UNIVERSITY OF CAPE TOWN

Department of Obstetrics and Gynaecology

MMed (Obstetrics & Gynaecology)

Audit Of Peri-Operative Care As Part Of The Enhanced Recovery Model For Caesarean Delivery

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Declaration Page

Declaration By Applicant

I, Abigail Blumenthal, declare that the work contained in this dissertation is my original work and work by others has been acknowledged as such.

The work has not been reported or published prior to registration for the above-mentioned degree.

The study was carried out while I was a registrar in the Department of Obstetrics and Gynaecology at the University of Cape Town as required for the MMed (O&G).

Applicant: Abigail Blumenthal

Signature of Applicant: Signed by candidate

Date: 10/03/2022

Table of Contents

Acknowledgements

I would like to thank Prof Fawcus for her continued support and encouragement in planning and completing this project. Prof Fawcus provided feedback and support with the design of the project as well as detailed feedback on the Ethics application and thesis.
I am grateful to the Mowbray Team, including Dr Anne Horak and Dr Chantelle Stewart for facilitating access to the patients and files. Dr Horak facilitated access to Mowbray Maternity Hospital as well as providing hospital specific guidelines. In particular I would like to thank Mr Malcolm Adams for his assistance in getting whatever files were needed.
I would also like acknowledge the support, advice and feedback I received from friends and colleagues in the writing of this dissertation.
I am forever indebted to my husband Mark and my children Zac and Leah for their support throughout the challenges of writing a dissertation whilst also training as a registrar in Obstetrics and Gynaecology.

List of Figures

Abbreviations

ACOG – American College of Obstetricians and Gynaecologists
BAME – Black and Minority Ethnic
BMI – Body Mass Index
CS – Caesarean Section
ERAS – Enhanced Recovery After Surgery
HAART – Highly Active Anti-retroviral Therapy
HIC – High Income Countries
HIV – Human Immune-deficiency Virus
HREC – Human Research Ethics Committee
IV - Intravenous
LMICs – Lower and Middle Income Countries
MMH – Mowbray Maternity Hospital
NICE – National Institute for Clinical Excellence
NBM – Nil By Mouth
NSAID – Non-steroidal anti-inflammatory
PRN – “Pro Re Nata” - Latin for “as needed”
REDCap - Research Electronic Data Capture system
UCT – University of Cape Town
UK – United Kingdom
US – United States of America

Abstract

Introduction

Mowbray Maternity Hospital (MMH) is a secondary level hospital serving a large population with low socioeconomic status. Around 10000 deliveries are done per year of which 40-50% are delivered by caesarean section (CS). There is much literature on peri-operative care for caesarean sections, under the model of fast-track surgery also known as Enhanced Recovery After Surgery (ERAS).

ERAS protocols have antenatal, intra-operative and post-operative components.
This audit aimed to evaluate how successfully MMH adheres to local and international guidelines for peri-operative care around elective caesarean section according to the ERAS model. It is hoped this will form the first step in a quality-improvement intervention resulting in better quality, evidence-based care appropriate for the low-resource setting.

Materials & Methods:

Women were invited to participate in the study in MMH postnatal ward between 24 and 48 hours after elective CS. Once consented, a structured questionnaire and data collection sheet was used to interview women and remaining details were obtained from the patient record.
This covered four aspects of ERAS programmes:

1. peri-operative hydration and nutrition
2. peri-operative analgesia
3. time interval postoperatively until removal of intravenous lines and urinary catheterisation
4. time interval until first mobilisation

The initial planned sample size was 50 women however after the start of the covid pandemic when in-person interviews were no longer possible, a folder audit was undertaken of the remaining files. A decision was made to therefore increase the sample size to increase the value of the data obtained from the folder audit given that there was to be more limited data from patient interviews. Anonymised data was entered into a secure online database using REDCap (Research Electronic Data Capture system). Data entry was verified by double entering all data. In total 75 folders were reviewed, of which 35% were interviewed face-to-face.

Findings

The audit showed that 92% of patients received exactly the same number of doses (four 10mg doses) of morphine post-operatively with more variation in the dosing of simple oral analgesics and no use of NSAIDs. It showed that 85% of patients had high pain scores (3 or more out of 5) in the first 24 hours post caesarean section but 85% also reported they were mildly or very happy with their pain management post-operatively. The audit highlighted that many patients were nil-per-os for prolonged periods of time peri-operatively; on average 23 hours without food and 19 hours without oral fluid. Drips and catheters were removed on average at 12.5 hours post-

operatively; and mobilisation occurred on average at 12 hours with few delays; the standard deviation was less than 1 hour.

Conclusions

The audit confirmed that Mowbray Maternity Hospital has good adherence to certain ERAS protocols. It confirmed that most patients were happy with their pain control despite often reporting high levels of pain. However, it highlighted several deficiencies such as poor use of regular simple oral analgesia and the lengthy duration of time for which many patients were fasted which could impact on general satisfaction with care, not to mention possible negative effects on tissue healing.

Background

An umbrella review of systematic reviews and clinical protocols has highlighted the important components of enhanced recovery relevant to obstetric surgery (1). The Enhanced Recovery After Surgery (ERAS) model was developed in the 1990s initially by bowel surgeons such as Henrik Kehlet under the title of “Fast Track Surgery” (2). At the time his multidisciplinary, multimodal model was developed, on average patients would remain in hospital for 10 days post sigmoid resection (3). Using this model, most patients were ready for discharge after 2 days. This has a range of benefits from improved patient satisfaction, reduced risk of problems associated with prolonged hospital stay such as venous thromboembolism or drip-site sepsis and reduced costs for healthcare systems.

Following the establishment of the ERAS society, an ever-expanding number of speciality specific models have been set up based on evidence-based guidelines and graded according to quality of evidence and the balance between desirable and adverse outcomes. The society also incorporates several formal tools and systems for auditing ERAS models to refine and improve care further. With respect to caesarean section, ERAS models incorporate a bundle of pre-operative, peri-operative and post-operative care components. Pre-operative components include better patient education, minimising fasting times and avoiding sedatives. Peri-operative components include multimodal analgesia including regional where feasible, maintaining normothermia, use of minimally invasive techniques, long-acting regional opioids and avoiding unnecessary IV lines, drains and catheters. Post-operative components include multi-modal analgesia, early mobilisation, early re-introduction of food and fluid including chewing gum and early removal of IV lines and catheters.

The ERAS Society recently commissioned guidelines for caesarean delivery. These have been published as three separate guidelines for pre-operative, peri-operative and post-operative care. Although the formal society guidelines for management of caesarean delivery were only recently published, many institutions had already introduced enhanced recovery programmes for caesarean delivery and have reported benefits in terms of patient satisfaction as well reduced use of resources due to lower rates of complications, and shorter duration of stay. In the English literature the majority of these guidelines and audits of ERAS practices have been in developed world settings however there has been movement to expand to ERAS protocols for developing economies (4).

Enhanced recovery protocols for caesarean delivery have antenatal components including patient education, maintaining good hydration until two hours prior to surgery, use of carbohydrate drinks two hours pre-operatively to prevent a catabolic state, the use of pre-operative prophylactic antibiotics and avoidance of sedatives or bowel preparation. Intra-operative components include the use of spinal anaesthesia, long-acting intra-thecal opioids, prevention of nausea and vomiting, pro-active maintenance of normothermia, minimally invasive surgical techniques (Joel-Coen method), delayed umbilical cord clamping and early skin to skin contact. Post-operative components include analgesia with regular paracetamol and ibuprofen with oral morphine for break-through pain, early removal of drips and catheters (ideally around 6 hours post-op), early oral intake (to prevent a catabolic state which may impair tissue healing), early mobilisation and

use of chewing gum. Chewing gum has been shown to improve the return to normal bowel functioning and reduce the risk of ileus (5). At Mowbray Maternity Hospital (MMH), some of these components are part of the current standard of care such as patient education in the form of counselling and patient leaflets. Some are not currently available such as oral morphine for post-operative analgesia. Some components do not form part of current practice but would not require extra-resources to introduce such as early oral intake or early removal of drips and catheters. Lastly some aspects of the Enhanced Recovery programme may be unsuitable for a low-resource setting. For example, early discharge from hospital in a context where patients struggle to find transport to return in case of complications and there is a very limited system of community-based care may potentially be inappropriate.

MMH is a busy public-sector unit with six to eight elective caesarean sections booked each day. Elective caesareans are performed in the same theatres as emergency operations which frequently delay elective procedures. As a result, a patient booked for elective caesarean who is fasted from 22:00 may only have her operation performed at 20:00 the following day after 22 hours of fasting. Many women are told they may not eat for 6 hours after the operation and there is no provision for food to be provided outside of the kitchen's meal times. As a result, if a patient does not have her own food she may not eat for up to 32 hours around the time of her operation. If too many emergencies are booked and the patient is postponed to the following day this may be even longer. Clearly this is far from ideal quality of care from the point of view of patient satisfaction but as described below it also represents a significant assault in terms of patient physiology. The ensuing catabolic state may impair patient healing resulting in increased risk of surgical complications. The length of time of actual fasting for patients undergoing CS at MMH has never been formally studied, thus this study presents an opportunity to do this. It is currently unclear how quickly catheters and other lines are removed after caesarean which may impact on infection rates as well as patient satisfaction. The degree of compliance with MMH's analgesia protocol is also unknown. Provision of good quality analgesia is thought to improve patient mobility thus reducing the risk of complications such as ileus and venous thromboembolism. It also improves patient satisfaction. Maternity care for black and ethnic minority women is currently under the spotlight due to the disproportionately poor healthcare outcomes experience by non-white women in high income countries. One of the areas highlighted by women from non-white ethnic groups is that their pain is not taken seriously or they are seen as having different pain thresholds despite no evidence to support this. (6–8)

This audit aims to evaluate how successfully Mowbray Maternity Hospital adheres to local and international guidelines for peri-operative care around elective caesarean section according to the enhanced recovery model. It also aims to better understand how women in a low-resource setting experience pain post caesarean section and their satisfaction with their care. It is hoped this will form the first step in a quality-improvement intervention resulting in better quality, evidence-based care appropriate for the low-resource setting.

Literature Review

ERAS protocols in other specialties

Prior to the 1990s, the conventional wisdom was that surgical stress was inevitable and that the patient required a prolonged period of rest post-operatively. It was felt that after bowel surgery in particular the bowel must be rested to allow healing. In 1997 Henrik Kehlet published an article detailing the physiological effects of pre-operative comorbidities, intra-operative surgical and anaesthetic stresses and post-operative management and how these might be minimised. In 1999 Kehlet published a study detailing how the hospital stay post-sigmoidectomy had been reduced from 10 to 2 days using a multimodal rehabilitation programme (2) (9). Dr Kehlet and other colleagues in Northern Europe formed a research group to evaluate and improve peri-operative care pathways in their different units. The group found marked differences in care pathways associated with marked differences in rates of complications and duration of hospital stay. The group developed a consensus protocol and then implemented it as part of an international observational study. Further studies have shown associations between compliance with the protocol and reduced rates of complications and better 5 year survival rates (10) (11).

The initial ERAS work was done in colorectal surgery, however other specialties have gone on to develop specific protocols including rectal and pelvic surgery and gynecological oncology (3). In conjunction with the development of ERAS protocols, the ERAS society has also developed an audit system to allow units to monitor adherence to protocols.

ERAS protocols specifically for caesarean section

Many units have instituted ERAS programmes for caesarean sections since around 2013, which have been based on ERAS guidelines from other specialties and local consensus on additional elements specifically relevant to caesarean. In 2017 a review of clinical protocols was done to produce an evidence-based guideline specifically for enhanced recovery after caesarean section. Many elements were based on the evidence from other surgical fields as the reviewers noted that very few systematic reviews have been performed in pregnant women. As with all ERAS programmes there are pre-operative, intra-operative and post-operative components.

