the EC (35) and lower experience levels have been associated with oligoanalgesia. (9) Our study showed very weak positive correlations between years of experience and Morphine administration however increasing experience within the ECP group shows strong correlation with larger doses of Ketamine (Table 4) While experience did not seem to

influence this single variable extensive further research is required to determine if and how experience levels of ALS providers impacts prehospital care, especially in light of the exodus of skilled ALS providers from operational practice in South Africa. (36)

ALS providers in our study did not appear to use multimodal analgesia. The basis for multimodal analgesia is the synergistic effects of the combination therapy, acting on different sites and pain pathways, which provides more effective analgesia and fewer adverse events as lower doses of each drug are used. (37) Prehospital RCTs have found the combination of Morphine and Ketamine to result in a significant reduction in Morphine dose (38) and to produce faster and superior pain intensity reduction than Morphine alone (39) with an improvement in haemodynamic parameters. (40)

In practice South African ALS providers have very limited pharmacological analgesic options available. The drugs available to all advanced qualifications are Entonox®, Morphine and Nitrates with only Emergency Care Practitioners (ECP) authorized to use Ketamine. Anecdotally Entonox® is not physically available on the vast majority of ambulances, leaving Morphine as the only analgesic available to most ALS providers. The high rate of unimodal analgesia in this study might reflect limited drug options rather than decision making.

The majority of ALS providers initiated analgesia took place on primary responses, with only a small percentage of inter-facility transfers documenting ALS provider initiated analgesia. Reasons for this include physician's orders or assumption that in-hospital analgesia is effective and would not require adjustment in the ambulance. Often drug infusions initiated in hospital will be continued throughout the transfer, and these cases would have been excluded from analysis. There is evidence in the literature that provision of analgesia in the hospital is suboptimal (41–45) and that patients frequently experience high levels of pain during inter-facility transfer. (46,47) Our study was not designed to detect oligoanalgesia and no conclusions are drawn regarding oligoanalgesia in Western Cape Hospitals or during transfer.

Prevalence of cardiac chest pain presenting to ambulance personnel has been reported to be between 17% (2) and 29% (4). ALS providers were likely to administer analgesia in pain of traumatic and medical aetiologies in roughly equal proportions; the finding that chest pain was the reason for drug administration in 42.6% cases was unexpected. While this data cannot be used to indicate prevalence of any disorders it does suggest the types of working diagnoses being made during treatment. In light of this the education and training regarding

cardiac related emergencies assumes significance as does access to and use of equipment such as 12 lead ECG and transmission of ECG tracings to specialists.

Statistically significant differences in Morphine doses were found between the qualifications. The magnitude of these differences is less than one milligram, and the clinical significance of these differences is probably negligible. The different qualifications do not appear to take different approaches to drug dosing in pain management.

LIMITATIONS

This study examines only cases in which drugs were administered and no conclusions regarding incidence or prevalence of acute pain can be drawn. Experience was inferred from date of registration and providers may have been registered for part of this time while not being active in a clinical environment thus actual experience for some may have been overestimated. ECP experience levels will have been underestimated, as each of these practitioners would have held an advanced qualification prior to qualifying as an ECP and experience at ALS level will be higher in this sub-set. Medical chart review has several limitations. While the research question and variables were selected as it was believed the underpinning data to have been the most accurately recorded, allowance must be made for inaccurate recording of variables.

CONCLUSIONS

Morphine doses administered by ALS providers are low and most drugs are administered as single boluses. It is difficult to determine if a clear pain assessment and analgesic strategy is being used and multimodal analgesia is not a feature of South African prehospital care. Experience levels of ALS providers are low and it is uncertain if qualification type influences pain management in any way. Chest pain is the reason for a significant number of drug administrations in the context of acute pain.

FUNDING

Funds were received from the Emergency Care Institute (ECI). The ECI played no role in the conception, design, data collection, analysis or writing of the manuscript.

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CONFLICT OF INTEREST

Wayne Smith is employed by the Provincial Government of the Western Cape.

DISSEMINATION OF RESULTS

The results will be disseminated to the executive management of the service concerned and an offer of a formal presentation will be made.

AUTHOR CONTRIBUTION

RM conceived and designed the study, supervised collection and recording of the data and was primarily responsible for analysis, interpretation of data and writing of the manuscript.

MM provided input and assistance with statistical consulting, writing of results and preparation of tables and figures.

WS supervised the original research dissertation on which the manuscript is based and assisted with writing of the manuscript.

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PART D: SUPPORTING DOCUMENTATION

ANNEXURE 1: JOURNAL INSTRUCTIONS

(From Journal website)

AFRICAN JOURNAL OF EMERGENCY MEDICINE

The African Journal of Emergency Medicine (AfJEM, ISSN: 2211-419X) is the official journal of the African Federation for Emergency Medicine. It is an international, peer-reviewed journal aimed in particular at supporting emergency care across Africa. AfJEM publishes original research, reviews, brief reports of scientific investigations, case reports as well as commentary and correspondence related to topics of scientific, ethical, social and economic importance to emergency care in Africa. Articles will be of direct importance to African emergency care, but may have originated from elsewhere in the world.

TYPES OF ARTICLES

Original Research: Original studies of basic or clinical investigations in areas relevant to emergency medicine. Reference to the relevance of the research in a resource poor setting is essential and should be alluded to in the discussion section. References and a structured abstract (see Preparation below) are required. Maximum length: 3,000 words, 5 tables and/or figures, plus the abstract (300 words) and references (max 50). The checklists found on the following websites should be used to structure your manuscript (a completed checklist showing that you adhered to the reporting format should be submitted with your manuscript):
a. For randomised control trials: http://www.consort-statement.org
b. For cohort, case-control, and cross-sectional studies: http://www.strobe-statement.org/
c. All other studies: http://www.equator-network.org/library/

2. *Review Articles*: Extensive reviews of the literature on a narrow clinical topic. References must include, but need not be limited to, the past 3 years of the literature. A structured abstract is required (see Preparation below). Maximum length: 3,000 words, plus the narrative abstract (max 300 words) and references (max 50). **Please contact the editor in chief before you submit a review.** The following reporting checklists should be used to structure your manuscript (a completed checklist showing that you adhered to the reporting format should be submitted with your manuscript):
a. A Resourced-tiered review checklist is the standard reporting format for publication in

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b. If your topic does not lean itself towards a resourced tiered review consider alternative reporting checklists for systematic reviews and meta-analyses such as Prisma checklist (http://www.prisma-statement.org) or similar. **Please check with the editor-in-chief before using a checklist other that the resources-tiered checklist.**

3. *Case Reports*: Brief descriptions of a previously undocumented disease process, a unique unreported manifestation or treatment of a known disease process, or unique unreported complications of treatment regimens. Case reports should be structured as follow: Introduction, Case report and Discussion. It should not contain an exhaustive review of the literature. Consider consent for patient identifiable information (download from website). A structured abstract (see Preparation below) is required. Maximum length: 1,000 words, plus abstract (max 150 words) and references (max 10), and 1 table or figure. Case reports listed for publication after 2015 are published online only and compiled within a virtual issue once a year.

