A retrospective audit of pain assessment and management post caesarean section at New Somerset Hospital in Cape Town, South Africa

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Declaration

I, **Dr Effraim Frackson Munsaka** hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor part of it has been, is being, or is to be submitted for another degree in University of Cape Town or any other university.

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Dr. Effraim Frackson Munsaka

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Date:

19/11/2021

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My brother (Jeff), sisters (Ethel, Chipo and Astridah), my parents (Frackson and Jerinah) and friends for their encouragement and support throughout

Abstract

Background: The most common major surgical procedure performed worldwide is the caesarean section (CS). Effective pain management is a priority for women undergoing this procedure, to reduce the incidence of persistent pain, (a risk factor for postpartum depression), as well as optimize maternal-neonatal bonding and the successful establishment of breastfeeding. Multimodal analgesia is the gold standard for post-caesarean section analgesia. At present, no perioperative pain management protocols could be identified for the management of patients presenting for CS at regional hospitals in South Africa. This audit aimed to review the folders of patients who underwent CS, with reference to perioperative pain management guidelines for CS.

Methods: A descriptive, retrospective, cross-sectional audit was conducted. Three hundred folders (10% of the annual number of caesarean procedures performed) from New Somerset Hospital, a regional hospital in Cape Town, South Africa were reviewed.

Results: The women were a mean age of 30 years (SD 6.2). Median gravidity was 3 (IQR 2-3) and parity was 1 (IQR 1-2); 52% had previously undergone a CS. In 93.3%, spinal anaesthesia was employed for CS. Pain assessment was poor, with only 55 (18%) patients having their pain assessed on the day of the operation. Analgesia was prescribed in over 98% of the patients, however, medication was only administered as prescribed in 32.6%. Non-steroidal anti-inflammatory drugs (NSAIDs) were prescribed in < 1.67% of cases. None of the patients received a patient-controlled analgesia (PCA), transversus abdominis plane (TAP) block, or wound infusion catheter as supplementary strategies.

Conclusions: Pain management for post-CS patient at this hospital is lacking. There is the need for the implementation of a structured assessment tool to improve administration of analgesics in these patients. In addition, the reasons for the omission of NSAIDs from the analgesia regimen requires investigation. Hospitals require post-CS pain protocols to guide management especially in resource-limited settings.

Keywords: caesarean section, post caesarean section, multimodal approach, pain control

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Section A: Introduction

The most common major surgical procedure performed worldwide is the caesarean section (CS).[1] Effective pain management is a priority for women undergoing this procedure, to reduce the incidence of persistent pain (a risk factor for postpartum depression), optimizing maternal-neonatal bonding, successful establishment of breastfeeding after delivery, and at the same time reduce the risk of post-operative pulmonary complications, early mobilization and recovery, and the length of hospital stay. The reported incidence of persistent incisional pain or the need for analgesia beyond six months after a CS varies markedly, between 1% and 18%.[2] A prospective observational study at a regional hospital in Cape Town showed that the first 24 hours after CS under spinal anaesthesia was the period with the highest incidence of moderate to severe pain (84%)[3]

Pain is a subjective phenomenon defined by the International Association for the Study of Pain as an 'unpleasant sensory and emotional experience associated with actual, or resembling that associated with actual, or potential tissue damage.[3-5] As a fifth vital sign, pain should be routinely assessed, managed (if indicated), and re-assessed. Given the subjectivity of pain, the gold standard for its assessment is a validated self-reporting tool. The most commonly used tools for evaluating pain intensity include the Likert-type numeric rating and the visual analogue scales[3,6,7] Other pain assessment tools available include the Verbal Rating Scale (VRS), McGill Pain Questionnaire,[8] Wong-Baker Faces Pain rating scale,[9] and the Pain Quality Assessment Scale.[3]

The American Pain Society (APS) recommends that planning for postoperative pain management should begin in the preoperative period, and physicians should focus on individualizing perioperative pain management using a multimodal approach.[10] The 2016 Guidelines on the Management of Postoperative Pain,[11] provide several recommendations relevant to this audit, including that: (a) Clinicians conduct a preoperative evaluation including

the assessment of medical and psychiatric comorbidities, concomitant medications, a history of chronic pain, substance abuse, and previous postoperative treatment regimens and responses, to guide perioperative pain management plans; (b) Clinicians adjust pain management plans based on the adequacy of pain relief and the presence of adverse events; (c) Clinicians use a validated assessment tool to track responses to postoperative pain treatments and adjust the treatment plans accordingly; (d) Clinicians offer multimodal analgesia, or the use of a variety of analgesia medications and techniques combined with non-pharmacological interventions, for the treatment of postoperative pain in children and adults.

Multimodal analgesia is the gold standard approach for post-CS analgesia management.[10] One strategy uses neuraxial morphine, scheduled non-steroidal anti-inflammatory drugs (NSAIDs), and paracetamol, and limits systemic opioids to the treatment of breakthrough pain.[13] The South African Society of Anaesthesiologists (SASA) also recommends multimodal analgesia as the most effective way of alleviating acute pain post CS and that patients be discharged on oral pain medication and/or suppositories.[14] Such analgesia options are appropriate for most parturients, but there are many women whose medical conditions require special consideration. Some conditions that will require alterations to pain management include preeclampsia, side-effects to previously administered analgesic medications, pre-existing chronic pain, obstructive sleep apnoea, psychiatric comorbidities, and any contraindication to neuraxial anaesthesia.[10]

At present, no perioperative pain management protocols appear to be in existence for the management of patients presenting for CS at a regional in South Africa. A protocol is defined as "a detailed written set of instructions to guide the care of a patient or to assist the practitioner in the performance of a procedure".[15] Protocols are useful tools to assist healthcare professionals translate guidelines into practice. Patients presenting to regional hospitals for CS would be expected to have a higher incidence of comorbidities than their counterparts in district level hospitals, and healthcare professionals at these institutions potentially have access to a wider range of analgesic options. Therefore, regional hospitals specific protocols should

include guideline-based information on the management of the higher risk patient presenting for CS.