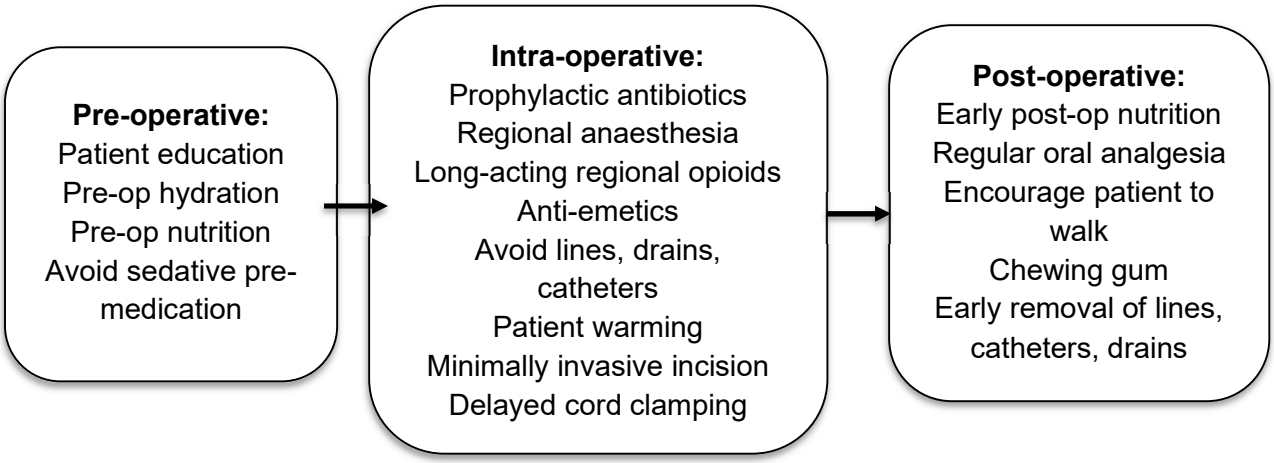


Figure 1 ERAS components - Information for above figure derived from guideline in reference (1)

Most recently the ERAS Society Guideline Committee commissioned the "ERAS Cesarean Delivery Guideline". They selected a group of authors including obstetricians, paediatricians, anaesthetists and nutrition specialists to review the literature and create an evidence-based consensus for pre-operative, peri-operative and post-operative care using elements from other ERAS protocols but also adding elements specifically beneficial for caesarean section such as early skin-to-skin contact and delayed cord clamping (Figure one). The guideline details the quality of evidence for each element as well as the consensus opinion of whether the desirable effects of the intervention outweigh the undesirable effects. This means that even where the evidence for the benefit may be relatively weak, if there is minimal chance of harm occurring from the intervention, it may be strongly recommended. The guideline is published in 3 parts; part 1 detailing antenatal and pre-operative recommendations, part 2 includes intra-operative recommendations and part 3 includes post-operative recommendations (12) (13) (14).

Many of the elements may be as or even more relevant to the lower-income setting as the higher-income settings however some may require caution before being instituted in the South African setting. Evidence suggests early discharge from hospital is safe in first world settings and is not associated with increased re-admission from hospital or morbidity and mortality (15) (16). However the protocols recommend home visits by community midwives 24 hours post-discharge which could be challenging in South Africa with many patients living in difficult or dangerous to access informal settlements, and many patients experience severe barriers accessing healthcare from home should complications occur (17) (18). The guideline also recommends single layer uterine closure for patients who do not plan to have further children. However, in South Africa where the majority of pregnancies are unplanned, this may be unwise unless concurrent bilateral tubal ligation is performed (19). A randomised controlled trial of ERAS versus standard care after caesarean section done in Kenya showed a significantly reduced length of stay from an average of 61 hours to 45 hours (4). This was not associated with increased admission rates however this was a small study of 160 patients and safety on a larger scale would need to be evaluated.

Quality improvement studies charting the introduction of ERAS protocols for caesarean section

Although the ERAS Society only recently produced a formal protocol for caesarean section, many units have designed and introduced their own protocols and published their experiences in doing so. As early as 2008, an Icelandic group introduced a fast-track programme for elective caesarean sections and reported discharging 66% of women within 48 hours without increasing re-admission rates (20). They also documented high levels of patient satisfaction with early discharge. Wrench et al reported that introduction of an enhanced recovery programme allowed a higher percentage of patients to be discharged the day after caesarean section without increasing rates of re-admission (16). A group in France reported that the introduction of an enhanced recovery programme improved patient mobility and allowed quicker return to autonomous control of urinary function however an increased risk of urinary retention was reported (15).

Associations between ethnicity and pain management

There is much dismay about the ongoing disparity in maternal morbidity and mortality outcomes between white women and women of other ethnic backgrounds (21). Systematic reviews in the US have shown that white patients are more likely to receive analgesia for acute pain that non-white patients (6). It is striking that in 2021 in South Africa, the majority of women deliver in midwife obstetric units which have no Nitrous oxide/oxygen for analgesia and many do not even have pethidine for pain relief. Between the three obstetric hospitals in the UCT circuit – Mowbray Maternity Hospital, New Somerset Hospital and Groote Schuur Hospital, only Mowbray offers any epidurals to women in labour and often fewer than ten per month. This means that about 0.05% of women delivering in the UCT drainage area have access to an epidural compared to more than half of women who deliver in the USA. Very few studies have looked at women's experience of pain post-caesarean section or even in labour in South Africa. Whether this is due to the focus on other priorities such as hypertension, bleeding and infectious diseases or whether it reflects an aspect of structural racism is open to debate.

Aims and Objectives

Study aim:

To audit perioperative management of women having elective CS at MMH with reference to features of enhanced recovery programmes.

Specific objectives

These covered four aspects of enhanced recovery programmes:

1. To describe peri-operative hydration and nutrition, around caesarean section
2. To describe peri-operative analgesia following Caesarean section and assess women's experience of pain and pain management after CS
3. To describe time interval postoperatively for removal of intravenous lines and urinary catheterisation post caesarean section
4. To describe time interval until first mobilisation post caesarean section

Methods

Study design:

A cross-sectional observational study design was used.

Study setting:

Women were recruited at Mowbray Maternity Hospital during 2019 and 2020. The majority of the face-to-face interviews were done over 5 months of 2019. Due to the impact of the pandemic on face-to-face interviews and the resultant changes made to ward staffing and discharge protocols, the decision was made to complete the study using a retrospective audit of other files from 2019. Mowbray Maternity is a public sector secondary level hospital in Cape Town which performs about 10,000 deliveries per year. It serves a low-income population from the immediate surrounding area and a wider drainage area providing care to women with low-risk and high-risk pregnancies. Around 45% of deliveries are by caesarean section, with about 20% being elective procedures. Those women with very complicated pregnancies requiring tertiary level care or access to an on-site blood bank are referred to Groote Schuur Hospital.

Inclusion criteria:

All women undergoing elective caesarean section at Mowbray Maternity were eligible for inclusion in the study. Women present on the post-natal ward between 24-48 hours post elective caesarean section were invited to participate in the survey and once consented, their notes were reviewed.

Exclusion criteria:

Minors (age less than 18 years) were excluded. To avoid conflating different issues, women with particularly difficult caesareans were excluded. This included more than two previous laparotomies, operation time longer than 90 minutes, estimated blood loss more than 1500 mls, visceral injury at surgery, Body Mass Index (BMI) more than 45, and severe neonatal

complications. Due to the altered pain experience, women who were current users of recreational drugs were excluded.

Data collection:

Women were invited to participate in the study in Mowbray Maternity postnatal ward between 24- and 48-hours post-surgery. Subjects were identified consecutively on the days when the principal investigator was rostered to the post-natal ward which limited the opportunity for bias. Once consented in English, Afrikaans or isiXhosa, a structured interview questionnaire and data collection sheet was used to interview women and retrieve data from the patient folder. These were administered by the on-site investigator, Dr Blumenthal who is competent in the three main languages of the Western Cape and the remaining details were obtained from the patient record. Women were asked about the timings of drip and catheter removal as well as their fasting times pre and post operatively. They were asked to rate their pain over the first 24 hours post-operatively using a visual analogue scale and also to rate their satisfaction with their pain management on a Likert scale. There is currently no standardised questionnaire to audit patient fasting times, peri-operative analgesia and patient satisfaction with analgesia under an Enhanced Recovery model. However, the ERAS society has commissioned and published in part a specific protocol for caesarean section so it is possible that in future, there will be an internationally recognised audit tool available for this purpose. The survey that was designed for this project, is included as Appendix A and was initially piloted on 5 women to ensure it was intelligible and fit for purpose. It is based on a questionnaire used for a similar project done previously in the UK and following consultation with other UK research groups doing similar audits. Anonymised data was entered into a secure online database using REDCap (Research Electronic Data Capture system). Data entry was verified by double entering all data.
The patient questionnaire can be found in Appendix A. The Data collection sheet for the survey can be found in Appendix B.
Once the Covid-19 pandemic took hold in South Africa, face-to-face interviews were no longer possible. Thereafter the remainder of the sample was done purely by auditing the folder and therefore it was not possible to get the patient's subjective pain scores for these women.

Sample size.

This is a descriptive study with no comparative aspects so a statistical estimation of sample size is not applicable. MMH performs 380 – 400 CS per month. Of these about 20% are elective procedures. A convenience sample of eligible women having CS was chosen. This was assessed to be a minimum of 50 women from which to ascertain practices and perceptions.

Data analysis

Data was analysed mostly using frequencies and percentages. Statistics were therefore done using RedCAP tools and Excel.

Ethics

The proposal and questionnaire was submitted to the Department research committee and then to the Faculty of Health Sciences Human Research Ethics Committee (HREC) (HREC REF 337/2019 – appendix F). Informed consent in the appropriate language was obtained from participants.
If maternal distress or severe pain was detected during the course of administering the questionnaire, the relevant care-giver was contacted
Patient information and consent forms are in Appendix C & D.
All information was anonymised and kept confidentially in a secure database.

Results

There were 90 women identified for inclusion in the study during the days available. Of these, 13 were excluded according to study criteria, 2 declined to participate because they were not feeling "up to an interview", and 26 women gave consent for face-to-face interviews, prior to surveying their folders. The remainder were file surveys only. In total, 75 women's files were reviewed, 26 (34.7%) of whom were also interviewed face-to-face. The files surveyed were taken from CS deliveries prior to the onset of the Covid-19 pandemic to avoid the potential bias of sampling from a time when staff numbers or bed pressures may have been extraordinarily constrained.
Therefore, each Figure heading will be followed by (N=75) or (N=26) to denote the source of the data. Information about medication administered, times of drip and catheter removal and mobilisation, time to first oral intake of fluid and time to discharge was taken from the patient record. Information about time spent without food, pain rating scores and satisfaction with pain control was taken from the face-to-face interviews (Appendix A1). Some information such as time to mobilisation or removal of drips and catheters was taken from both face-to-face interviews as well as the file survey so that where information was missing from the file, it could be taken from the interview. However, where the results differed, data taken from the file was used.

Patient Characteristics and Demographics

The mean age of the women surveyed was 31 years ranging from 20 to 41, two thirds of whom were aged 25-35 (Figure 2).