4. *Practical Pearl*: Descriptions of novel approaches to provision of emergency care; and practical "tricks of the trade" describing aspects of emergency medicine management. An abstract is not required (enter: Not required, practical pearl when prompted). Maximum length: 800 words, 5 tables and/or figures and references (max 5). A manuscript template is available at http://www.afjem.com/ and can be used for submission. Note that author details should be included in the manuscript.

5. *Brief Research Reports*: Reports of preliminary data and findings or studies with small numbers demonstrating the need for further investigation. References and a structured abstract (see Preparation below) are required. Maximum length: 1,500 words, plus the abstract (max 300 words) and references (max 10) and 3 tables and/or figures. Checklists described for original research above should be used to structure your manuscript (a completed checklist should be submitted with your manuscript)

6. *Concepts*: Descriptions of clinical and nonclinical problems and solutions; descriptions of novel approaches to planning, management, or provision of emergency services; and practical " how-to" articles describing aspects of emergency medicine management (includes African country acute care profiles) . A narrative abstract (see Preparation below) is required. Maximum length: 3,000 words, plus the abstract (max 300 words) and references (max 50).

7. *Editorials (commissioned and including op-ed*): Authoritative comments or opinions on major current problems of emergency physicians or on controversial matters with significant implications for emergency medicine; or, qualified, thorough analysis and criticism of articles appearing in AfJEM. Maximum length: 1,500 words plus references (max 5). An abstract is not required.

8. *Correspondence*: Discussion, observations, opinions, corrections, and comments on topics appearing in AfJEM; very brief reports or other items of interest. Maximum length: 500 words, plus references (max 5). An abstract is not required. Please enter: Not applicable, Correspondence when prompted to enter an abstract. Letters discussing an AfJEM article should be received within 6 weeks of the article's publication. The article must be included in the references. Authors of articles about which letters are received will be given the opportunity to reply, which will not be shared with the letter writer prior to publication. Letters of political or other topics unrelated to the science of medicine, as well as those containing personal criticisms, will not be published.

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Preparation

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The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

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Reference to a chapter in an edited book:

3. Mettam GR, Adams LB. How to prepare an electronic version of your article. In: Jones BS, Smith RZ, editors. *Introduction to the electronic age,* New York: E-Publishing Inc; 2009, p. 281–304.

Note shortened form for last page number. E.g., 51–9, and that for more than 3 authors the first 3 should be listed followed by 'et al.' For further details you are referred to 'Uniform Requirements for Manuscripts submitted to Biomedical Journals' (J Am Med Assoc 1997;**277**:927–34) (see also http://www.nlm.nih.gov/bsd/uniform_requirements.html).

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ANNEXURE 2: ORIGINAL PROPOSAL

A description of practices of analgesia administration by Advanced Life Support paramedics in the City of Cape Town

STUDENT: Ryan Matthews
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SUPERVISOR: Dr Wayne Smith
BSc, MBChB, EMDM, FCEM (SA)
Division Emergency Medicine
University of Cape Town

This study is in partial fulfilment of the MPhil Emergency Medicine degree

Declaration:

I, Ryan Ernest Matthews, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signature: Date: 2014

CONTENTS

Title

A description of practices of analgesia administration by Advanced Life Support paramedics in the City of Cape Town

Summary/ Abstract

Acute pain is a significant reason for patients to seek healthcare and has high prevalence in both Emergency Centres and in the pre-hospital environment. Pain relief is an important role of emergency care and is of ethical concern. Despite this oligoanalgesia appears to be common in emergency care. Various emergency care provider practices are described in the literature and there is evidence that pain management practices are associated with specific patient and provider characteristics. There are currently no data on local pain management practices by prehospital personnel. This study aims to describe and document pre-hospital pharmacological analgesia administration practices by Advanced Life Support paramedics in the City of Cape Town. A retrospective descriptive survey will be conducted by examining consecutive patient report forms completed by relevant personnel in the service of the Provincial Government of the Western Cape, Metro EMS.

Definitions

Advanced Life Support	A person registered on the 'ANT', 'ECT' or 'ECP' register of the Professional Board for Emergency Care Practitioners (PBEC) of the Health Professions Council of South Africa (HPCSA) and rendering care to their relevant scope of practice.
Analgesia	"*Insensibility to pain without loss of consciousness". (1)*
Critical Care Assistant (CCA)	A person holding the Critical Care Assistant certificate and eligible to register on the 'ANT' register of the Professional Board for Emergency Care Practitioners (PBEC) of the Health Professions Council of South Africa (HPCSA) and rendering care to the 'ANT' scope of practice.
Emergency Care Practitioner	A person registered on the Emergency Care Practitioner's (ECP) roll of the Professional Board for Emergency Care Practitioners of the Health Professions Council of South Africa and rendering care to the ECP scope of practice.
Emergency Care Technician	A person registered on the Emergency Care Technicians' (ECT) roll of the Professional Board for Emergency Care Practitioners of the Health Professions Council of South Africa and rendering care to the ECT scope of practice.
Emergency Centre	"*The area of a medical facility devoted to providing emergency medical care"*. (2)
National Diploma Paramedic (NDip)	A person holding a National Diploma in Emergency Medical Care and eligible to register on the 'ANT' register of the Professional Board for Emergency Care Practitioners (PBEC) of the Health Professions Council

	of South Africa (HPCSA) and rendering care to the 'ANT' scope of practice.
Pain Relief	*"…. the therapeutic relief of clinical pain….pain relief may be said to occur if a patient reports a reduction in a subjectively defined clinical pain state after intervention."* (3)
Paramedic	An emergency services worker registered with the Professional Board of Emergency Care (PBEC) of the Health Professions Council of South Africa (HPCSA) on either the 'ANT' or 'ECP' registration rolls. Also known as 'Advanced Life Support'

Background (Literature Review) and Rationale

Pain is described by the International Association for the Study of Pain as "*An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage*"(4). An alternate description is "*…the physiologic response to a noxious stimulus…*" (5) Pain involves both physiological and emotional responses and addresses both the stimulus of pain and the effects the stimulus has on the victim. Pain is a very subjective and multi-factorial entity.(6)

Acute pain is a common symptom in emergency medicine (7,8) and may be the single most frequent reason for seeking any healthcare.(9) The Global Burden of Disease Report shows significant representation by disorders involving pain. (10) Both Ischaemic Heart Disease and Injury are significant contributors to global burden of disease. (11) In South Africa specifically road accidents as well as injury have been significant contributors to the national disease burden for some time now. (12) Many of these disorders involve pain and it can be expected that emergency medicine systems will encounter them. A study (8) of consecutive patients presenting to an urban American Emergency Centre (EC) over a 7 day period found that out of 1665 patient encounters, 1019 involved an aspect of pain, of which 869 presented with a chief complaint of pain. This represented 52% of all patient encounters in the EC (8) and up to 78% of adults report a chief complaint of pain (7) on EC visits. More than half of non-critical patients report pain scores greater than 4/10 and 18% reported scores greater than 8/10. (13)