Prior to making recommendations to develop and implement protocols, it is good practice to conduct an audit to describe current clinical practice. Clinical audits are used to improve patient care and evaluate outcomes as part of a continuous cycle essential in evidence-based medicine to optimize and update patient care.[16] This audit aimed to review the folders of patients who underwent CS with particular reference to perioperative pain management guidelines for CS.

Outline of Dissertation

This dissertation proceeds as follows: the next section (Section B) contains the detailed protocol for the study as submitted for ethical and hospital approval. Section C presents the accepted manuscript submitted to the South African Family Practice Journal and section D has concluding remarks.

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Section B: Paper published in South African Family Practice

Title: A retrospective audit of pain assessment and management post caesarean section at New Somerset Hospital in Cape Town, South Africa

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Introduction

The most common major surgical procedure performed worldwide is the caesarean section (CS).[1] Effective pain management is a priority for women undergoing this procedure, to reduce the incidence of persistent pain (a risk factor for postpartum depression), as well as optimizing maternal-neonatal bonding and the successful establishment of breastfeeding after delivery.[Ψ] The reported incidence of persistent incisional pain or the need for analgesia beyond six months after a CS varies markedly, between 1% and 18%.[2] A prospective observational study at a regional hospital in Cape Town showed that the first 24 hours after CS under spinal anaesthesia was the period with the highest incidence of moderate to severe pain (84%)[3]

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[Ψ] Also, it reduces the risk of postoperative pulmonary complications, early patient mobilization, improved mood and recovery, and reduces the length of hospital stay

chronic pain, substance abuse, and previous postoperative treatment regimens and responses, to guide perioperative pain management plans; (b) Clinicians adjust pain management plans based on the adequacy of pain relief and the presence of adverse events; (c) Clinicians use a validated assessment tool to track responses to postoperative pain treatments and adjust the treatment plans accordingly; (d) Clinicians offer multimodal analgesia, or the use of a variety of analgesia medications and techniques combined with non-pharmacological interventions, for the treatment of postoperative pain in children and adults.

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Method

A descriptive, retrospective, cross-sectional audit was conducted at New Somerset Hospital, a regional hospital in Cape Town, South Africa. Ethics approval was granted by the University of Cape Town, Faculty of Health Sciences, Human Research Ethics Committee (HREC Ref: 703/2018) and subsequent authorization was obtained from the Western Cape Government Health Research Department (Ref: WC_201901_008)

This audit was a query review (17) which requires that at least 10% of cases or a minimum of 40 cases be reviewed. This study looked at patients who underwent CS over a one-year period from 1st December 2017 to 31st November 2018. Approximately 220-250 CS are conducted per month at New Somerset Hospital, or 3000 per year. Therefore, 300 folders (10%) were reviewed. The principal author obtained the information from the theatre register for procedures done during that period and compiled a list of all patients who had undergone a CS[ξ] using names and folder numbers. The list was then entered into an Excel spreadsheet and their folder numbers were randomized using the inbuilt randomization feature to generate a list of 300 random folders for the review.

[ξ] The patient information was obtained from a theatre register for a theatre that should primarily do C/S. However, when doing the actual data collection, it was found that more procedures were undertaken during that period

Measurements

The information obtained from the folders included sociodemographic and health information, management of the CS, and the modalities of postoperative pain assessment and management. The REDCap software (v3.8.4) data collection tool was used to upload the information, with password protection. A pilot trial of 20 folders was done initially to test the usability of the tool and subsequently discarded. As illustrated in Figure 1, 358 folders were randomly selected as

58 folders were excluded because the surgical procedure was not a CS and the appropriate number added to the list to make 300 in total.