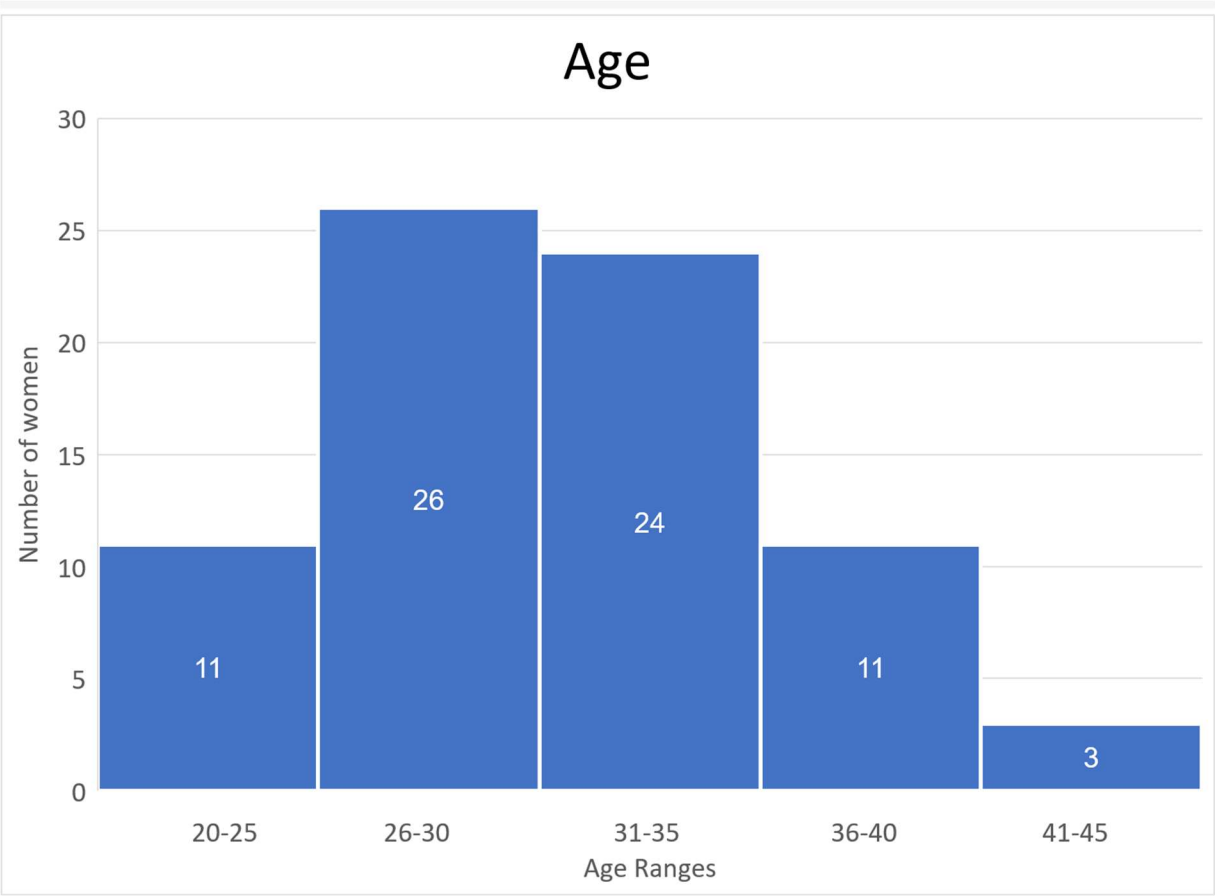


Figure 2 Age of women included in audit (N=75)

The majority of women were gravida 2 or 3 (range 1 to 6) and para 2 or 3, (range 1 to 7). This included the index pregnancy (Figures 3 and 4).

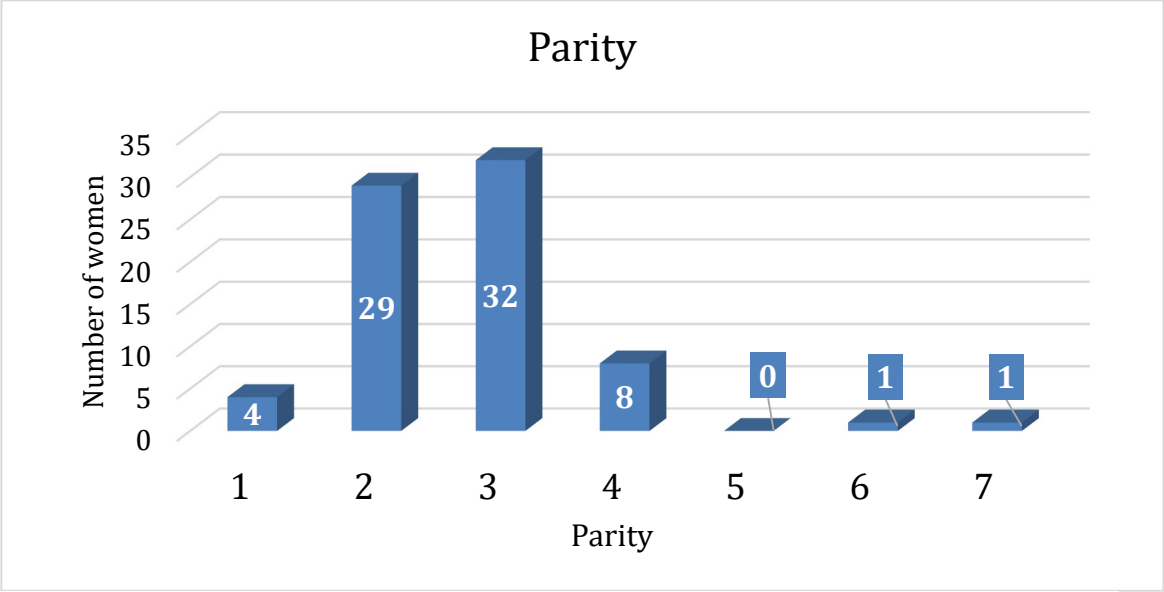


Figure 3 Parity of women included in audit (N=75)

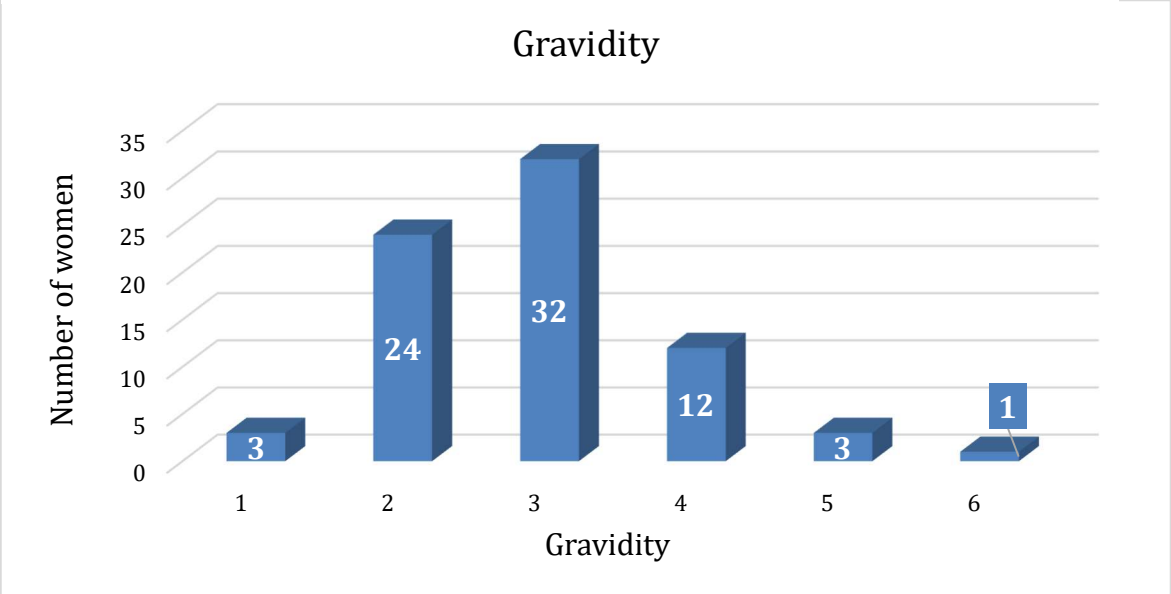


Figure 4 Gravidity of women included in audit (N=75)

Of the women surveyed, 40 (53%) were having their second abdominal surgery, and the remainder were evenly split with 17 (23%) having their first and 18 (24%) having their third. Higher orders of abdominal surgeries were excluded to avoid having skewed pain experience.

Regarding comorbidities, 19 (25.3%) women were HIV positive, all on HAART. There were 8 (10.7%) women who were diagnosed with hypertension (gestational or chronic) and one woman had gestational diabetes (Figure 5). The referral criteria in Cape Town means that the majority of gestational diabetics are managed at tertiary level.

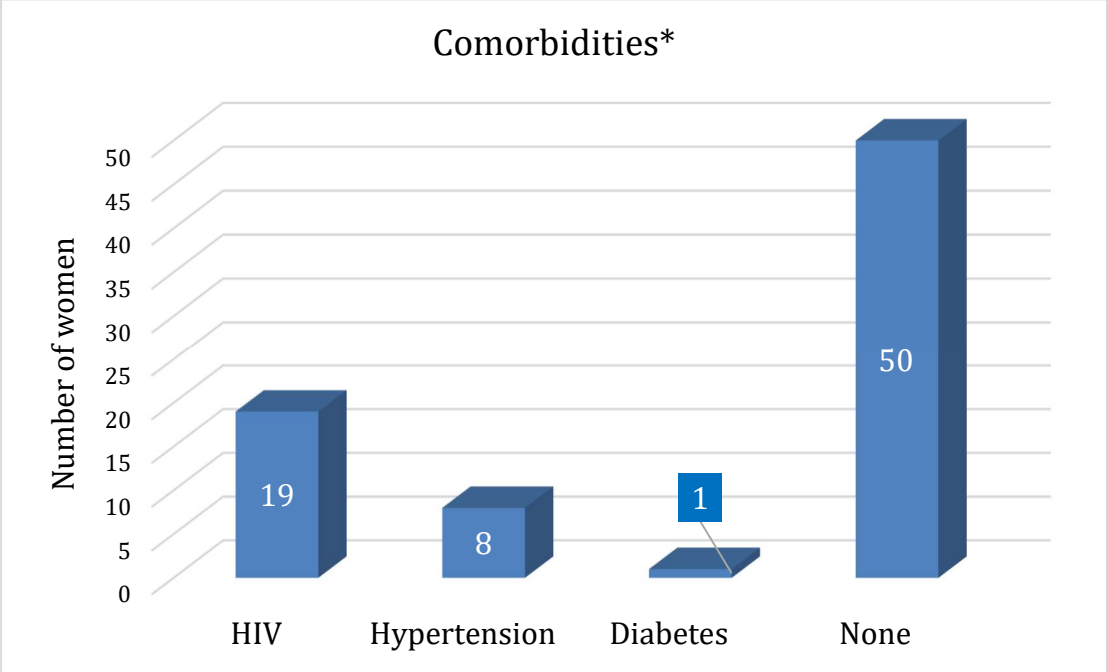


Figure 5 Numbers of women with comorbidities (N=75)

*3 women had more than one comorbidity

Peri-operative care

For peri-operative analgesia, 74 (100%) of women surveyed had a spinal anaesthetic, all of which were done with fentanyl, a potent but short acting opioid however 2 of these (3%) failed requiring conversion to general.

There were 55 (74%) women who had no additional intra-operative analgesia beyond the regional anaesthesia. In other words more than a quarter of the women, 19 (26%), required additional analgesia during the surgery.

Of the 74 women who had a spinal, 3 (4%) women needed a combination of intravenous analgesia intraoperatively for pain relief (either morphine and fentanyl or fentanyl and ketamine). There were 5 (7%) received intravenous fentanyl alone. In the anaesthetic charts 2 (3%) women received intravenous pethidine however this is typically used in very small doses to treat shivering due to the spinal and therefore may not have been given for analgesia. Four women (5%) had documented infiltration of bupivicaine to the CS wound at the end of the operation which is another recommended practice on the ERAS protocol. Furthermore, as mentioned above, 2 (3%) required conversion to general anaesthesia due to pain (Figure 6).