This high prevalence of pain is mirrored prehospital. In a yearlong Australian observational study (14) of 315 273 patient contacts 34.5% presented with pain (40.1% being due to trauma, 39.1% medical and 17% cardiac in origin). In Teramo, Central Italy, pain was present in 68% of cases, with intensity being moderate to unbearable in 41.75% (n=383) of cases. (15) The prevalence of pain in patients encountered by ambulance personnel has been found to be 80% in patients with extremity fractures.(16) It can be concluded that a significant number of patients transported by ambulance will be in pain.(17)

The effects of acute pain on patients manifest both physiologically and psychologically.(16) Pain is one of the triggers of the 'injury response' involving inflammation, hyperglycaemia, hyperalgesia, lipolysis, protein catabolism and changes in water and electrolyte flux. (18) Increased sympathetic activity affects the cardiovascular system as well as respiratory, coagulation and immune systems (18) and thus alters vital signs. (19) Cardiac effects may

include ischaemia and dysrhythmias, and wound healing is also impacted. (16). Acute pain is both common and a contributor to disability long after injury.(20)

Regarding long term disability, large pain stimulus can permanently change spinal cord function, through excitatory effects of amino acids, resulting in chronification of pain.(21) Acute pain can establish the biological foundation necessary to sustain chronic pain within hours of onset.(22)

Pain following traumatic injury has been found to contribute significantly to the development of Acute Stress Disorder (ASD) and Post Traumatic Stress Disorder (PTSD) (23), with rates of PTSD in patients suffering from pain secondary to a motor vehicle accident (MVA) ranging from 30% to 50%.(24) Significant from an Emergency Medical Service (EMS) perspective is that pain contributes to anxiety, making patient treatment even more complex in an already challenging environment.(13) A decrease in pain severity has been linked to lower PTSD symptomology in adult victims of trauma. (24)

Considering Major Depressive Disorder's ranking within the global burden of disease (11^{th}) (10), and that depression is the fourth leading cause of disability worldwide (25) and the fact that pain and depression frequently exist in the same patient as co-morbidities (26), pain management as a discipline assumes significance in the global burden of disease.

While questions regarding the management of pain in the EC have been asked (7,13,27,28) , in the pre-hospital environment the situation appears just as dire. Only 18% of patients transported for hip and lower extremity fracture received analgesia in one study (29) and others found only 25% of patients in severe pain (30) and only half of patients with fractured neck of femur (31) received morphine.(31) In an analysis of 1073 patients with suspected extremity fractures treated and transported by EMS over the period of one year only 1.8% received analgesia (16 received nitrous oxide and 2 received morphine). (32) This research also underscored the importance of prehospital pain management; when analgesia was administered prehospital it occurred on average two hours earlier than if it was left till the EC. (29,31) In the EC whether or not the patient complained of pain to the EC staff made no difference to administration of analgesia nor did the description of the pain, the Glasgow Coma Score (GCS) of the patient nor did patient characteristics. However prehospital administration of analgesia predicted faster and more aggressive EC pain management (31)

The Emergency Medical Services Outcomes Project found alleviation of discomfort, including pain, to be one of the most relevant outcome measures of pre-hospital treatment

and the treatment of pain to have the greatest effect on patients. The relief of suffering should be a goal of EMS management. With acknowledgement to risk and the acuity of the situation, and given the frequency with which pre-hospital personnel encounter acute pain, management of the disorder should be a priority.(16) One author has written that relief of pain may be the most important and one of the few worthwhile interventions the EMS can undertake. (33)

Studies that investigate the efficacy of analgesic drugs available in emergency care show the efficacy of such agents. Morphine is considered to be effective and safe for pre-hospital analgesia (5), and various doses are described in the literature. (5,34,35)

Morphine and ketamine have been studied for prehospital pain management, both individually and in combination and found to be effective and safe. (20,36) Nitrous Oxide has been found to be effective in a randomised controlled trial (RCT) studying acute traumatic pain of moderate intensity.(37)

Since prehospital pain is prevalent, both clinically and operationally significant as well as treatable, one has to ask the question as to why it appears to be systematically poorly managed.

The literature attributes poor pain management to both patient and provider factors:
Poor analgesia in the EC may be due to improper training, poor quality management, a lack of proper research, improper attitudes to opioid analgesics and fears around their safety when compared with anti-inflammatories. (38)

Being a subjective phenomenon, patient self-report using objective pain scales are the best method of pain evaluation. (5) Objective pain management tools do exist and have been validated for use in emergency care. The Visual Analogue Scale, in which a patient marks a 100mm line on a piece of paper, has been validated in the EC. (39) Adequate pain assessment has been found to be feasible pre-hospital (40) and both the Numerical Rating Scale (NRS) and the Verbal Rating Scale have also been validated for use in emergency care and are suited to the prehospital environment. (41,42)

Despite the validity of pain assessment scales it has been shown that EMS personnel may significantly underestimate patients' pain. It has been further suggested that pain management is often based on the provider's perception and interpretation of the patient's condition and not on objective pain assessment alone. (43)

Personnel use various inputs for pain assessment (44) including years of experience, gender, age and previous pain experience, 'gut feel', patient behaviour and perceived cultural differences in the expression of pain. Also influencing assessment and management are vital signs and clinical condition, injuries and history of the incident. (43,44). It is still unclear whether physiological parameters (vital signs) are reliable in the assessment of pain as (6,45,46), as only a weak correlation between respiratory rate and pain has been proven (47) and factors such as hypoxia and hypovolaemia may blur the picture. (19)

EMS training reinforces 'worst case scenario' situations in which 'life over limb' thinking predominates. Consequently pain may be viewed as being of secondary importance, a symptom rather than a disease or disorder requiring treatment. (28,48)Personnel may not view it as their task to make diagnosis and thus may want to preserve symptoms for evaluation by a doctor. Frequently deferment of pain relief has been practiced until a definitive diagnosis has been made. This has especially been the case in acute abdominal pain, despite evidence showing that adequate analgesia did not alter diagnostic accuracy and in some cases may be helpful in examination and diagnosis.(49) This belief still appears in EMS decision making with at least one study describing the potential masking of symptoms to be a reason to withhold analgesia. (44) Fear of interfering with neurological assessment as well as venous access and issues surrounding patient consent also influence management. (16)

There is often a shortage of equipment, light and trained assistants out of hospital which may cause management to be less efficient and contribute to pain. Further the painful condition may still be evolving and may change rapidly.(18)

Provider biases may influence pain management. While clinicians deny ethnicity is a factor, race has been found to influence management (28) with minority groups (in the USA) being vulnerable to oligoanalgesia (9) and Caucasian victims of trauma more likely to receive prehospital analgesia (50). While sex did not necessarily influence rate of total analgesic administration it did influence type of analgesic administered, with females less likely to receive morphine (30) while a second EC study (51) showed that females tended to receive higher rates of analgesia as well as stronger analgesics. This was attributed to a greater expression of pain and not necessarily a patient gender bias on the part of providers, though there is evidence that physician gender (52) and race (9) influences pain management.