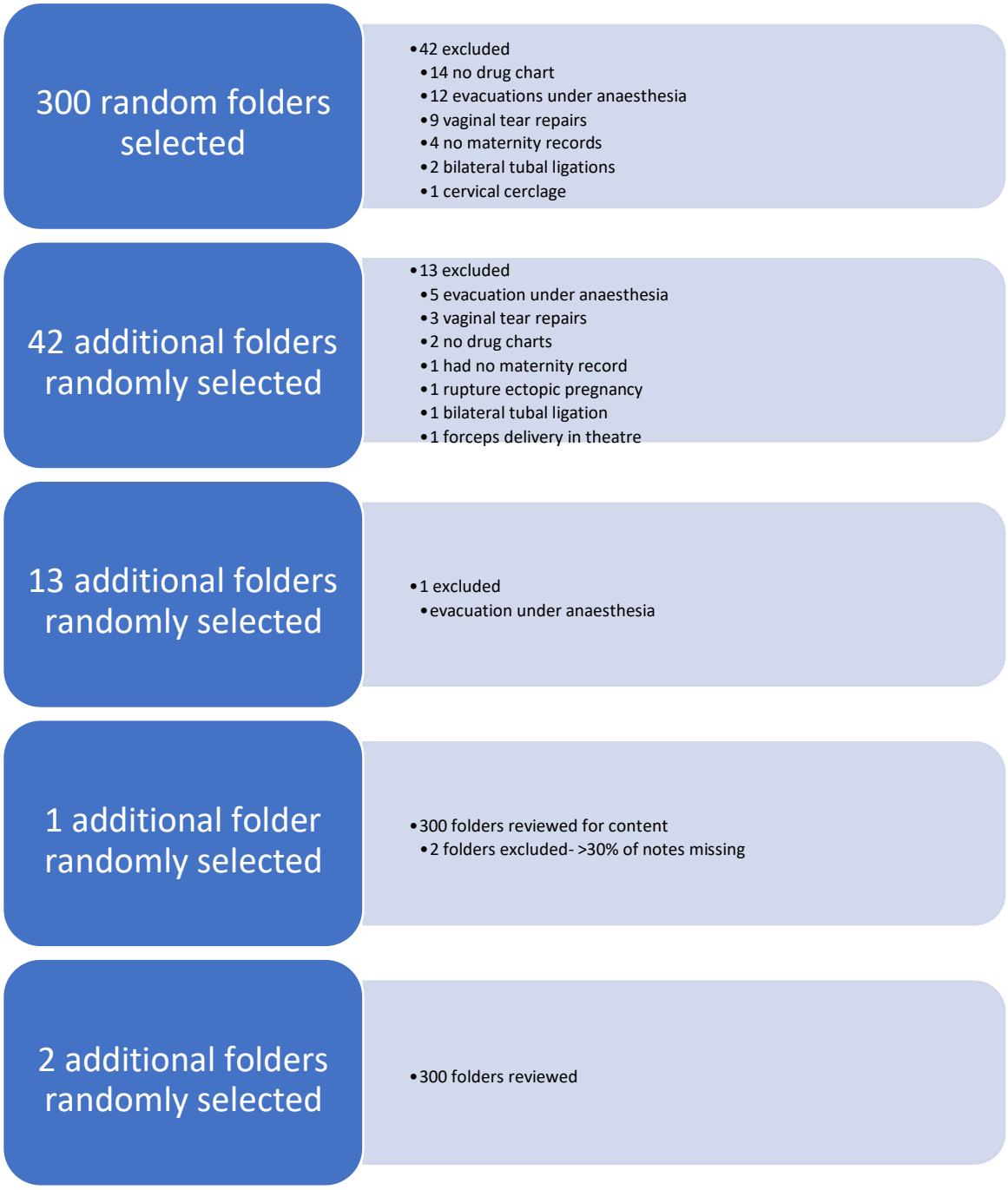

Figure 1: Flow chart of folder selection process to obtain 300 random folders

Results

Sociodemographic history

As seen in Table 1, the women were a mean age of 30 (SD 6.2) years old. The most common comorbidities were HIV (18%); hypertension related to pregnancy (9%), and asthma (4%). Median gravidity was 3 (IQR2-3) and parity was 1 (IQR1-2). Fifty-two percent had previously undergone a CS (median 1; IQR1-2).

Table 1: Sociodemographic and health profile of patients (n=300)

Activity	**Mean (SD)**
Age (y)	29.96 (6.2)
Comorbidities	**n(%)**
Hypertensive Disorders of Pregnancy	27 (9%)
Asthma	12 (4%)
HIV	53 (17.7%)
Epilepsy	4 (1.3%)
Depression	3 (1%)
Eczema	1 (0.33%)
Syphilis	1 (0.33%)
Avascular necrosis of the hip	1 (0.33%)
Past Obstetric History	**Median (range); IQR)**
Gravidity	3 (1-9 IQR: 2-3)
Parity	1 (0-6 IQR: 1-2)
Previously had a CS	157 (52.3%)
Median number of CS (n=157)	1 (1-3; IQR: 1-2)
Previously experienced a miscarriage	90 (30%)

Median number of miscarriages (n=90)	1 (1-6 IQR: 1-1)

SD = standard deviation; IQR = interquartile range; CS = caesarean section

Management of CS

Spinal anaesthesia was used in 93.3% of the patients for the management of CS. Based on the folder review, common practice at this hospital during the study period was the intrathecal administration of 10 mg of 0.5% hyperbaric plus 10 □g of fentanyl. This was sometimes supplemented with one or more of the following agents: intravenous (IV) paracetamol, ketamine, and fentanyl. Patients who required general anaesthesia (GA) received a combination of morphine, IV paracetamol and fentanyl for pain relief. Other analgesic agents included ketamine, alfentanil and local infiltration with plain bupivacaine. However, only one (1) patient received a wound infusion catheter while none had transversus abdominis plane (TAP) blocks employed.[ϕ] Details of intraoperative management appear in Table 2.

[ϕ] Both US and PCA's are available in this hospital

Table 2: Management of current CS (n=300)

Indication for CS	**n (%)**	
Fetal	103 (34.33%)	
Fetal and maternal	77 (25.67%)	
Maternal	120 (40.00%)	
Type of anaesthetic received		
General	20 (6.7%)	
Spinal	280 (93.3%)	
Intra-operative pain management	**Patients receiving GA (n=20)**	**Patients receiving Spinal (n=280)**
IV/IM morphine	16 (80%)	6 (2.14%)
IV paracetamol	17 (85%)	20 (7.14%)
IV ketamine	3 (15%)	13 (4.6%)
IV fentanyl	10 (50%)	11 (3.92%)
IV NSAIDS	0	4 (1.42%)
IV alfentanil	7 (35%)	0
Local anaesthesia infiltration (0.25% Plain Bupivacaine)	5 (25%)	16 (5.71%)
Wound infusion catheter	0	1 (0.36%)
Peripheral nerve block	0	0

IM = intramuscular

The most common indications for CS were maternal (40.00%), namely previous CS, declining vaginal birth after CS (VBAC), and hypertensive disorders of pregnancy, especially preeclampsia.

Other indications included: fetal (34.3%) and both fetal and maternal (25.6%). Of the 300 live births (280 spinal, 20 GA), 288 of the neonates went straight to their mothers following delivery, and 12 required NICU care (11 GA, 1 spinal anaesthetic).

Postoperative Pain Management

Pain Assessment

Spinal anaesthesia was the most common modality used for the management of CS (93.3%). This technique should allow the opportunity for earlier and better establishment of pain control in the postoperative recovery area, as patients are wide-awake immediately after their procedures and regression of the spinal block can be assessed. A pain assessment was recorded as having been conducted based on the presence of any form of documented pain assessment in either the doctors' or nurses' notes e.g. 'mild pain' or 'patient complaining of pain'. The Verbal Rating Score (VRS) was the only scoring system used for the assessment of pain during the period under review. The rate of documented follow-up of the response to pain management was low, with 13 of the 55 patients who had their pain assessed on the day of surgery (day 1), having their pain reassessed after administration of analgesia (24%) (Table 3).On day 2, 21/31 (64%) of patients had their pain assessed, and were reassessed after administration of analgesia. On day 3, 13/30 (43%) of patients had their pain reassessed after administration of analgesia.