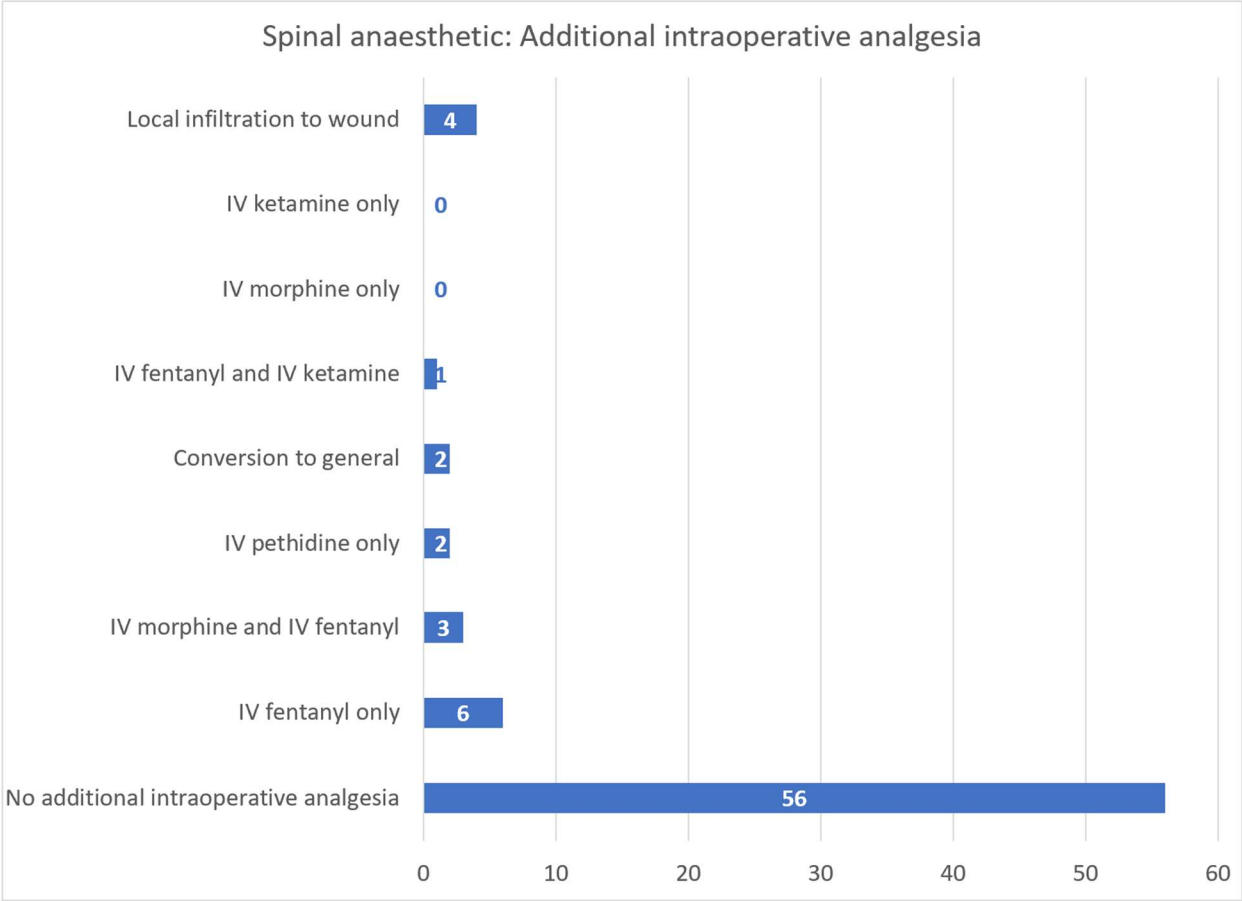


Figure 6 Additional intra-operative analgesia for patients receiving a spinal anaesthetic (N=74)

The average duration of surgery was 38 minutes ranging from 17 to 81 minutes (operations longer than 90 minutes were excluded from the audit as a surrogate for unusually complicated surgery).

Post operative care

For post-operative analgesia (N=74 – post-operative drug chart was missing for 1 patient), 16 (21%) of women received paracetamol twice or fewer times in the first 24 hours and 30 (41%) received it three times. No women were documented to have received non-steroidal analgesia neither rectal suppositories nor orally post-operatively. Parenterally, 68 (92%) of women received 4 doses of 10mg intramuscular morphine by 24 hours post operation. For the remainder, 4 (5%) received 3 doses and 2 (3%) received 5 doses. This meant most women received 40mg of morphine within the first 24 hours for breakthrough analgesia. There were 41 (55%) women who had received one dose of tramadol, always 50mg by the end of 24 hours.
The intravenous line, catheter removal and mobilisation were usually documented as being done together. The mean time from end of surgery to removal of lines and mobilisation was 12.4 hours ranging from 10 to 14.5 hours with a standard deviation of 47 minutes.

With regard to fasting times, on average women were without fluid for 19 hours (range 6 to 31 hours) (Figures 7 and 8). Of the women interviewed face-to-face, 20 (77%) reported wanting fluid earlier and being denied it.

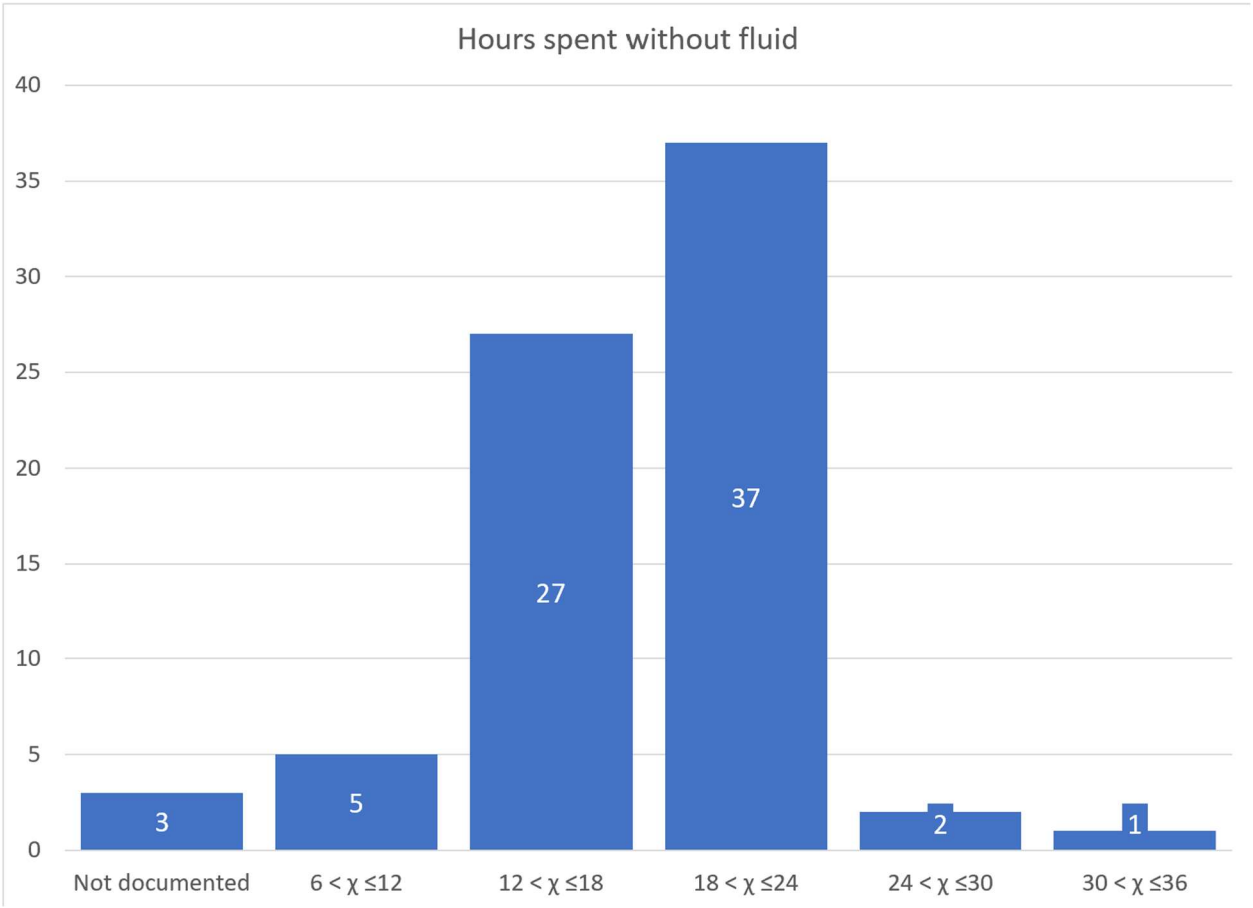


Figure 7 Hours spent without fluid peri-operatively (N=75)

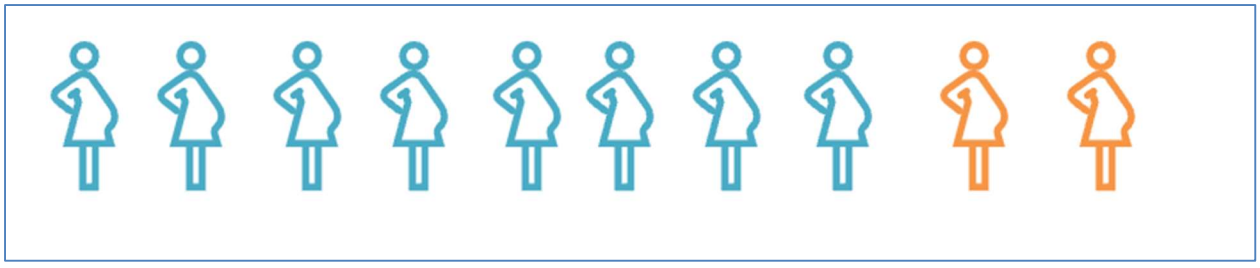


Figure 8 Infographic showing 8 out of 10 women wanted fluids earlier than they were given (N=26)

The 26 women interviewed face-to-face were asked about how long they were unable to eat for peri-operatively. On average women were without food for 23 hours (range 16 to 37.5 hours) and 9 (35%) reported wanting to eat earlier than they were permitted to do so (Figures 9, 10).

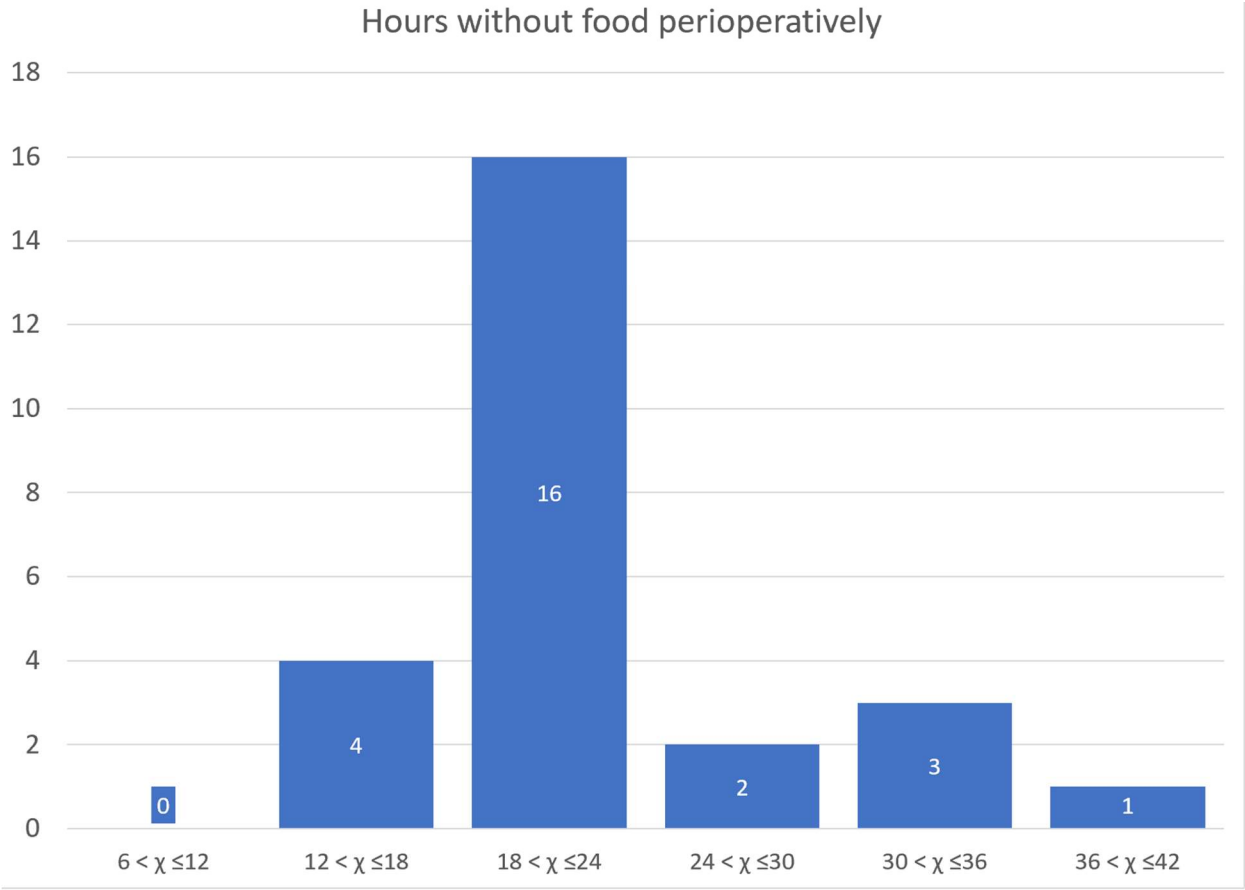


Figure 9 Hours spent without food perioperatively (N=26)