Further patient factors include reluctance to report pain and refusal of analgesia (28) or patients not requesting analgesia.(16)

Particularly vulnerable to oligoanalgesia are the elderly and children.(9)This is possibly due to the belief that children perceive pain differently, won't 'remember' the incident or due to unfamiliarity with paediatric presentation of pain.(53)

Knowledge deficits, fear of adverse events, provider attitudes to pain, inadequate multi-disciplinary communication, lack of consensus on methods and the EMS culture surrounding pain all have been found to contribute to inadequate pain management. (28)

In addition to the use of objective pain management instruments adequate training, knowledge and the presence of a clear guidelines and protocols improve pain management.(16,28) Implementation of a quality control programme improved pain management in a physician based French EMS system (54) and pain protocols improved paediatric pain management in an EC. (53) Low intensity training in pain management has resulted in better pain management for both physicians and prehospital personnel.(16) The lack of continuity between prehospital and EC pain management described by Berben and colleagues (28) strongly argues for integrated pain management protocols and feedback from the EC improves general EMS management. (43)

EMS is mostly protocol driven with little truly independent practice being undertaken by prehospital personnel. Many North American EMS services rely on physician direction when deciding on medication administration and European EMS systems are frequently physician based (5,54). In the United States reluctance to contact medical control, or reluctance on the part of medical control to authorise analgesia impacts pain management as well as under dosing. (16) Leadership and role models, or lack thereof, and inadequate or non-existent protocols influence EMS pain management. (28)

Seeing that the presence of a guideline or protocol has been shown to improve pain management (16,28,54)it is strange that a system rooted in protocol would generate so much evidence of poor pain management practices

Evidence of poor pain management even in the presence of a protocol was not necessarily restricted to paramedics. A ten year retrospective study of a physician driven helicopter service showed that 43% of patients were subjected to oligoanalgesia. This included patients who were not administered analgesia as well as those that received pain management that

was unsuccessful. Further significant practice variation amongst physicians and a physician gender bias was associated with varied pain outcomes (52).

South African Advanced Life Support paramedics apply a national protocol independent of medical control. Elements of medical control are being introduced in South Africa through two relatively new qualifications, The Emergency Care Technician (ECT) and the Emergency Care Practitioner (ECP). In this model the ECT is required to consult with an ECP, or Medical Officer (MO), prior to the administration of morphine

In South Africa the drugs used for management of pain are morphine and Entonox™, with morphine being confined to the Advanced Life Support (ALS) scope of practice (55). Ketamine has recently been introduced for use by the ECP. These drugs have been shown to be safe and effective for prehospital use.(34,37,56) ALS personnel have access to Nitrates (Isosorbide Dinitrate in tablet form and Glyceryl Trinitrate as a spray) for chest pain and this is used according to recognised guidelines(55,57) (It must be noted that nitrates relieve ischaemic chest pain by improving blood flow, not necessarily by acting as an analgesic).All personnel have been trained in splinting and immobilisation techniques. The current ALS protocol alludes to a rate of administration for morphine, 1mg per minute while titrating to effect, without offering a specific weight based dose or definite targets to be reached (55). A dosage of 0.1mg/kg followed by 0.05mg/kg doses every 5 minutes has been found to be effective in the treatment of pre-hospital pain (58) though this is disputed elsewhere.(59) Minimal adverse events were reported though the time period over which pain reduction was measured in this study, 30 minutes (58), may not be entirely appropriate for the pre-hospital environment. Fears around adverse events may contribute to oligoanalgesia and under dosing. (44)

While ketamine is available the number of practitioners using this drug is very limited. Nitrous Oxide is within the scope of practice of all personnel; however anecdotal evidence suggests that it is not physically available on most ambulances preventing management of pain in many cases where ALS personnel and intravenous analgesics are not available.

Unlike doctors, worldwide EMS has a tiered qualification structure in which not all personnel may administer analgesia. Many patient contacts may be handled by personnel not having access to analgesia which consequently skews statistical analysis. Jennings (14) has made mention of differing qualification levels and scope of practice.

Other contributory factors are a lack of knowledge regarding cultural influences and bias, disbelief around reporting as well as racial and ethnic stereotyping (38) and time since qualification has also been reported to influence provider practice. (52)

Motivation for study

Acute traumatic pain is frequently encountered by EMS and appears to be poorly managed.

Pain is a subjective experience that can vary greatly between patients and the management of both pain and suffering is of ethical and clinical relevance. The literature associates several provider and patient characteristics with differences in the management of pain. The subjective nature of pain complicates assessment and management and results may not be generalizable between patient populations. Given the variability in terms of operation, qualification and scopes of practice between different EMS systems it may be difficult to apply findings in one system to another service, strongly motivating for research of each system individually.

Currently we have no data on pre-hospital analgesia practices in South African EMS. It is necessary to undertake descriptive studies of the South African EMS system to help determine whether patterns described in the literature are present in South African EMS and to describe and document local practice.

Research Question

What are the administration practices of Advanced Life Support Paramedics with regards to prehospital pharmacological analgesia for acute pain in the City of Cape Town?

Aim

To describe and document pre-hospital pharmacological analgesia administration practices by Advanced Life Support paramedics in the City of Cape Town.

Objectives

5. To describe the type, dosage, dosage frequency and route of analgesic drugs administered by Advanced Life Support personnel when managing prehospital acute pain.
6. To determine the patient characteristics of patients receiving prehospital analgesic drugs in terms of gender and age.
7. To describe injury and disorder types for which prehospital analgesic drugs are administered.

8. To describe the qualifications and implied experience levels of paramedic providers of prehospital analgesia.

Methods:

Study design

This study will be a retrospective, descriptive survey of randomly selected patient report forms that contain an entry of analgesic administration, generated by Metro EMS in the City of Cape Town. Stratified Random sampling will be used. Metro EMS is the ambulance service of the Provincial Government of the Western Cape.