Table 3: Frequency and method of pain assessment and reassessment

Activity	**Day 1 n(%)**	**Day 2 n(%)**	**Day 3 n(%)**
Pain Assessed (n=300)	55 (18%)	33 (11%)	30 (10%)
Method of assessment	n=55	n=33	n=30
VRS	17 (31%)	26 (79%)	21 (70%)

Patient complained of pain	38 (69%)	7 (21%)	9 (30%)
Pain reassessed after administration of analgesia	13(24%)	21 (64%)	13 (43%)
Consistent reassessment	2	3	2
Intermittent reassessment	11	18	11

Pain management

In the chart review, data was extracted on what analgesics were prescribed, and what analgesics were administered based on documented evidence of administration. Analgesia was prescribed in over 98% of the patients, with the medication administered as prescribed in 32.6% of patients on the first day and 37% on the second day (Table 4). Oral paracetamol and morphine were prescribed in 99.7% and 82% of cases respectively on Day 1. Minimal use of oral NSAIDs was evidenced by low prescription rates throughout (1.33 – 1.67%). None of the patients received either patient-controlled analgesia (PCA) or transversus abdominis plane (TAP) block, while only one patient received a wound infusion catheter (with local anaesthetic) as supplementary strategies. Details of prescription and administration of analgesia appear in Table 4.

Table 4: Prescription and administration of analgesia.

Activity	**n(%) Day 1**	**n (%) Day 2**	**n(%) Day 3**
Analgesia prescribed	299 (99.67%)	300 (100%)	296 (98.67%)
Analgesia received as prescribed			

Yes	98 (32.67%)	113 (37.67%)	98 (32.67%)
No	4 (1.34%)	1 (0.33%)	4 (1.34%)
Intermittent[Φ]	193 (64.34%)	186 (62%)	190 (63.33%)
Declined	4 (1.34%)		4 (1.34%)
Medicine not obtained from pharmacy	1 (0.33%)		1 (0.33%)
Type of analgesia prescribed			
Oral paracetamol	299 (99.67%)	298 (99.33%)	293 (97.67%)
Oral NSAID	5 (1.67%)	4 (1.33%)	4 (1.33%)
IV/IM morphine	246 (82%)	184 (61.33%)	168 (56%)
PCA	0	0	0
IV/IM pethidine	0	0	0

Discussion

This retrospective audit of 300 folders explored the documentation and implementation of pain assessment and management over a period of one year in women who had undergone CS at a regional hospital in Cape Town. The typical woman presenting to this hospital for this procedure was 30 years old and presenting for a second or third CS (52.3%). Our folder review showed consistency in the prescription of analgesia postoperatively with the use of more than one form of analgesic, mostly paracetamol and morphine. However, very few patients received NSAIDs, and no supplementary blocks, wound infusion catheters, or PCA devices were employed, such that the principle of multimodal analgesia was not followed. In addition, the prescribed medicines were not reliably administered. The subjective character of pain and the complexity of the feelings evoked by pain make reliable measurement by health professionals a

[Φ] Intermittent was defined as analgesia was prescribed but no indication in the chart that it was administered as prescribed with sign off by attending nurse or clinician

key factor in successful management.[18] However, limited documentation of pain assessment and reassessment was observed.[19]

The most used postoperative pain assessment tools are unidimensional and assess only pain intensity, which is just one aspect of the sensory dimension.[20] These include the Numerical Rating Scale (NRS) and the Verbal Rating Scale (VRS). The McGill Pain Questionnaire is one of the most frequently used multidimensional pain assessment tools[21] and measures aspects of pain including the physical and emotional characteristics[20]. In this study, the VRS was the only documented pain assessment method. According to Williamson,[22] most patients prefer the VRS because it is easier to use compared to NRS and the Visual Analogue Scale (VAS) even though it lacks sensitivity and the data it captures can be misunderstood. On the day of surgery, the VRS was used in 31% of the folders. Since this is a retrospective chart review, it is possible that pain was assessed in more patients but was not documented. However, this lack of documented pain assessment provides a learning point for medical personnel and the development of a protocol. All pain should be regularly monitored and evaluated,[23] management should be documented and followed up. Poor documentation hinders periodic appraisal of clinical practice and has potential medico-legal implications.[3,24]

Neuraxial anaesthesia techniques, specifically spinal anaesthesia, was the most commonly used method for CS in this chart review (93.3%). This is a strategy that is being adopted throughout the world as it has been associated with reduced rates of maternal mortality.[25] In addition, it has been shown that patients undergoing CS under general anaesthesia have a higher frequency of pain than patients receiving spinal anaesthesia.[26,27] The most common practice at this hospital appeared to be intrathecal administration of 10 mg hyperbaric bupivacaine plus 10□g fentanyl. Compared to general anaesthesia, spinal anaesthesia provides for early assessment and engagement of the patient in the management of pain. In line with the SASA Acute Pain Guidelines,[14] a patient has the right to be believed, to be properly assessed, to access appropriate effective pain management strategies, to be educated on the effective pain management options, and to be cared for by health professionals with training and experience

in the management of pain. This approach provides for patient engagement and maintaining patient autonomy.