Figure 10 Infographic showing 1 in 3 women wanted food earlier than it was given (N=26)

Twenty-six women were asked to score their pain for the first 24 hours post caesarean section using a visual analogue score:

No women scored themselves as without pain using the visual analogue score (figure 11). Of the 26 women interviewed, 14 (54%) scored their pain as 2 or 3 out of 5 and 12 (46%) scored their pain as 4 or 5 out of 5. Despite this, 22 (84%) stated they were mildly or very happy with their pain management; and 2 (8%) said they were mildly unhappy or very unhappy (Figures 12 & 13).

Figure 11 visual analogue pain score

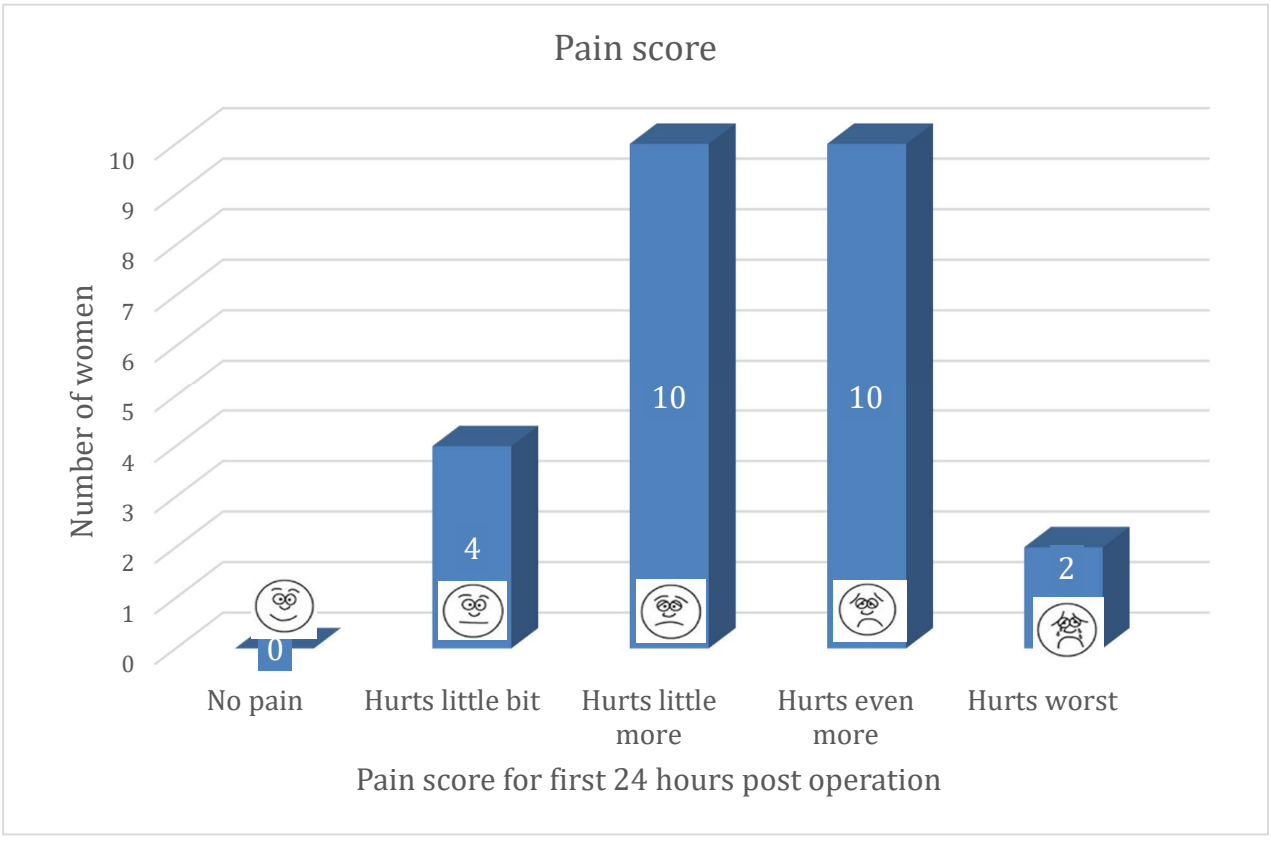


Figure 12 Patients' subjective pain score for the first post-operative day (N=26)

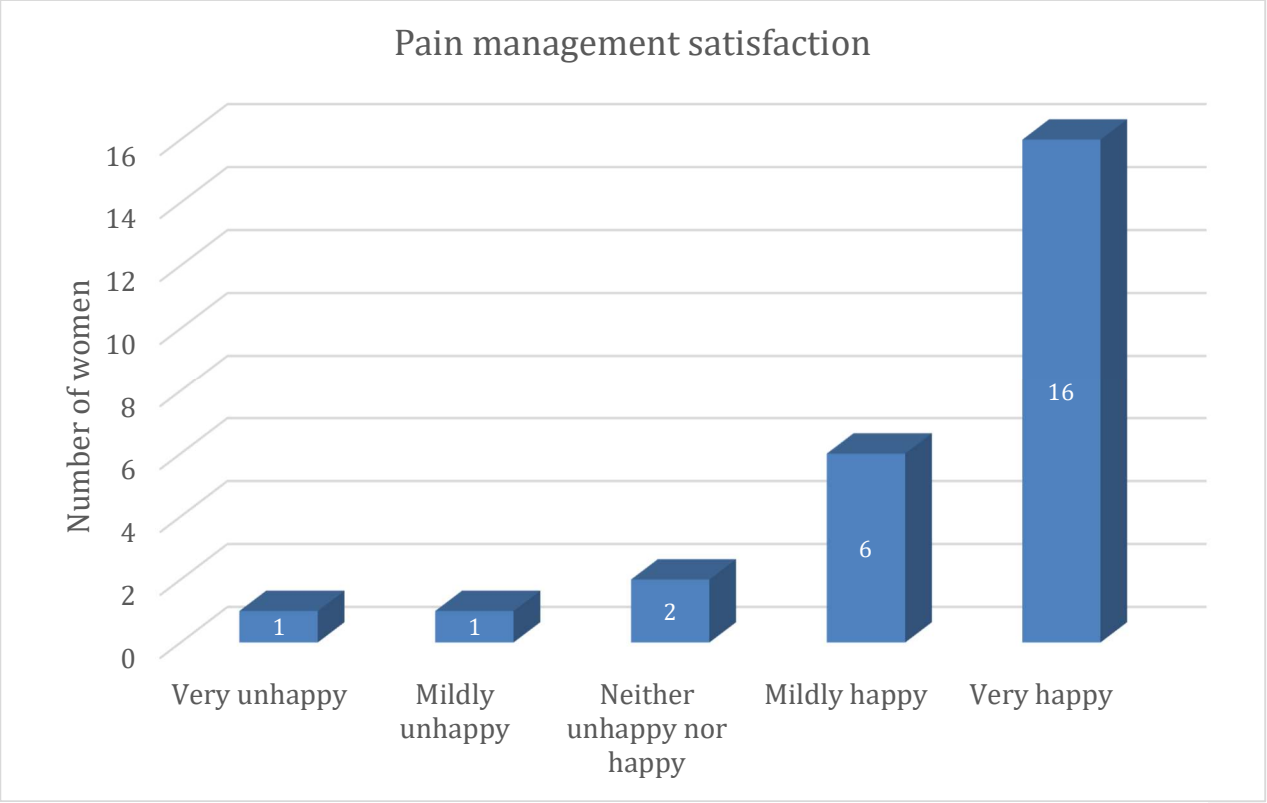


Figure 14 Patients' reported satisfaction with their pain management (N=26)

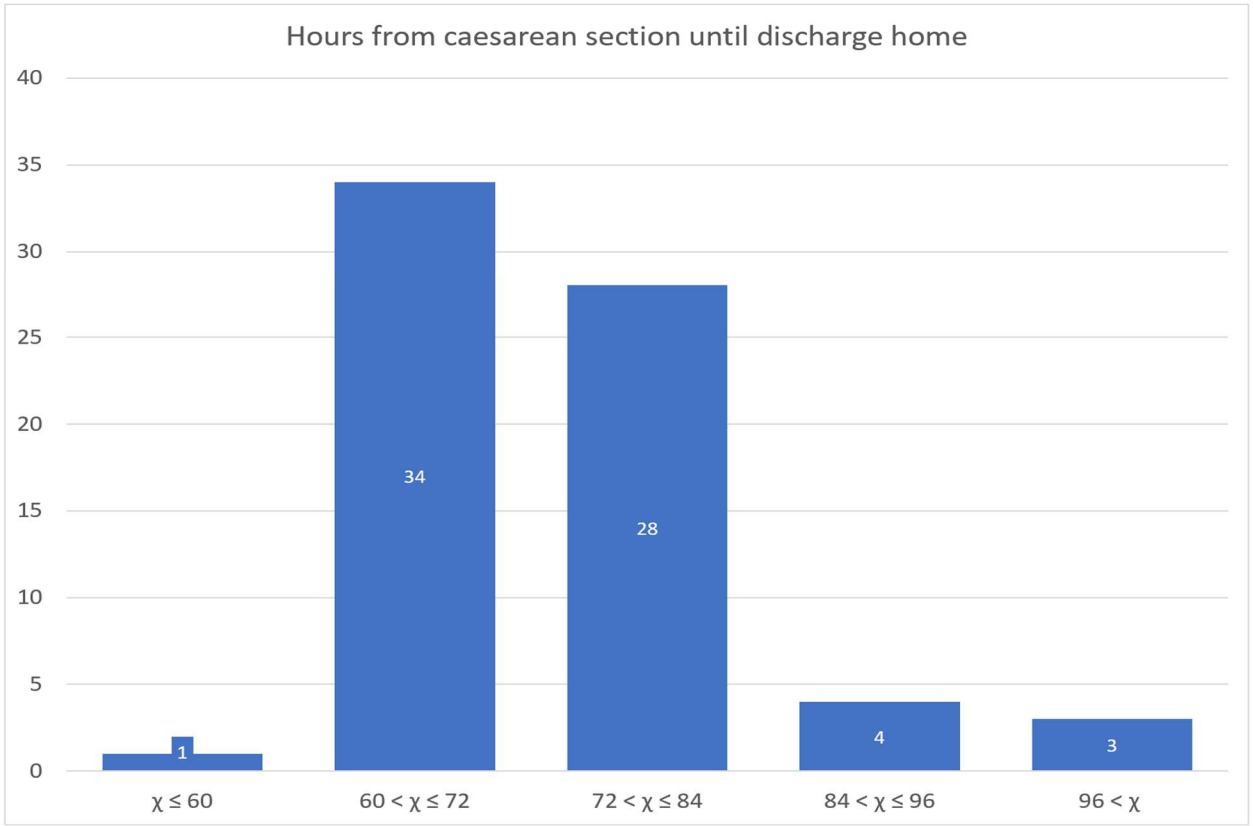


Figure 13 Length of stay from the time of surgery to discharge (N=70 – data missing from 5 patients)

The mean time from caesarean section to discharge was 75 hours with a range of 45.5 to 140 hours. There were 62 (89%) patients who were discharged between 60 and 84 hours post operation. (Figure 13). The time of discharge was not documented in 5 folders.