Inclusion criteria

- Documentation generated by vehicles staffed by ECT, CCA, National Diploma or ECP qualified personnel will be eligible to form part of the sample
- All eligible patient report forms recording administration of Entonox™, if any, by Advanced Life Support paramedics.
- All eligible PRFs patient report forms recording administration of morphine and/or ketamine.
- All eligible patient report forms recording administration of nitrates

Exclusion criteria

- Patient report forms of patients younger than 18 years of age will be excluded.
    - Approval from the Minister of Health is required for non-therapeutic research on children; however regulations on this are unclear.
- All patient report forms not recording administration of Entonox™ , Morphine or Ketamine
- Patient report forms containing analgesia administered by a provider other than an ALS paramedic (such as a doctor).
- Patient report forms where any part of the form is illegible or where any information has been omitted or incompletely recorded in terms of the data subset required for this study.

Sample Selection and Data Collection

- Patient report forms will be investigated and the outcomes of interest recorded on an electronic spreadsheet (Microsoft Excel, Microsoft Corporation, Redmond, WA).
- Patient report forms will be obtained from the archive of the Western Cape Emergency Medical Service whose headquarters is located at Pinelands Ambulance Base.
- All patient report forms are archived by geographical division, date and ambulance roster. Shift rosters are catalogued with patient report forms. From this it can be determined which vehicles were staffed by the personnel of interest.
- Documentation generated on these vehicles will be perused and all patient report forms containing an entry of Entonox ™, morphine, nitrates or ketamine will be separated from those forms that do not contain such an entry.
- As all patient report forms are archived by EMS Division, each Division (Northern, Southern, Western and Eastern Divisions) will form one group or cluster of a stratified random sampling template. The sampling will be done by EMS Division but no analysis of Divisions will take place.
- Documentation will be sampled from a 12 month period, estimated to be from May 2013 till May 2014.
- The patient report form containing entries of analgesic administration in each group will be ordered by vehicle and date and packed out on a table in order. The number of documents in each group will be counted to determine the size of the population (N) in each cluster.
- Numbers from 1 to N will be entered into a spreadsheet and a random number generator (Microsoft Excel, Microsoft Corporation, Redmond, WA) will be used to generate random numbers between 1 and 10 000 for each cluster and then allocated against the number of patient report forms in the cluster. The random numbers, and corresponding patient report form numbers will be sorted smallest to largest and the patient report forms corresponding to the lowest 100 random numbers will be drawn into the sample (n).
- Should a selected patient report form meet exclusion criteria, such as age of patient or incomplete data, it will be discarded. The randomisation will then be repeated until a minimum of n=100 for each cluster are reached. Record will be kept of the number of discarded documents.
- The samples from each cluster will be combined to form the study population. A minimum of four hundred patient report forms will be collected and captured, with a subminimum of one hundred from each stratum.

- Data regarding length of ALS provider qualification, and therefore implied experience, will be obtained from the iRegister of the HPCSA. The provider's registration number will appear on the patient report form and can be cross checked on the iRegister.
- Data is limited to that present o the patient report form and as such provider race and pain intensity scores might not be recorded as they are not guaranteed to be present on the form.
- To obtain some context, the ambulance control room will be approached to determine the total volume of calls attended to during the study period.
- Some providers may record a description of the pain or a pain score. If a patient report form contains either this will be recorded.

Data management

Data will be extracted manually from the patient report forms and transcribed to an electronic spread sheet (Microsoft Excel, Microsoft Corporation, Redmond, WA). The electronic spreadsheet will be password protected to ensure the integrity of the data. The spreadsheet will be placed on a USB flash drive and stored in a locked cabinet when not being used for data collection or analysis.

Statistical considerations

Data will be in an Excel (Microsoft Excel, Microsoft Corporation, Redmond, WA) database and analysed using Statistica ver 12 (2014). This is primarily a descriptive study and descriptive analysis techniques will be used. Normally distributed continuous variables (e.g. Age and experience [in years]) will be described using means and standard deviations and medians and interquartile ranges will be used to describe continuous data that are not normally distributed or ordinal variables. Population parameters will be estimated using 95% confidence intervals. Categorical data (such as mechanism of injury) will be analysed using frequency distributions indicating absolute and relative counts. For binary proportions 95% confidence intervals will be used to estimate population parameters. Data will be presented graphically using histograms and bar charts.

Some comparison between variables is envisioned (e.g. total dose compared to years of experience) and the following general analysis guidelines will be followed:

For a comparison of 2 continuous variables Pearson's correlation coefficient will be used if data are normally distributed and Spearman rank order correlation if data are not normally distributed.

- Comparing 2 categorical variables will be performed by means of a Pearson's chi-squared test with Fisher's exact test if small expected frequencies are observed.
- When comparing a continuous variable with a binary variable a T-test will be used if data are normally distributed and a Mann-Whitney U test if data are non-normally distributed
- When comparing a continuous variable with a categorical variable an ANOVA will be used if data are normally distributed and a Kruskal-Wallis ANOVA if data are non-normally distributed. Post hoc testing with Bonferroni adjusted p-values will be performed when significant results are obtained.

A p-value of <0.05 will represent statistical significance. A sample size of 385 cases has been calculated to provide statistical significance. There is evidence for seasonal variation of traumatic conditions (60-62)which may influence analgesia administration by paramedics. To compensate for this variation, data will be randomly selected from a 12 month period by stratified randomisation.

Ethical considerations

- Data will be collected anonymously. No personal or identifying details will be collected, except for HPCSA registration numbers which will be held separate and confidential as described below.
- Permission from the Western Cape Provincial Government and Metro EMS is required.
- Paramedic HPCSA registration numbers could possibly lead to identification of individuals.
    - To protect individual identities HPCSA registration numbers will be transcribed onto a decoding sheet, in the form of a password protected electronic spreadsheet (Microsoft Excel, Microsoft Corporation, Redmond, WA), in which a study number will be allocated against HPCSA registration numbers. The study number will be used for data analysis and reporting. The decoding sheet will be stored on a USB flash drive and stored separately in a locked cabinet.

Limitations

- The patient report form does not record patient or provider race.
- The patient report form of the METRO EMS does require providers to record pain intensity and no inferences regarding reduction of pain intensity or pain relief will be made.
- This is a retrospective study and limited to data present on the ambulance patient report form.

- This study cannot determine prehospital pain prevalence.

Data dissemination plan

Data will be disseminated as:

A publication in a peer reviewed journal

Continuing medical education (CME) lecture for EMS personnel

Project timeline

2014	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT
EM-DRC										
Sx-DRC			x							
Ethics				x						
Interviews (Data Collection				X	x	x				
Transcribing of Data							x			
Data Analysis							x	x		
Compilation of Final Report								x	X	
Submission										X

Resources and budget

The project will be self-funded

Budget				
February – December 2014				
Item	**Description**	**Unit cost**	**N° of Units**	**Total cost**
Consumables				
1. materials and supplies	Paper	500	1	500-00
2. materials and supplies				
3. specialized services				
4. office supplies, printing & reproduction for data collection	Printing	500	1	500-00
5. office supplies, printing & reproduction for reports		300-00	1	300-00
Personnel				
	Research assistant	1000-00	1	1000-00
Research travel				
1. travel to sites	Fuel	500-00	1	500-00
2. other, specify				
Minor research equipment				
1.				
2.				
3.				
Sub-Total				
Total				**2800-00**

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ANNEXURE 3: HUMAN RESEARCH ETHICS COMMITTEE APPROVAL

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

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 5492 • Facsimile [021] 406 6411
Email: Sumayah.arieffdien@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

14 May 2014

HREC/REF: 318/2014

Dr W Smith
Emergency Medicine
Private Bag X 24
Bellville **7535**

Dear Dr Smith

Project Title: A DESCIPTION OF PRACTICES OF ANALGESIA ADMINISTRATION BY ADVANCED LIFE SUPPORT IN THE CITY OF CAPE TOWN-Mphi-R Matthews

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

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

Approval is granted for one year until the 30 May 2015.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

We acknowledge that the following student Ryan Matthews is also involved in this study.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.