Multimodal analgesia should include scheduled NSAIDS and paracetamol with opioids reserved for severe breakthrough pain.[28] The APS guidelines recommend that pharmacological agents should include a neuraxial opioid in conjunction with nonopioid adjuncts such as scheduled NSAIDs and paracetamol, with additional opioids reserved for severe breakthrough pain.[10] It has been suggested that intrathecal morphine be a gold standard for post-caesarean pain as it provides excellent and prolonged postoperative analgesia[28] This folder review revealed that postoperatively, most patients received an analgesic regimen of mostly morphine and paracetamol. Of concern was a very low prescription rate for NSAIDs (4-5%) despite drugs like Ibuprofen being readily available as it is included in on the Standard Treatment Guidelines and Essential Medicines List for South Africa.[29] There is documented evidence that NSAIDs have opioid-sparing effects, with a consequent reduction in opioid-related side effects.[30] The combination of NSAIDs and morphine has been used extensively, and NSAIDs have been shown to reduce morphine use by 33-47%,[31] when administered either as a single bolus or scheduled medication. Furthermore, the combined use of paracetamol with diclofenac resulted in a 38% reduction in the use of morphine, compared against patients receiving paracetamol only.[32] Non-steroidal anti-inflammatory are mild-to-moderate analgesics which, when combined with paracetamol have synergistic anti-inflammatory properties and should form the backbone of pain management in these patients. The very low prescription rate for NSAIDs in this chart review despite numerous guidelines recommending their use is concerning. There is an urgent need to establish the reasons behind this finding.

Other analgesic modalities worth exploring include PCA, TAP blocks and wound infusion catheters. This review observed that none of the patients received PCA or TAP blocks while only one patient had a wound infusion catheter (with local anaesthetic). This is not unusual in resource-limited settings were lack of adequate staffing, education, and postoperative monitoring facilities limit how much can be offered to a patient.[33] Bilateral TAP blocks and

wound infusion catheters,[33,34] have been shown to reduce postoperative opioid consumption and nausea and vomiting, and are associated with lower postoperative pain scores. However, continuous wound infiltration via a catheter requires supplementary equipment (catheters, infusion pumps that may not be readily available,[33] while a portable ultrasound machine is required to safely perform TAP blocks. Disposable PCA devices, on the other hand, have the advantages in that they do not require electricity or battery usage, but remain expensive and not readily available compared with fixed-dose opioid prescriptions, coupled with the high volume of obstetric cases.[33]

This review, as with many retrospective chart reviews, was fraught with many challenges. These highlight areas requiring further research, the need for training clinicians in better record keeping, pain evaluation and management, and the need to develop post-CS pain management protocols at this hospital. The South African Acute Pain guidelines (SAAP) recommend constituting a pain team and the need to document and evaluate.[14] At this hospital, the practice appears to be that anaesthetists are only involved in the pain management of post-CS patients admitted to intensive care or high care unit. The development of a protocol with the relatively available drugs will provide the necessary guidance for institutions across the country where constituting such multidisciplinary teams may, for various reasons, be challenging.

Retrospective chart reviews are limited by convenience sampling, the inability to determine causation (only association), reliance upon the accuracy of written record, difficult to control bias and confounders,[35] misclassification bias, and temporal relationships often difficult to assess. A future prospective study would be more appropriate for the capture of relevant information in real time including pain assessment tools used, the socioeconomic status of the women, cultural/behavioural perspectives on pain and its management, challenges in assessment and recording of pain management by health professionals, and ward follow-up of patients. However, based on the findings in this review, a pain management protocol for CS specific for the type of anaesthesia that has been applied, and which includes scheduled NSAIDs is needed. This protocol should be developed with clear delineation of responsibilities between

anaesthetists, obstetricians and nurses, and then implemented suing a quality improvement cycle with re-evaluation every 3-6 months to ascertain its utility and effect on patient outcomes.

Conclusion

Pain management is not merely about the reduction of pain; it is also about the optimization of recovery through reliable and accurate assessment of pain.[3] Effective postoperative pain management is imperative in increasing patient safety and satisfaction, and reducing costs to the health care services.[20,36] It is concerning that according to this chart review, post-CS patients are not being assessed for pain nor receiving adequate pain management. A significant proportion of the pain interventions appeared to be based on the professional knowledge of the practitioner and are not supported by evidence-based guidelines of pain management.[11] There is need for a post-CS nurse-led pain management protocol which specifies (i) the roles of multidisciplinary team members, (ii) appropriate assessment tools for setting and culture, and (iii) multimodal analgesia. Hospitals should have pain teams responsible for pain management that conduct regular audits to ensure protocols for quality improvement are in place, as well as ensure better patient care. Where such teams cannot be constituted for various reasons, practitioners can be guided by a national protocol based on readily available drugs, and safe alternative strategies.

Acknowledgements

The authors would like to thank Margot Flint, Agya Prempeh, and Lizel Loo for the assistance rendered during data collection, analysis and preparation of this document.

Declaration of conflict of interests

The authors have declared that no competing interests exist.

Authors' contribution

All authors contributed to the design of this study, analysis and interpretation of the data. E.M. and R.P. drafted the original manuscript while D. vD provided critical revision**.**

Funding source

This review was not supported by any grants or other funding.

Data availability statement

The data that support the findings of this study are not publicly available due to ethical restrictions.

Disclaimer

The views expressed in this article are those of the authors and not an official position of the New Somerset Hospital or the University of Cape Town

Ethics declaration

The work presented in this paper was granted ethical approval by the University of Cape Town, Faculty of Health Sciences, Human Research Ethics Committee (HREC ref: 703/2018) and the Western Cape Government Health Research Department (ref: WC_201901_008).

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Section C: Conclusion

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APPENDICES

Appendix A: Document of ethical approval

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

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.arlefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

01 November 2018

HREC REF: 703/2018

Prof R Parker
Division of Anaesthesia and Perioperative Medicine
D-23
NGSH

Dear Prof Parker

PROJECT TITLE: RETROSPECTIVE AUDIT OF PAIN ASSESSMENT AND MANAGEMENT POST CAESAREAN DELIVERY AT NEW SOMERSET HOSPITAL (MMeD Candidate - Dr M.E. Frackson)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) 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 November 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Munsaka Frackson will also be involved in this study.

Please quote the HREC REF in all your correspondence.