Discussion

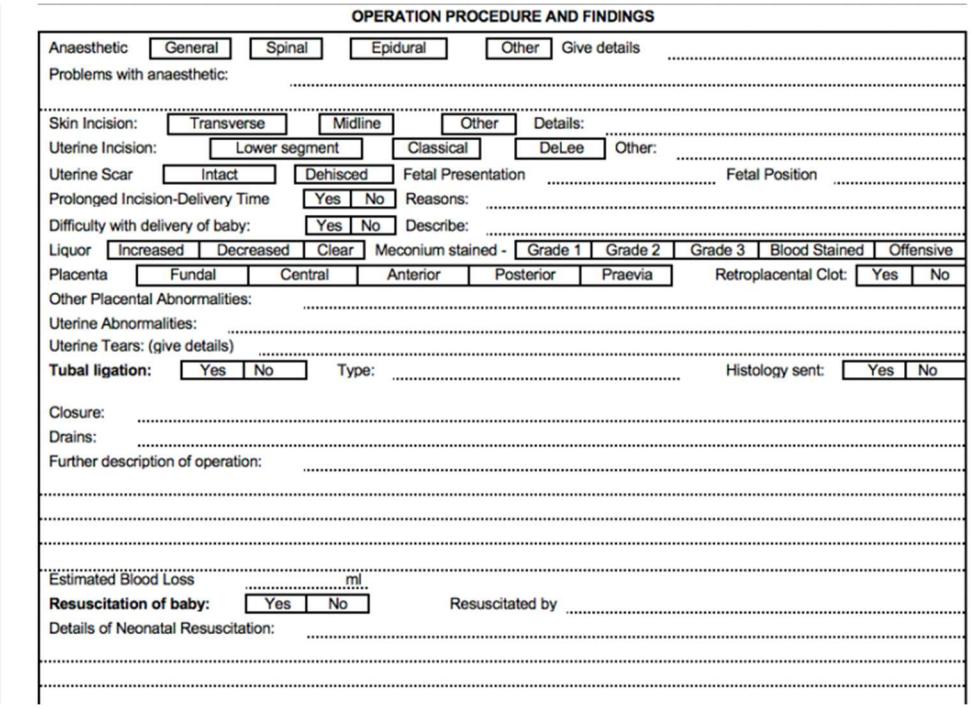
Enhanced recovery after surgery offers a model of care whereby optimisation of numerous often minor aspects of care offers a cumulative benefit maximising patient satisfaction and reducing complication rates. This in turn shortens hospital stay and use of resources which is particularly important in lower resource settings. However, considering caesarean section in LMICs, this must be balanced against the availability of adequate postnatal care in the community and the ability of patients to access transport if shorter duration of hospital stay was found to be associated with increased risks of readmission.

In this audit we looked at several aspects of intraoperative and post-operative care and their alignment with local protocols. We also looked at how those local protocols currently align with ERAS models and hope to identify areas where effective improvements in quality of care and patient experience can be made.

Perioperative analgesia

ERAS models in general and specifically the ERAS guideline for caesarean section recommend regional anaesthesia as superior where it is appropriate (13). It is associated with better pain control, organ function, mobility, post operative nausea and vomiting and reduced number of days spent in hospital and adverse events (22). It is recommended that long acting intrathecal opioids such as morphine or diamorphine are used rather than short acting opioids such as fentanyl as they provide much longer pain relief. Our audit showed that although the majority of women (96%) had a spinal anaesthetic, all were given intrathecal fentanyl as the opioid. There is a concern that use of intrathecal morphine might put the patient at risk of respiratory depression however as we will show later, all the patients received significant doses of intramuscular morphine in the postnatal wards and evidence suggests the risk of respiratory depression with low dose intrathecal morphine is equal to or lower than the risk of parenterally administrated morphine(23).

ERAS also recommends local infiltration to the wound which was found by a Cochrane review to improve postoperative analgesia (24). Our audit found that this was documented as being done in 5% of women however given that it is not part of the printed operative summary in the South African Maternity case record shown in Figure 14, there is a possibility that it might be under-



OPERATION PROCEDURE AND FINDINGS

Anaesthetic [General] [Spinal] [Epidural] [Other] Give details .....

Problems with anaesthetic: .....

Skin Incision: [Transverse] [Midline] [Other] Details: .....

Uterine Incision: [Lower segment] [Classical] [DeLee] Other: .....

Uterine Scar [Intact] [Dehisced] Fetal Presentation ..... Fetal Position .....

Prolonged Incision-Delivery Time [Yes] [No] Reasons: .....

Difficulty with delivery of baby: [Yes] [No] Describe: .....

Liquor [Increased] [Decreased] [Clear] Meconium stained - [Grade 1] [Grade 2] [Grade 3] [Blood Stained] [Offensive]

Placenta [Fundal] [Central] [Anterior] [Posterior] [Praevia] Retroplacental Clot: [Yes] [No]

Other Placental Abnormalities: .....

Uterine Abnormalities: .....

Uterine Tears: (give details) .....

Tubal ligation: [Yes] [No] Type: ..... Histology sent: [Yes] [No]

Closure: .....

Drains: .....

Further description of operation: .....

Estimated Blood Loss ..... ml

Resuscitation of baby: [Yes] [No] Resuscitated by .....

Details of Neonatal Resuscitation: .....

Figure 15 Operation Note page of the handheld Maternal Case Record

reported (25).

Local anaesthetic has some bacteriostatic and anti-inflammatory properties which may aid wound healing (26) (27). It is recommended by PROSPECT (**Pro**cedure **spec**ific recommendations for pain management**)** which is an evidence-based set of guidelines for the management of pain for specific surgical procedures. It is particularly recommended where a long-acting opioid was not used intrathecally (28). The guidelines also recommend that paracetamol and NSAIDs are started orally, intravenously or rectally intra-op and continued post-operatively. Several studies have linked these interventions with lower post-operative opioid requirements (14) (29).

It is notable that 23% of women in this audit required additional intra-operative analgesia in the form of intravenous opioids given that all women were given short acting opioids in the spinal.

Post operative analgesia

The ERAS model recommends regular oral analgesia with parenteral opioids as breakthrough pain control. The NICE guidelines for caesarean section recommend regular oral paracetamol and NSAIDs with weak oral opioids and stronger opioids if needed and parenteral opioids if pain control is very poor. MMH guidelines recommend paracetamol regularly with Morphine 4 hourly PRN for pain (Appendix E). Indomethacin suppositories may be used for women with no pre-eclampsia and those who are HIV negative however it is rarely prescribed. This is due to an

institutional concern of an association between NSAID use and necrotising fasciitis. Some case reports have suggested an association between NSAID use and necrotising group A streptococcal infections (30) (31). However, given the widespread use of NSAIDs post-operatively causative effects may be difficult to tease out without randomised controlled trials which have not been done. The example of the association between NSAID use in varicella and invasive group A strep infection is similarly unclear as to whether NSAIDs are a causative agent. It is possible that use of NSAIDs cause invasive group A strep infection but it is also possible that patients with invasive group A strep infection have higher fevers and therefore parents use more NSAIDs resulting in the association (32).

Outside of the Metro West hospitals NSAIDs form part of major guidelines for analgesia post-caesarean (14) (28) (33). Several studies have shown NSAIDs compare favourably to opioids in terms of pain control and side effects including sedation and constipation (29) (34). There are contra-indications listed in the guidelines; these include asthmatic patients sensitive to NSAIDs, inflammatory bowel disease, gastric ulcers, renal impairment, thrombocytopaenia, significant haemorrhage or pre-eclampsia. However even for pre-eclampsia there is debate about the quality of evidence precluding their use. ACOG guidelines advise that NSAIDs should be avoided in women with hypertensive disorders of pregnancy if hypertension persists for more than 1 day post-partum (35). A meta-analysis showed that there is little convincing evidence that NSAIDs increase the risk of severe hypertensive crises or worsening renal impairment (36). However all of the studies included in this meta-analysis were done in high income settings and the differences between the pre-eclamptic population in high and low income settings in terms of risks of mortality, morbidity and access to renal replacement therapy in the event of complications is stark (37). A cautious approach to renal protection is important in South Africa due to poor access to renal replacement therapy and renal transplantation and the association of a history of pre-eclampsia amongst end-stage renal disease patients (38). Whether this association is causative is unclear.

Paracetamol is considered to be an important part of effective multimodal pain control strategies. Evidence for paracetamol for post-operative pain is very variable in quality but some studies have shown a significant benefit and the risk of harm in the short term is low. Each dose is effective for about 4 hours so it is therefore important that it is given regularly (39). This audit showed that many women at MMH receive paracetamol much less frequently than recommended in the 24 hours post-caesarean section. One possible method to resolve this would be to allow women to self-administer at least the simple analgesics as they will do on discharge at home. Previous studies have shown high patient satisfaction with such a method (40). Challenges in the middle-income public sector setting include concerns about language barriers and some studies into self-administered analgesia have excluded non-first language English speakers. However, these same patients are given the boxes of medication to take at home where they have less access to support and advice from healthcare professionals. Excluding patients whose first language is not English or even not English, Afrikaans or isiXhosa from easier access to regular analgesia is therefore illogical and may fit into the pattern of women from BAME backgrounds often receiving poorer pain control in healthcare settings, especially around labour and caesarean delivery (7) (8).

Intermittent intramuscular morphine forms the mainstay of post-caesarean analgesia at MMH whereas internationally and in the ERAS movement, the aim is to reduce opiate requirements and usage. Morphine has significant side effects including significant nausea and constipation. It can also cause respiratory depression particularly in women who are more susceptible such as those

with a very elevated BMI. One review of intramuscular opioids for post-operative pain relief included studies showing rates of respiratory depression as high as 37% (41). ERAS models seek to minimise opioid usage as side effects such as nausea and vomiting often impede early eating and drinking which is associated with quicker recovery. Drowsiness can limit mobilisation which can increase risk of other complications such as ileus, venous-thromboembolism and can affect mother-child bonding and breastfeeding which are important post-caesarean section.
Morphine was previously prescribed PRN at MMH but it was found that many women were left for long periods without analgesia and therefore it was changed to be given regularly. This is understandable in the context of not giving regular NSAIDs and using short acting opioids in the spinal however this obviously leaves room for alternative pain management models in the unit.
Tramadol is introduced usually on day 2 post-operation, although sometimes towards the end of day 1. It tends to be prescribed as 50mg, 6 hourly regardless of women's weight although the recommended dose is 50-100mg (1mg/kg), every 6 hours. The data in the audit shows that many women were still in significant pain on day 1 despite having received the standard 40mg of intramuscular morphine, such that 55% required the introduction of tramadol during day 1.