Hrec/ref:318/2014

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS017: Annual Progress Report / Renewal

Record Reviews/Audits/Collection of Biological Specimens/Repositories/Databases/Registries

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.5.2016
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	28/3/2015

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	24 March 2015		
HREC REF Number	318/2014	Current Ethics Approval was granted until	30 May 2015
Protocol title	A description of practices of analgesia administration by Advanced Life Support paramedics in the City of Cape Town.		
Principal Investigator	R.E. Matthews		
Department, Office Internal Mail Address	Division of Emergency Medicine		
1.1 Does this protocol receive US Federal funding?		☐ Yes	✓ No

2. Protocol status (tick ✓)

☐	Research-related activities are ongoing
✓	Data collection is complete, data analysis only
Please indicate (in the block below) the titles and HREC reference numbers of any projects currently making use of the Database/registry/repository.	
nil	

3. Protocol summary

Total number of records or specimens collected, reviewed or stored since the original approval		530
Total number of records or specimens collected, reviewed or stored since last progress report		
Have any research-related outputs (e.g. publications, abstracts, conference presentations) resulted from this research? If yes, please list and attach with this report.	☐ Yes	✓ No

4. Signature

Signature of PI	Date	24 March 2015

ANNEXURE 4: EMERGENCY SERVICE PERMISSION

Western Cape Government
Health

DIRECTORATE: **EMERGENCY MEDICAL SERVICES**
ENQUIRIES: **Dr Shaheem de Vries**
shaheem.devries@pgwc.gov.za
☎: +27 21 932 1367

Attention: Ryan Matthews

RE: REQUEST FOR PERMISSION TO CONDUCT RESEARCH

Dear Mr. Matthews,

Your letter on the above matter refers.

Thank you for the request to conduct research within the Western Cape Government Emergency Medical Services. Your proposal has been evaluated by the Emergency Medicine Division Research Committee and has been recommended for approval by this office.

I am therefore pleased to inform you that such approval is hereby granted.

I wish you well in your endeavor and trust that you will keep this office and its department informed of your findings when these become available.

Yours sincerely

Dr Shaheem de Vries
Head: Emergency Medical Services
Western Cape Government Health

Date: 3rd July 2014

WCG Health: EMS - Emergency Communications Centre
Private Bag X24, Ballvlei (+27) 21 932 1367 (+27) 21 931 6490
www.capegateway.gov.za

ANNEXURE 5: DATA COLLECTION TABLE

				ENTONOX®		MORPHINE		NITRATES		KETAMINE								
PRF	STUDY NR	QUALIFICATION	EXPERIENCE	DOSES	TOTAL	DOSES	TOTAL mg	DOSES	TOTAL mg	DOSES	TOTAL mg	PAIN CATEGORY	INJURY	MECHANISM	BODY REGION	AGE	GENDER	PRACTITIONER NOTES (VERBATIM)

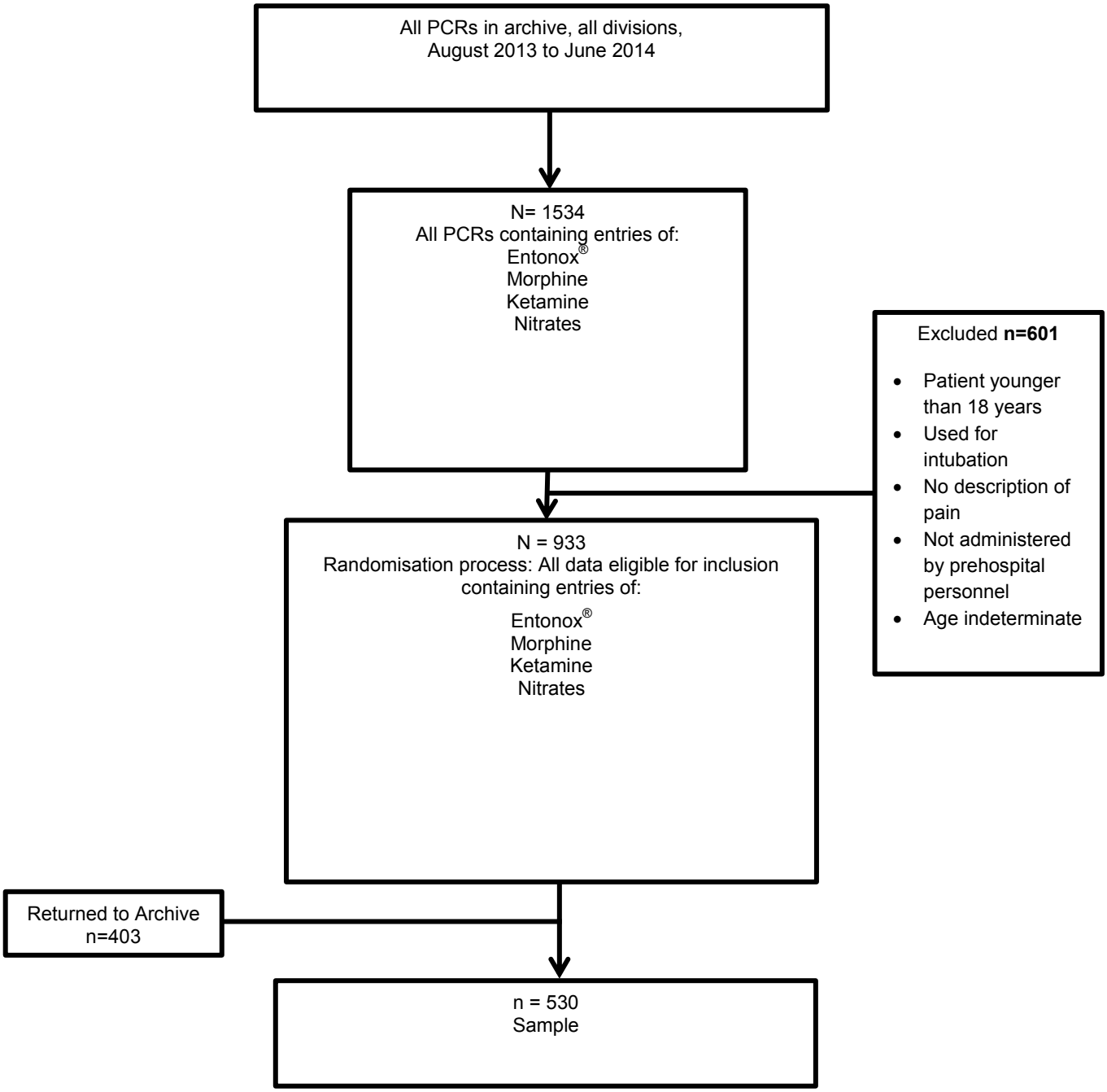
ANNEXURE 6: AMMENDED DATA COLLECTION CODES