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

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies

Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix B: Data Collection Document

Record ID

SOCIODEMOGRAPHIC DETAILS
Age
Level of education
Primary School
High School
Diploma/certificate
Graduate
Postgraduate
PhD
None
No information
Employment status
Employed
Unemployed
Ethnicity
Black
Caucasian
Indian
Coloured
Other
Marital status
Single
Separated
Married

Cohabiting
Other
Suburb
Milnerton

Other
Medical History
Gravidity
Parity
Miscarriages
Comorbidities
Hypertensive disorders of pregnancy
DM
CHD
Asthma
COPD
HIV
PTB
Other
Previous C/S
0
1
2
3
4
Other
MANAGEMENT OF CURRENT C/S
Indication for C/S
Pathological CTG

Foetal outcome
Alive
MSB
FSB
Other
If alive, please specify
To NICU
To Mother
Type of anaesthetics
GA
Spinal
CSE
Epidural
Other
Intraoperative pain management
Spinal
Morphine
IV paracetamol
IV Ketamine
IV Fentanyl
NSAIDs
Alfentanyl
Local infiltration
Wound infusion catheter
Peripheral nerve block eg TAP blocks
POSTOPERATIVE PAIN MANAGEMENT
Analgesia prescribed
Yes
No
N/A
Other
Analgesia received as prescribed

	Yes
	No
	Intermittent
	Declined
	Other
Pain Assessed	
	Yes
	No
Methods of pain assessment	
	Verbal Rating Scale
	Visual Analog Scale
	Numerical Rating Scale
	None
	Other
Reassessment of pain	
	Consistent
	Intermittent
	No record
Pain Management	
	Paracetamol
	NSAID
	Tramadol oral
	Morphine
	PCA
	Pregabalin
	Clonidine
	Ketamine infusion
	Amitryptilline
	Lidocaine infusion
	Pethadine
	Oxycodeine
	Epidural
	Other
If Paracetamol	

Oral
IV

Appendix C: Instructions To Authors:

Journal South African Family Practice

Overview

The author guidelines include information about the types of articles received for publication and preparing a manuscript for submission. Other relevant information about the journal's policies and the reviewing process can be found under the about section. The

compulsory cover letter forms part of a submission and must be submitted together with all the required **forms.** All forms need to be completed in English.

Original Research Article

Report of original scientific research conducted in family medicine and primary care, ethical approval essential. **See full structure of original research articles below.**

Word limit	7000 words (excluding the structured abstract and references)
Structured abstract	250 words to include a Background, Methods, Results and Conclusion
References	40 or less
Tables/Figures	no more than 7 Tables/Figure
Ethical statement	should be included in the manuscript

A **systematic review** follows the same basic structure as an original research article:

- Structured abstract: Background, methods, results, conclusion.
- Objectives: Focus on a clinical question that will be addressed in the review.
- Methods section: Describe in detail the search strategy, criteria used to select or reject articles, attempts made to obtain all important and relevant studies and deal with publication bias (including grey and unpublished literature), how the quality of included studies was appraised, the methodology used to extract and/or analyse data.
- Results: Describe the homogeneity of the different findings; clearly present the overall results and any meta-analysis.

Scientific Letters

Short scientific report of original research, ethical approval essential. Case studies can be submitted as scientific letters.

Word limit	1800 words (excluding the unstructured abstract and references)
Structured abstract	250 words
References	20 or less
Tables/Figures	no more than 1 Tables/Figure

Open Forum

These contributions may discuss topical issues within the field of family medicine and primary care; innovations in clinical practice or conference reports.

Word limit	1800 words (excluding the abstract and references)
References	40 or less
Abstract	up to 150 words, unstructured
Tables/Figures	data in the text should not be repeated extensively in tables or figures

CPD Articles

Articles are published as part of the continuous professional development (CPD) programme of SAFP.

Word limit	1800 words (excluding the unstructured abstract and references)
Unstructured abstract	250 words
References	30 or less
Tables/Figures	no more than 2 Tables/Figure
Ethical statement	should be included in the manuscript, if applicable

Editorial

Scientific editorials can be used to highlight progress in any scientific field related to family medicine and primary care. Guest editorials on invitation basis.

Word limit	800 words
Tables/Figures	a maximum of 1 figure or table
References	10 or less
Conclusion	ensure that there is a clear message in the conclusion

Letters to the Editor

Short comment in response to publications in previous editions or related matters.

Word limit	800 words
Tables/Figures	a maximum of 1 figure or table
References	10 or less
Conclusion	ensure that there is a clear message in the conclusion

Corrections

A correction provides the platform to communicate important, scientifically relevant errors or missing information in a published article. Any changes after publication that affect the scientific interpretation (e.g., changes to a misleading portion of an otherwise reliable publication, an error in a figure, error in data that does not affect conclusions or addition of missing details about a method) are announced using a Correction. Read our submission procedure for **corrections** and **publishing policies**.

Compulsory title	The title of the submission should have the following format: 'Corrigendum: Title of original article'.
Submission File	completed **Correction Submission Form** (required)
Compulsory supplementary file	any supporting documents or emails, **Author Change Request Form** (if applicable), **Corresponding Author Change Request Form** (if applicable)

Cover Letter

The authorship, disclosure statements, copyright, and license agreement form is our compulsory cover letter which needs to form part of your submission. Kindly download and complete, in English, the provided **form**.

Anyone that has made a significant contribution to the research and the paper must be listed as an author in your cover letter. Contributions that fall short of meeting the criteria as stipulated in our policy should rather be mentioned in the 'Acknowledgements' section of the manuscript. Read our **authorship** guidelines and **author contribution**statement policies.

Original Research Article full structure

Title: The article's full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of four paragraphs labelled Background, Methods, Results and Conclusion.

- Background: Summarise the social value (importance, relevance) and scientific value (knowledge gap) that your study addresses.
- Methods: Clearly express the basic design of the study, and name or briefly describe the methods used without going into excessive detail.
- Results: State the main findings.
- Conclusion: State your conclusion and any key implications or recommendations. Do not cite references and do not use abbreviations excessively in the abstract.

Introduction: The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

- Social value: The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by use of evidence from the literature.
- Scientific value: The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic, and should clarify the knowledge gap that this study will address. Your argument should be supported by use of evidence from the literature.
- Conceptual framework: In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.
- Aim and objectives: The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design: This must address the following:

- Study design: An outline of the type of study design.
- Setting: A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.
- Study population and sampling strategy: Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size

calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.