Patient pain scores and satisfaction with pain control

The contrast between women's subjective pain scores and their happiness with the hospital's management of their pain was particularly striking (N=26). Around half of women – 12 (46%) scored their pain as 4 ("hurts even more" - ) or 5 ("hurts most" - ) out of 5 and yet the vast majority - 22 (86%) women said they were mildly happy or very happy with the management of their pain. The reasons for this apparent incongruity are unknown. It could be that women have low expectations of our management of their pain and they expect to be in significant pain after caesarean section. It could also be that when asked to score their own pain they do not feel as though they are judging anyone and therefore answer more honestly but when rating the hospital's care, they do not wish to be disparaging and therefore are less critical than they might otherwise be. They may also be anxious about the effect being honest might have on their own care despite the consent form emphasising this would not be the case. Reflexivity in research examines the context of the researcher in the community and the patients' relationship to the researcher. In the South African socio-political background, it is important to consider the womens' reponses in the context of a white doctor asking questions of mostly non-white women from low-income backgrounds. It could be that having a question where they rate the overall care they have received in the hospital and a separate question about how they feel their pain was managed might allow patients to be more candid about that specific area of care. It could also be that to having an open qualitative question such as "Can you explain why you feel this way?" might give more helpful information in addition to a simpler rating scale. Despite the incongruity, nonetheless 2 (8%) women reported being dissatisfied with the management of their pain and a further 2 (8%) reported feeling equivocal about it. Whilst the number of patients who were surveyed in person was small this still means that 1 in 6 patients did not state they were happy with the management of their pain which is unfortunate.

Post-operative eating and drinking

A key component of ERAS models is the early return to eating and drinking post-operatively. This is based on the argument that prolonged periods of fasting result in a catabolic state, leading to breakdown of protein to form carbohydrate for metabolism. It is thought that this is likely to be counterproductive in the context of a healing body post-operatively. A number of studies have shown that contrary to older models of care where nursing staff would wait for a set number of hours to allow patients to eat and drink or wait for return of bowel sounds or bowel function, early resumption of oral intake is associated with shorter hospital stay, better patient satisfaction and that even where patients had undergone bowel surgery, there was no increased risk of anastomotic leak (42). In MMH some women spent a very long period of time without food peri-operatively. Up to 8 women are booked for elective caesarean section per day so that even if no emergencies are booked and there are no delays at all, realistically it is almost impossible for more than 6 patients to be operated on before 12pm and electives are commonly started as late as 21:00. Despite this, all the electives were told to be NBM from 22:00 the night before. If surgery is cancelled late in the evening due to further emergency cases, a patient may have been NBM for 23 hours, allowed to eat a small meal before being kept NBM again for the next day. Post-operatively they are again told they may not eat for at least 6 hours despite guidelines advising that women should be allowed to resume oral intake when thirsty and hungry (33). Interestingly there is some evidence that periods of pre-operative calorie or protein restriction over the week prior to surgery may pre-condition the body and thus reduce the metabolic stress of surgery however there is no evidence of the safety of this model in pregnancy (43).

Subsequently to this audit, some improvements have already been made; MMH has opted to somewhat stagger fasting times for the elective caesarean patients. The first four electives are starved from midnight whereas patients numbered 5 and onwards are allowed a light breakfast at 6am and clear fluid until 10am. It has not yet been examined whether this improves patient satisfaction.

Post-operative mobilisation, removal of urinary and intravenous catheters

Early mobilisation is thought to beneficial post-delivery to reduce the risk of venous thromboembolism as well as the association with earlier return of bowel function and avoidance of ileus. Patients at MMH are mobilised at 12 hours post-operatively with good adherence to this timing. Some studies suggest even earlier mobilisation may be beneficial up to as early as 6 hours post-partum (44). Significantly earlier than this is unlikely to be feasible due to the effect of neuraxial anaesthesia. Some studies have looked at specific step counts to achieve post-operatively as these have been associated with lower risks of morbidity (45). However, it is unclear whether this association is causative; it may be that women who have an early undetected morbidity struggle to mobilise for example with early intra-abdominal sepsis or pelvic haematoma.

Early removal of IV cannulas and catheters is recommended partly to assist with early mobilisation but also because intravenous lines and catheters are common sources of infection. One meta-analysis compared early removal of urinary catheters (within 2 hours of caesarean) to delayed (12-24 hours post-operatively). It showed significantly less dysuria, urgency and bacteruria in the early removal group (46). However, other studies have shown that early removal of urinary catheters is associated with increased risk of urinary retention requiring re-catheterisation (47).

Interestingly, some studies have looked at whether urinary catheterisation is necessary at all for stable electives where haemodynamic instability is not expected. They showed significantly reduced bacteriuria and no increase in the risk of urinary tract injury however given the small studies and the rarity of this complication, much larger studies would be needed to properly evaluate this as a safe model (48). NICE guidelines recommend urinary catheter removal at 12 hours (33). It seems reasonable therefore that MMH guidelines aim for and continue to achieve this target. There is no specific evidence for early removal of intravenous lines other than part of the ERAS package of care but logically it seems reasonable that removal will aid mobilisation and prevent them being inadvertently left in for long periods which can be a potential site for sepsis.

Early discharge

On average the mean time from caesarean to discharge was 75 hours which is in keeping with the MMH protocol of discharge on day 3 post-operation. Many ERAS models are designed to facilitate early discharge from hospital post-operation and inpatient stays for a variety of often significantly complex surgery have reduced dramatically. For example, colorectal surgical ERAS models have been associated with a hospital day of 6 days from a previous average of 12 days (42) (47). For caesarean sections, many units have used ERAS models to allow discharge much earlier than was previously the norm as early as day 1 post-operation (44). The questions remains whether this approach is sensible in a middle-income country setting where women's access to transport either public transport infrastructure, access to a private vehicle or even ability to be transferred back to hospital rapidly by ambulance may be much poorer than in a high-income country where most ERAS models have been designed and examined. In addition, provision of post-natal care in the community may be much more limited. Some studies have attempted ERAS models in middle and low-income settings including Uganda and Bhutan (4) (49). Studies have not shown an increased risk with early discharge however they are small and different challenges may be faced in different settings. Having said that during the covid pandemic due to the extreme bed pressures during peak waves, protocols were adjusted to allow for discharge on day 2 post-caesarean. Given the ongoing rural to urban migration in South Africa and rising rates of obesity and comorbidities as well as the potential for future covid waves or other pandemics, optimising peri-operative care to assure earlier discharge is as safe as possible is clearly vital, even if discharge on day 1 may not be an appropriate target.

Conclusions

This audit has shown that MMH has good adherence to several areas of standard practice guidelines and ERAS models such as removal of IV lines, catheters and early mobilisation but poorer adherence in other areas in particular peri-operative fasting times and post-operative analgesia.

Enhanced recovery after caesarean section continues to be examined extensively in high-income settings but receives much less attention in low and middle income settings presumably due to the larger burden of morbidity and mortality caused by other conditions, in pregnancy, namely

non-pregnancy related infections, hypertension and haemorrhage (50). However, a number of areas thought to be reduced by the ERAS model such as pregnancy-related infections are a significant source of morbidity and mortality in South Africa, not to mention the cost to the healthcare system and economy.
ERAS should not be written off as a “first world problem” and a range of targets can be easily embraced to improve patient care and satisfaction and potentially even to save costs in the public healthcare service.
Recommendations are provided for future research and quality improvement interventions

Limitations of the study

The project was able to encompass several different aspects of ERAS at MMH, however the study was limited by its small sample size given the time constraints of the investigator and requirements for completion of the postgraduate degree; as well as the concurrent Covid pandemic. It would be ideal to have had more investigators and more time to perform a more comprehensive audit of all aspects of the leading ERAS guidelines, then perform an intervention towards quality improvement and then repeat the audit. This would hopefully make a greater move towards improving peri-operative care in a resource limited setting and even potentially reduce costs to the healthcare system.
A study like this is obviously not designed to assess whether giving analgesia more frequently or early removal of catheters etc. is associated with early discharge because there are no intervention and control groups. Differences in an audit like this are more likely to be due to differences between the patients such as patients who had more complicated surgery might have been slower to mobilise and need more analgesia.
The study population was restricted to woman having had elective CS and uncomplicated surgery so its findings may not be generalisable to women having emergency CS or those with anticipated complicated surgery.
The repercussions of the covid-19 pandemic resulted in a significantly restricted number of face-to-face interviews, half of the intended number. This reduces the weight of the conclusions that can be drawn regarding patient experience. Even if face-to-face interviews had been possible during this period, the data obtained may not have been generalisable as staffing levels were generally lower than during normal periods and the PPE processes for surgery on women with covid-19 may have increased the delays in theatre over and above the norm.
Also, the problem of reflexivity as described earlier in the discussion could influence women’s responses to questions about satisfaction with care.
Performing a project such as this alongside busy service delivery work means that there is opportunity for bias in that patients in pain may decline to be interviewed on a particular day where the lead-investigator has capacity and when the patient is feeling better, the investigator may have other clinical commitments. Other opportunities for bias include poor recall of patients from a time when they were hungry or in pain. Contemporaneous recording during the 24 hours post-operation may provide more accurate records but clearly require more significant resources from the investigators.
Some aspects of ERAS guidelines are more difficult to implement in the South African setting. For example, long-acting opioids are less easily available than in the UK so whilst we can record

that short acting opioids were given, there is little benefit to this if no better alternative can be used.

Recommendations for a future intervention

After this project the eventual aim would be to implement a quality improvement intervention. This would then be followed by a repeat audit of practice specifically looking at patient satisfaction with pain control, time to mobilisation and discharge and it is hoped that this would lead to improvements in care.

The areas targeted would include:

Pre-operative measures such as:

- Improving patient education about caesarean section in the ward or clinic
- Optimising fasting times
- Administering a dose of paracetamol at induction of anaesthesia

Peri-operative measures such as:

- discussing with anaesthestists whether preservative-free morphine could be used in the spinal instead of fentanyl
- considering whether use of local anaesthetic to the wound should be done routinely
- Routine use of anti-emetics

Post operative measures such as:

- Expanding the use of NSAIDs post-caesarean
- In patients who are using NSAIDs allow PRN opioids instead of 4 hourly administration
- Exploring whether patients can self-administer simple analgesics using a tick-sheet
- Allowing patients to drink and eat when thirsty or hungry post-operatively
- Encouraging early mobilisation when patients feel able
- Consider whether to allow earlier discharge from hospital where certain criteria are met

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Appendix A1: Questionnaire

AUDIT OF PERI-OPERATIVE CARE AS PART OF THE ENHANCED RECOVERY MODEL FOR CAESAREAN DELIVERY

Patient Study Number
_____
Date of interview
_____
Interviewer
_____

SECTION A: PATIENT CHARACTERISTICS:

1. **Do you have any other health conditions?**
   a. **Diabetes** ☐
   b. **High blood pressure** ☐
   c. **HIV** ☐
2. **How many operations have you had on your abdomen before this pregnancy?**
   a. **None** ☐
   b. **One** ☐
   c. **Two** ☐
   d. **Three or more** ☐
3. **Have you used tik, dagga, heroin or other recreational drugs in the last year?**
   a. **Yes** ☐
   b. **No** ☐

SECTION B: REMOVAL OF LINES

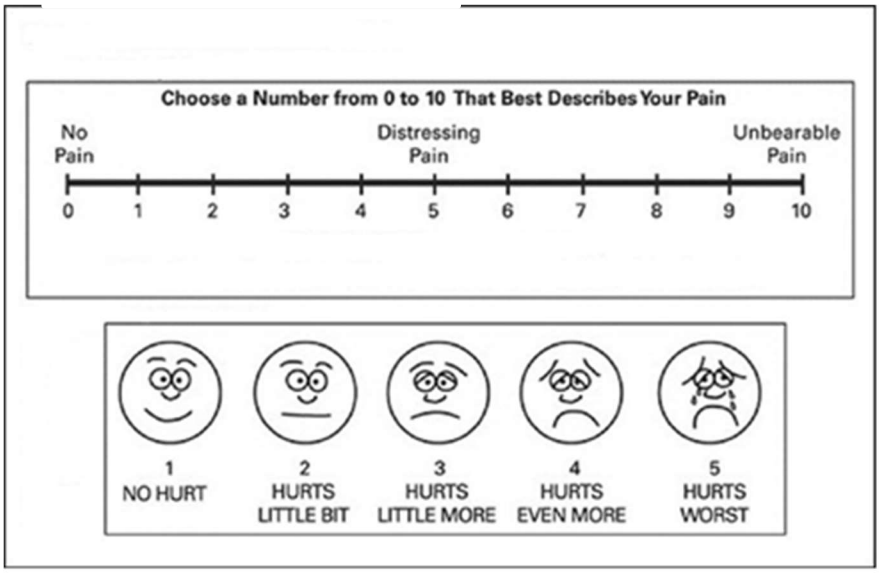
1. **What time was your catheter removed? _____ / Not yet**
2. **What time was your intravenous drip removed? _____ / Not yet**