Category	Code
INJURY	
Soft tissue injuries	1
Fractures, amputations and dislocations	2
Non-traumatic pain	3
Burns	4
Stab wounds, gunshots and punctures	5
Chest pain	6
Back pain	7
BODY REGION	
Head/Face/Neck	1
Torso and Genitalia	2
Upper and lower extremities	3
Multiple	4
Cardiac/Visceral	5
MECHANISM	
Motor vehicle accident/Pedestrian vehicle accident	1
Fall	2
Gunshot	3
Stabbing	4
Sprain/blunt trauma/assault	5
Burn	6
Visceral pain	7
PARAMEDIC QUALIFICATION	
Critical Care Assistant (CCA)	3
Emergency Care Technician (ECT)	4
National Diploma, Emergency Medical Care (ND EMC)	5
Emergency Care Practitioner (ECP)	6
ROUTE	
Intravenous (IV)	1
Intramuscular (IM)	2
PAIN CATEGORY	
Trauma	1
Medical	2
CALL TYPE	
Primary Response	1
Inter-facility Transfer	2
GENDER	
Male	1
Female	2

ANNEXURE 7: PRACTITIONER STUDY NUMBER AND EXPERIENCE

Study Number	Name	HPCSA registration number				Qualification Code	Obtained	First Registration	Experience in highest Qualification	Experience In EMS
		CCA	ECT	ND EMC	ECP					
1	Joe Soap		xxx			4	2012	2008	2	6
2	Jane Soap	xxx				3	2013	2010	1	4

ANNEXURE 8: SAMPLING FLOW CHART



ANNEXURE 9: TABLE OF LITERATURE

Reference	Geographical location	Aim	Main Finding
Jennings *et al* 2010	Australia	Obtain and understanding of the epidemiology prehospital pain.	Pain was prevalent in this population (34.5% of patients) with traumatic and medical pain presenting roughly equally (40.1 & 39.1%) and cardiac pain representing a significant number as well (17%).
Lord *et al 2009*	Australia	Identify an association between ambulance dispatch priority and pain severity	Pain severity did not influence ambulance dispatch priority.
Kosinski *et al* 2014	Poland	Determine incidence and characteristics of pain experienced by patients	44% of patients experience pain, with non-trauma being the greatest. Moderate to severe pain was common.
Galinski *et al* 2010	France	Determine the prevalence of pain in prehospital emergencies (urban)	• Just under half (42%) of patients suffered from acute pain and of those 64% suffered from moderate to severe pain. • Cardiac aetiologies and trauma were associated with more severe pain.
Marinangeli *et al* 2009	Italy	Evaluate incidence, site, diagnoses of acute pain in prehospital period	Pain present in 63.75% of cases with moderate to severe pain intensity in 41.75% of cases with trauma being the most important contributor (36.8%).
Berben *et al* 2011	Netherlands	Determine prevalence of prehospital pain in the Netherlands and effect of the National EMS analgesia protocol.	Pain prevalence was 70% (75% NRS > 4 – moderate to severe)
Buckenmaier *et al* 2009	Iraq & Afghanistan	Determine pain severity and effect of pain on emotional status during evacuation of war wounded.	Pain severity was typically greater than 4/10 and poorly relieved during transport. Higher levels of anxiety and stress were recorded.
Easton *et al* 2012	Australia	Assess the validity of retrospectively collected pain scores in trauma patients	Significant disparity exists between immediate and recalled pain scores following trauma.

Farrant *et al* 2012	South Africa	Measure prevalence and burden of pain in HIV positive patients attending HAART clinics	Patients experience high pain levels.
Narisimooloo *et al* 2011	South Africa	Investigate the prevalence, severity, and management of pain in HIV positive patients in South Africa.	Pain prevalence is high and up to 1/3 have inadequate pain management.
Rauf *et al* 2013	South Africa	Investigate prevalence of chronic pain in primary health care clinics in a specific area.	Pain prevalence was high with a high intensity.
Igumbor *et al* 2012	South Africa	Estimate prevalence of pain in rural and peri-urban health facilities an characterize pain in a specific area.	• 594 (74.6%, 95% CI: 63.2-81.4%) used facilities because of pain • Majority female ((n = 396, 66.7%) vs (n = 198, 33.3%; P = 0.01) • Primary reason for visit in 393 (49.4%, 95% CI: 32.1-61.0%) • Secondary reason for visit in 201 (25.3%, 95% CI: 12.8-33.7%).
Thiadens *et al* 2011	South Africa	Evaluate pain incidence and management in a paediatric trauma unit.	Pain incidence is relatively low.
Galinski *et al* 2011	France	Determine prehospital pain prevalence in children and identify factors associated with pain relief.	More than 1/3 of children have severe pain with trauma being the only factor associated with severe pain.
Luger *et al 2003*	Austria	Evaluate quality of pain assessment by EMS.	EMS providers under estimate patients' pain severity.
Guru & Dubinsky 2000	Canada	Determine how well pain is assessed and treated in the EC.	Pain assessment and management in the EC is inadequate.
Lord & Woolard 2011	Australia	Examine strength of correlation between pain severity score and vital signs in adults.	Oain scores do not correlate with vital signs readings.
Bossart, Fosnocht & Swanson 2007	USA	Evaluate correlation between change in pain intensity and change in heart rate.	There is poor correlation between change in [ain intensity and heart rate.