- Intervention (if appropriate): If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.
- Data collection: Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.
- Data analysis: Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used orsteps followed in qualitative data analysis.
- Ethical considerations: Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

Results: Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should conform to the **SI convention** and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion: The discussion section should address the following four elements:

- Key findings: Summarise the key findings without reiterating details of the results.
- Discussion of key findings: Explain how the key findings relate to previous research or to existing knowledge, practice or policy.
- Strengths and limitations: Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.
- Implications or recommendations: State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.
  Conclusion: Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

Acknowledgements: Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution. Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named. Refer to the acknowledgement structure guide on our *Formatting Requirements* page.

Also provide the following, each under their own heading:

- Competing interests: This section should list specific competing interests associated with any of the authors. If authors declare that no competing interests exist, the article will include a statement to this effect: *The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.* Read our **policy on competing interests**.
- Author contributions: All authors must meet the criteria for authorship as outlined in the **authorship** policy and **author contribution** statement policies.
- Funding: Provide information on funding if relevant
- Data availability: All research articles are encouraged to have a data availability statement.
- Disclaimer: A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.

References: Authors should provide direct references to original research sources whenever possible. References should not be used by authors, editors, or peer reviewers to promote self-interests. Refer to the journal referencing style downloadable on our *Formatting Requirements* page.

Appendix D: Reviewer Comments and Responses

Responses to Reviewers: A retrospective audit of pain assessment and management post Caesarean delivery at a regional Hospital in Cape Town

We would like to thank all the reviewers for their considered review of our work. We believe their inputs have contributed to a stronger piece which we believe will be of value to the reader.

Reviewer Comment	Response
In the abstract and introduction, ***caesarean section is abbreviated to CS.*** *However, the abbreviation of the term is not applied to the rest of the manuscript. Further, the terms 'Caesarean Section' and 'Caesarean Delivery' are used interchangeably and without abbreviation. I recommend you use one of these (either is acceptable) and then use the abbreviation you have defined consistently throughout the document.* ***Additionally, the spelling of 'Caesarean' changes in the discussion to the American spelling (Cesarean).***	We have edited the text to be consistent in the use of the term caesarean section and the abbreviation CS throughout.
You state in the manuscript that there are at present "no perioperative pain management guidelines" for the	Thank you for highlighting our incorrect use of terminology which we realise has led to some confusion. Indeed, there are numerous guidelines. However, there are no protocols at

management of post-CS pain in regional hospitals in South Africa. There are in fact multiple guidelines in existence, many of which you reference in the manuscript (International guidelines such as reference 11 and the SASA Pain Management guidelines – which specifically cover CS). The Caesarean Section Monograph 2013 has a brief section on pain management which suggests intramuscular pethidine and NSAIDS as standard. Are you suggesting that there should be specific guidelines for South African regional hospitals (separate from district hospitals and tertiary hospitals)? I think this could be clarified: perhaps by stating that existing guidelines do not address some aspect you are concerned about. I also believe that a standard South African post-CS pain management guideline endorsed by both obstetric and anaesthetic disciplines would be of value. Perhaps clarify your meaning here: what is the specific gap you are addressing?	institutions which serve a role in translation of guidelines into practice specifying drug availability and practice implementation. We have thus replaced the word "guideline" with the word "protocol" where appropriate. Guidelines do state that a multimodal approach is recommended. The specific gap we are addressing is the need for protocols to encourage guideline implementation.

In the abstract, in the results, you mention the unemployment rate. Is this a relevant key finding for the abstract?	We have restructured the abstract with a focus on the meaningful results and subsequently deleted this.

The spinal anaesthesia rate in the study is not consistently quoted. In the abstract you quote this as 99.64% - but later the rate is quoted as 93.3%. It appears you are alternating between the rate within the spinal group (99.64%) and the overall group (93.3%). This should be amended.	Thank you for identifying our error which we have amended throughout. It should consistently be 93.3%
In the introduction, you quote the SASA analgesic recommendations but reference a High Spinal Guideline. Did you mean to reference this publication? The High Spinal Guideline is specifically written for the management of a high spinal during CS, rather than postoperative pain recommendations.	The reference makes mention of the recommended guidelines for the management of pain in caesarean sections. However, we have since substituted and referenced the most recent 2016 SASA guidelines on Acute Pain.

You mention that neuraxial morphine is a common strategy (and is indeed probably considered to be the gold standard in high income settings). I think you should specifically deal with this issue: state that none of your patients received it (if this is the case). It is true that it is not considered appropriate in LMIC yet – see reference: (Post-caesarean	This has been corrected to read “one of the strategies”

delivery analgesia in resource-limited settings: a narrative review. DOI: 10.1016/j.ijoa.2019.05.009). However, it would be a good thing to include in the discussion, and perhaps state your views on whether this should be considered (given that it obviates the need for post CS opioid to some degree, and at lower intrathecal doses does not appear to need additional respiratory monitoring). I do not believe we should be recommending it in state hospitals at this juncture, but you should discuss this briefly.	
Methods section: format reference 15 appropriately	Thank you for the comment. The formatting has been adjusted accordingly

Reference 16 is used to justify the spinal prescription – but that Ngaka study took place in Mowbray and GSH – while your study took place in NSH. Do you mean there is a uniform metropolitan policy? Why was this study referenced?	Our apologies, we realise that this is the results section and therefore the inclusion of a reference here is inappropriate. We have removed this reference here.
You mention that wound infusion catheters were not used. Are these recommended? Do you think they should be used in all patients (or just in those with higher predicted analgesic need)? And should we be considering TAP blocks in all patients that do not receive neuraxial morphine? (they do not appear to help if patients have received neuraxial morphine, and there is debate concerning the need for ultrasound).	Thank you very much for that comment. Our results actually show that one patient received a wound infusion catheter postoperatively. These strategies come with various challenges especially in limited resource settings like the hospital under review. The "discussion" section has been expanded to address these concerns.
Please check Table 2. The 'Spinal anaesthesia received' numbers appear to be 280/300 (93.3%) – but then in patients receiving spinals , you have 279/280 receiving them (99.64%) – and then these two percentages are quoted at various times in the manuscript.	Thank you very much. We have deleted the 279/280 part as it is rather confusing and does not add any further information. The "spinal anaesthesia received" has been corrected to consistently reflect 93.3%