SECTION C: TIME WITHOUT FOOD AND DRINK

1. **What time was your last food prior to your operation? _____**
2. **What time was your last drink prior to your operation? _____**
3. **What time was your first food after your operation? _____**
4. **What time was your first drink after your operation? _____**
5. **What time were you allowed/ helped to get out of bed after your operation? _____**

SECTION D: SATISFACTION WITH CARE

1. **Was your operation done on your scheduled date / postponed to the next day?**
2. **Please tell me how strong was your pain over the first 24 hours after your operation:**



3. **Overall how happy are you with our treatment of your pain over the first 24 hours after your operation?**
    a. **Very unhappy** ☐
    b. **Mildly unhappy** ☐
    c. **Neither happy nor unhappy** ☐
    d. **Mildly happy** ☐
    e. **Very happy** ☐

Appendix A2: Data To Be Collected From The Patient Record

Patient Study Number
_____
Date of interview
_____
Interviewer
_____

PATIENT CHARACTERISTICS:

1. Gravidity _____
2. Parity _____
3. BMI > 45 _____
4. Age _____

INTRA OP

5. Time of delivery _____
6. Type of anaesthetic: a. Spinal ☐
   b. General ☐
   c. Epidural ☐
   d. Spinal converted to general ☐
   e. Combined spinal epidural ☐
7. IV morphine dose (mg) _____
8. IV fentanyl dose (mcg) _____
9. IV ketamine dose (mg) _____
10. Intrathecal fentanyl dose (mcg) _____
11. Epidural fentanyl dose (mcg) _____
12. Local infiltrated to wound: Yes ☐
13. Operation duration (mins) _____

POST OP:

14. Number of paracetamol doses in 0-24 hours _____
15. Number of brufen doses in 0-24 hours _____
16. Number of indomethacin doses in 0-24 hours _____
17. Number of IM morphine doses in 0-24 hours _____
18. Total IM morphine dose in 0-24 hours (mg) _____
19. Hours to removal of catheter from end op to removal _____
20. Hours to removal of drip from end op to removal _____
21. Hours to first mobilisation from end op to mobilisation _____
22. Hours from caesar to discharge

Appendix B: REDCap Data Collection Form (Exported To PDF)

1)

S number

2) _____

P t Age

3) _____

O conditions which may affect analgesia/ length

o

- ☐ HIV
- ☐ hypertension
- ☐ history of substance use
- ☐ BMI >45

4)

G ity

5) _____

P

6) _____

T f anaesthetic

7) ○ nal ○ General ○ Epidural ○ Spinal converted to general ○ Combined spinal epidural

IV Morphine dose in mg

8) _____

IV anyl dose in microg

9) _____

IV cetamol dose in mg

10) _____

IV mine dose

11) _____

Ir necal fentanyl dose

12) _____

e ral fentanyl dose in microg

13) _____

L nfiltrated to wound

14)

- ○ Yes
- ○ No

O ion duration mins

_____

15) Number of paracetamol doses in hours 0-24

◯ 0
◯ 1
◯ 2
◯ 3
◯ 4

16) Number of brufen doses in hours 0-24

◯ 0
◯ 1
◯ 2
◯ 3
◯ 4

17) Number of indomethacin doses in hours 0-24

◯ 0
◯ 1
◯ 2

18) Number of morphine doses in hours 0-24

◯ 0
◯ 1
◯ 2
◯ 3
◯ 4
◯ 5
◯ 6

19) intramuscular morphine from hour 0-24

_____

20) Hours to removal of catheter

21) Hours to removal of IV line

_____

22) Hours to mobilisation

_____

23) Was surgery done on scheduled date or postponed

◯ scheduled date
◯ postponed to next day

24) Hours without food pre-op

_____

25) Hours without drink pre-op

_____

26) Hours without food post-op

_____

27) Hours without drink post-op

_____

28) Pain rating for 0-24 hours

0 5 10

(Place a mark on the scale above)

29) Satisfaction with pain control

Unhappy | Neither happy nor unhappy | Happy

(Place a mark on the scale above)

Hours from caesar to discharge

_____

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Department of Obstetrics and Gynaecology

Appendix C: Patient Information Leaflet

AUDIT OF PERI-OPERATIVE CARE AS PART OF THE ENHANCED RECOVERY MODEL FOR CAESAREAN DELIVERY

INTRODUCTION

You are invited to take part in a research study about how women are cared for in hospital after they have had a caesarean section. Participation in this study is completely voluntary and you may choose to withdraw at any time. This leaflet will give you information about why the study is being done, who can take part in it, as well as any risks and benefit to you.

You will be asked to answer a questionnaire with the help of an interviewer. The questions will be divided into 4 categories:

a. Some background information about your general health
b. The time your intravenous drip and catheter were removed
c. How long you were kept without food and drink before and after your operation
d. How satisfied you were with your pain control in the first 24 hours after your operation

Other information about the medication you received during and after your operation will be found in your file.

STUDY TITLE

Audit of Peri-operative care as part of the Enhanced Recovery model for Caesarean Delivery

RESEARCHERS

Dr Abigail Blumenthal, Prof Susan Fawcus and Dr Anne Horak

This study has been approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town. If you would like any further information, please feel free to contact us. After reading this information leaflet you will be asked to sign an informed consent form to take part in the study. You will also be given a copy of this consent form.

WHY IS THIS STUDY BEING DONE?

Caesarean section is the most frequently performed operation in the world. There are new guidelines about how best to look after women who have a caesarean to lower their chance of complications. We want to see how well Mowbray is keeping to these guidelines and where we can make improvements. We hope that the information gained will allow us to improve our obstetric services in the future, enabling better birthing experiences and patient satisfaction.

STUDY PARTICIPANTS

- Any woman at Mowbray Maternity who has had a booked or "elective" caesarean section in the last 24 to 48 hours is able to take part in the study
- Participation in this study is completely voluntary and you can choose to stop at any time
- To be part of the study we will ask you to complete a questionnaire with the help of a trained interviewer in a language of your choice. This should take ten minutes
- If you do not wish to answer any of the questions, you may skip them
- If you don't understand any questions, we will take time to explain it to you
- Not choosing to participate in the study or opting out during the study will not impact on the health care that you are receiving in any way

RISKS

This study involves a questionnaire about your caesarean section experience which does not pose any risk to you.

BENEFITS

There is no financial reward in taking part in this study. You may not benefit directly from participating in this study however, the information acquired during the study will assist us in improving care after caesarean section.

CONFIDENTIALITY

- The questionnaire will be completed in a private area.
- The questionnaire will **not** have your name on it so no one will be identify you. It will have a special code on it. Only the researchers will know what your code is and this information will be kept in a secure office in Mowbray Maternity Hospital.

- Only the researchers will have access to the completed questionnaires and research data.
- When the study is completed the research data will be stored in the Department of Obstetrics and Gynaecology of the University of Cape Town.
- This research forms part of work towards a Master's degree at the University of Cape Town and will be submitted for examination within the university. The results of this study will be anonymous and you will not be identified in any results.
- You will be asked to sign a consent form for yourself

CONTACT INFORMATION

If you have any further questions, comments or queries regarding this study please feel free to contact Dr Abigail Blumenthal (On-site researcher) at 0724629372.

If you need any further information regarding your rights as a research participant you can contact the Faculty of Health Sciences Human Research Ethics Committee at 021 406 6338.

Thank you for your time.

UNIVERSITY OF CAPE TOWN

Department of Obstetrics and Gynaecology

Appendix D: Patient Consent Form

AUDIT OF PERI-OPERATIVE CARE AS PART OF THE ENHANCED RECOVERY MODEL FOR CAESAREAN DELIVERY

I have agreed to participate in a research study about women's care before and after caesarean section. The study is being conducted by members of the Department of Obstetrics and Gynaecology. The study has been approved by the Faculty of Health Sciences Research Ethics Committee of the University of Cape Town. The purpose of this study has been explained to me in a language of my choice by a member of the research team.

I understand the study involves the completion of a questionnaire with the help of a trained interviewer in one of the three languages of my choice (ie. English, Afrikaans, isiXhosa). My participation is voluntary and I have the right to withdraw from this study at any stage. I may choose not to answer any question if I so wish. It has been explained to me that this will not affect my medical care and that the study poses no risk to me.

I understand that I may not benefit directly from this study and that there is no financial reward for taking part in this study but the information collected may benefit other pregnant women in the future.

I agree to my responses being used for education and research. It has been explained to me that confidentiality will be maintained where possible and that I will not be personally identifiable in the database or any manuscripts that may subsequently be produced for publication.

I have been given adequate opportunity to ask questions about this study and have been provided with an information leaflet about the study as well as a copy of the informed consent form. I have read this consent form and the information it contains and had the opportunity to ask questions about them.

_____	_____
NAME OF PARTICIPANT	SIGNATURE
_____	_____
NAME OF RESEARCHER	SIGNATURE

DATE: ___/___/___

Appendix E: MMH Analgesia protocol

19. POST-OPERATIVE ANALGESIA

WHY:

- Effective post-operative analgesia:
    - assists mothers with earlier mobilisation thereby reducing the risk of DVTs
    - allows mothers to better care for their new-borns, allows effective breast-feeding and enhances the mother-baby bond

HOW:

- A multimodal approach to post-operative analgesia is essential as well as early intervention before the pain starts:
    - immediately post-operatively with general anaesthesia
    - 2 - 4 hours post-operatively with spinal anaesthesia (combination of Bupivacaine/Fentanyl)
- Local infiltration of the wound with Bupivacaine can also be performed post-caesarean section
- Analgesia should be given as prescribed and not on a PRN basis so that patients remain pain-free.
- A combination of paracetamol/opiate is recommended
- Morphine 10mg intramuscularly **EVERY 4-6 HOURS** should be administered for the first 24 hours post-op. It should be accompanied by an anti-emetic Ondansetron which is given as a 4mgms iv stat dose by the anaesthetist immediately postoperatively. Thereafter, it can be given as an IM 4 mg dose daily.
- Paracetamol 1g orally should also be commenced immediately post-operatively and be administered regularly every 6 hours.
- Tramadol (opioid) 50mg 8hrly orally can be given once Morphine administration has stopped.
- Nursing staff should be knowledgeable about the advantage of regular timeous administration of analgesia.
- Patients discharge analgesia should be Paracetamol and Tramadol for 1-2 weeks.
- **We are currently not using any NSAIDS at Mowbray because of the potential risk of sepsis**

Appendix F: Approval Letters

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_201907_022
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: PROF Sue Fawcus, DR Abigail Blumenthal

Re: AUDIT OF PERI-OPERATIVE CARE AS PART OF THE ENHANCED RECOVERY MODEL FOR CAESAREAN DELIVERY

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Mowbray Maternity Hospital	**Dr Chantal Stewart**	**021 659 5579**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR M MOODLEY
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE:
CC

Dr Melvin Moodley
Director: Health Impact Assessment
18 OCT 2019

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 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

12 July 2019

HREC REF: 337/2019

Prof S Fawcus
Obstetrics & Gynaecology
H-floor, OMB

Dear Prof Fawcus

PROJECT TITLE: AUDIT OF PERI-OPERATIVE CARE AS PART OF THE ENHANCED RECOVERY MODEL FOR CAESAREAN DELIVERY (MMED CANDIDATE - DR A BLUMENTHAL)

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

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

Approval is granted for one year until 30 July 2020.

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)

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.

The HREC acknowledge that the student, Dr Abigail Blumenthal will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: 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.