Kelly 1998	Australia	Determine minimum clinically significant VAS pain scores and check variance according to certain patient characteristics.	• Minimum clinically significant pain scores was 9mm. • Certain patient characteristics do not change level of clinical significance of VAS pain scores.
Bijur, Silver & Gallagher 2001	USA	Assess the reliability of the VAS to assess pain	The Vas is reliable for assessment of pain.
Todd *et al* 1996	USA	To determine the change in severity that constitutes minimum clinically significant difference (VAS scale)	Minimum clinically significant difference is 13mm.
Gallagher, Liebman & Bijur 2001	USA	To determine the change in severity that constitutes minimum clinically significant difference (VAS scale) in a heterogenous cohort.	Minimum clinically significant difference is 13mm.
McLean *et al* 2004	USA	To determine feasibility of pain assessment in the prehospital setting using the Vas and NRS.	Pain assessment is feasible in the prehospital setting.
Lord 2009	Australia	Systematically locate evidence regarding validation of pain assessment tools for use with cognitively impaired adults in prehospital settings.	No tools specifically developed for prehospital use exist.
Michael, Sporer & Youngblood 2007	USA .	Examine effect of socio economic factors (ethnicity, income, age, sex) on administration of analgesia for isolated extremity fractures.	• Women less likely than men to receive analgesia. • Longer time under EMS care was associated with increasing likelihood of receiving analgesia as was increasing severity of pain score.
Thomas *et al* 2005	USA	Performance of specific service with regards to pain assessment as well as safety and efficacy of fentanyl	• Prehospital pain management was provided well. • Fentanyl showed good effect with minimal cardiorespiratory compromise.
Frakes *et al* 2009	USA	Evaluate analgesic administration to trauma patients during critical care transport	Absence of analgesic administration associated with: initial pain level (self-report NRS <4), pain scale documentation, transport program. No clinical factors.

Jennings, Cameron & Bernard 2012	Australia	Identify characteristics associated with clinically important pain intensity reduction during prehospital care.	• Overall a 42% of cases in a 1 year period achieved clinically significant pain reduction. • 45-69 year old (older) groups less likely to achieve pain reduction. • Initial pain score strong predictor of pain reduction (moderate –severe pain more likely to achieve reduction).
Young *et al* 2013	USA	Determine relationship between prehospital analgesia and patient characteristics, characteristics of the encounter and use of a pain scale in blunt trauma	• Caucasians, women and older patients were more likely to receive analgesia (bivariate analysis). • Only race and time was significant among patients who received analgesia
McDermott, Nichols & Lovell 2014	United Kingdom	Compare acute pain management in cognitively impaired vs cognitively intact persons following fractured neck of femur.	Several inconsistencies exist in the management of pain in cognitively impaired patients.
Infinger & Studnek 2014	USA	Describe prehospital management of pain in patients who suffered a fall	• Younger patients more likely to receive analgesia. • Pain from extremities/hip more likely to receive pain eds. • Patients with a pain score were 4,41 times more likely to receive pain meds. • Patients with pain score assigned more likely to receive meds.
Albrecht *et al* 2013	Switzerland	Assess how oligoanalgesia was associated with physicians practice variation	• Oligoanalgesia present in 43% of cases. • Significant physician practice variation. • Oligoanalgesia associated with lower level of physician experience and female gender.
Lord, Cui & Kelly 2009	Australia	Establish impact of patient sex on analgesia provision by paramedics	Administration of any analgesic showed no sex difference but females were less likely to receive morphine.
Platts-Mills *et al* 2013	USA	Compare analgesia administration for older vs younger patients by EMS guided by a pain management protocol protocol.	Older patients less likely to receive treatment.

Simpson *et al* 2013	Australia	Describe rate and effectiveness of prehospital analgesia in older patients with suspected fracture. Identify predictive factors associated with analgesia provision	• Analgesia rate was 60% (67% for hip fracture) • Proportion of hip fracture victims receiving analgesia was higher than other sites. • Use of analgesia higher when pain scores recorded.
Bendall, Simpson & Middleton 2013	Australia	Describe the use of IV Morphine, IN Fentanyl and inhaled methoxyflurane in the out-of-hospital setting.	• Paramedics mostly use single agent analgesia (87%), Methoxyflurane most common. • Females and paediatrics are less likely to receive opioids and IN Fentanyl more likely in younger ages and opioids in older ages.
Siriwardena, Shaw & Bouliotis 2010	United Kingdom	Investigate rates of and factors associated with assessment and treatment of pain in AMI and fracture	• Pain scores recorded in 77,4% and two pain scores in 64.2%. • AMI higher rate of pain assessment (85%vs75%). Also associated with level of alertness. • Analgesics only administered to few cases (38%). Most not received analgesia though 75%AMI patients received GTN.
Bakkelund *et al* 2012	Norway	Evaluate prehospital use of morphine in chest pain and trauma	• Majority patients were chest pain patients. • Morphine was only administered in 21% chest pain and 31% trauma patients. however NRS score available for more chest pain (64% than trauma (31%).
Faddy & Garlick 2005	Australia	Determine safety profile of 50% Nitrous Oxide	Significant events have a low incidence and 50% Nitrous Oxide is safe for use by lay responders.
Ducasse *et al* 2013	France	Evaluate efficacy of N2O and O2 compared to medical air for prehospital moderate traumatic acute pain.	N2O and oxygen is efficacious for treating out-of-hospital acute traumatic pain.
Bijur *et al* 2005	USA	Determine proportion of patients in acute pain with less than 50% reduction I pain intensity 30 mins after IV 0.1mg/kg morphine	• 67% of patients with 0.01mg/kg morphine reported less than 50% pain reduction. • 0.1mg/kg Morphine is not effective for pain relief.

Birnbaum *et al* 2007	USA	Compare relief and safety of Morphine 0.1mg/kg with 0.15mg/kg in the EC	0.15 mg/kg of morphine is safe and statistically superior than 0.1mg/kg but did not provide clinically superior pain relief.
Bounes *et al* 2008	France	Determine best IV morphine titration. Comparison of 2 doses	Both dose groups 30 mins after injection comparable NRS scores (NRS<30) 66% lower dose vs 76% higher dose.
Galinski *et al* 2005	France	Randomised double blind comparison of Morphine and Fentanyl in a prehospital setting.	Morphine and Fentanyl are comparable in treating severe out of hospital pain.
Smith *et al* 2012	USA	Determine whether intermittent IV Fentanyl provides superior pain relief to intermittent IV Morphine.	There is no significant differences in effectiveness between IV Morphine and IV Fentanyl and both are equally safe.
Frakes *et al* 2006	USA	Evaluate need for and outcomes from fentanyl administration by dedicated critical care transport teams	• Fentanyl resulted in mean pain reduction of 3.7 NRS units • Better pain outcomes with doses above 2 µg/kg.
Johansson, Kongstad & Johansson 2009	Sweden	Determine whether low dose ketamine together with Morphine improves pain scores and haemodynamic parameters compared to Morphine alone.	Addition of Ketamine improves pains scores without side effects.
Jennings *et al* 2012	Australia	Determine if Morphine and Ketamine together is superior to Morphine alone for out-of-hospital trauma analgesia	Addition of Ketamine to Morphine is provides superior analgesia to Morphine alone but with increased minor adverse events.
Jennings *et al* 2014	Australia	Determine differences in persistent long term pain for patients treated with Morphine or Ketamine.	There is no difference in long term pain in patients receiving Morphine or Ketamine.

ANNEXURE 10: FLOW CHART OF SYSTEMATIC LITERATURE SEARCH