In the Pain Assessment section: did assessment alter treatment? Did you record the actual assessments? It would be interesting to know if patients were in pain (given that only 1/3 got the prescribed treatment). The lack of administration of pain medication is a shocking finding if the patients were in pain, but perhaps understandable (or at least defendable) if they were not in pain.	We have clarified in the paper that for Pain assessment we looked for documented evidence of pain assessment having been conducted either in the doctors' notes or nurse notes e.g. 'mild pain' or 'patient complaining of pain', for the particular day in question. The actual pain scores recorded in the notes were not extracted in the chart review. We have also clarified what information was extracted in the chart review regarding analgesic prescription and administration.
In the Discussion, the spelling of Caesarean is Americanised (Cesarean). I would stick to your abbreviation.	This has been noted and corrected
You mention the opioid sparing effects of NSAIDs and paracetamol in the discussion. It might be worth alluding to the controversy in the US with opioid addiction (which some have linked to the 5th vital sign concept). It is worth pursuing opioid sparing effects: this should be stressed.	Thank you

You do not mention who is responsible for the pain prescriptions in NSH. Is it the anaesthetic team or the obstetric team? And does that team have a protocol which you could use to compare to? The Caesarean section monograph mentions that pain teams and anaesthesia should be involved: is this the case in your institution? This is important, because it may just mean that the issue is a standard protocol.	No pain protocols appear to be in place currently. Unless the patient is getting admitted to ICU, most pain prescriptions are done by the obstetric team. This paper endeavours to highlight the need for pain teams or develop protocols that can be adapted to the setting and regularly evaluated. No protocols appeared to be in place.
Line 255-258: this is not a complete sentence.	We have noted and corrected accordingly. Thank you
As a general comment, I think the main findings of this study are that your institution is failing to assess pain, failing to prescribe adequate analgesia and failing to administer the prescribed analgesia. This is a	Thank you for this recommendation. We have revised the conclusion to make clearer recommendations.

strong, negative finding. It is especially problematic given all the negative outcomes associated with a failure to provide adequate post-CS analgesia (which you mention). Do you believe that this is a South African problem, or just your institution? Are there audits from similar settings (especially within South Africa) that support this? While it is my belief that your findings are emblematic of a broader national (and international) issue, I think you need to make the case for generalisability to increase relevance to the readers.	
Reviewer C	
Overall I like the paper. Well done to that author.	We thank you very much.
Page 2 line 31: *grammar (there is need a)*	We have noted and corrected accordingly. Thank you
page 4 lines 73-75: *I've practiced in a number of South African hospitals, and it is not a*	We have noted. The referenced paper is a review and does not state where the practice has been adopted. However, we have restructured the sentence to read "… one of the strategies…"

common practice/strategy to use neuraxial morphine for CS. You've referenced this statement; you should rather state who suggests this strategy or where it is used according to your reference.	
page 15 line 187: *be consistent with you're wording, either regional or secondary-level hospital throughout the paper.*	We have noted and corrected it accordingly. Thank you very much
page 15 line 204: *if it's important to mention that pain intensity is just one aspect of the* *sensory dimension of pain, then you need to at a minimum mention the other aspects.*	Thank you very much for the comment. We have since adjusted the “discussion” section and added references that highlight other dimensions of pain assessment

page 16 line 229-230: *Should is an authoritative word and must be used when you're quoting an authoritative figure which you must mention in the text. otherwise it is an opinion of the author of reference 28.*	We have noted and adjusted accordingly. Thank you
page16 line 232-233 234: *be consistent with abbreviations. once you've started using NSAIDs CS, continue doing so. You need to only expand it when you use the abbreviation for the first time. (I think)*	We have noted and corrected accordingly. Thank you

Appendix E: Letter indicating acceptance of paper for publication

From: aosis@safpj.co.za

Subject: SAFP External Review Decision 5320 - Accepted for publication

Date: July 21, 2021 at 9:44 PM

To: Dr Effraim F. Munsaka munsakaeff@gmail.com

Cc: Dominique van Dyk dominiquevandyk@gmail.com, Romy Parker romy.parker@uct.ac.za

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Ref. No.: 5320

Manuscript title: A retrospective audit of pain assessment and management post Caesarean delivery at a regional Hospital in Cape Town

Journal: South African Family Practice

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Dear Dr Munsaka

Thank you for your revised manuscript. We have reached a decision regarding your submission. I am pleased to inform you that your manuscript has now been accepted for publication.

The Editorial Office will contact you by 28 July 2021. If you need any assistance, kindly contact the Editorial Office at submissions@safpj.co.za with any questions or concerns.

Thank you for submitting your interesting and important work to the South African Family Practice.

Kind regards,

Assoc. Prof. Von Pressentin

Division of Family Medicine, School of Public Health and Family Medicine,

University of Cape Town

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Frequently Asked Question

What can I expect from the publication procedure?

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On the acceptance of a manuscript for publication by the Editor-in-Chief, the editorial staff will work towards preparing the manuscript for online publication by performing a technical review of the publication process. The accepted manuscript will be prepared and handed over from the review office to the finalisation and publication office.

Here, the first stage is the language editing that is returned to the corresponding author for review. This will be the final opportunity for the author to make text changes to the manuscript. At a later stage, the editorial staff will send the author one set of galley proofs, at which time the author will have two working days to mark any typographical errors. It may not be possible to incorporate author corrections in the printed version of the manuscript in the event of the author having failed to respond to the proofreading requests. Authors should visit their personalised home page frequently to assess the location or stage of the manuscript.

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