University of Cape Town

Department of Obstetrics and Gynaecology

A review of intrauterine device placement during caesarean section at level two facilities in the Metro West, Cape Town.

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i) Declaration

I, Marcelle Schutte, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ii) Abstract

Study rationale In the Western Cape there are many intrauterine contraceptive devices (IUDs) inserted during caesarean section (C/S). Little is known about the long-term outcomes in the Metro West area.

Objective To assess placement of IUDs at C/S and describe follow-up, with a view to compile best practice guidelines for insertion and follow-up in our clinic setting.

Method A retrospective descriptive audit of clinical records was performed of all women who received an IUD at C/S between January and June 2018 at Mowbray Maternity Hospital (MMH) and New Somerset Hospital (NSH) in Cape Town.

Results There were 2310 and 1376 C/S performed at MMH and NSH respectively. The IUD insertion rate was 17.4% (n=402) at MMH and 14.3% (n=197) at NSH. Almost two third of insertions were performed at the time of emergency caesarean section (59.1%; n=276). The majority of women experienced no immediate complications (84.4%). Only 77 women attended follow-up. The continuation rate at follow-up was 71.6%. The overall expulsion rate in hospital and at follow-up was 3%. Strings were visible in 53.2% of patients. An ultrasound was performed in 67.5 % (52/77) of patients. The IUD removal rate at follow-up was 24.7% (19/77).

Discussion The poor follow-up rate is concerning, and measures must be taken to address this. The continuation rate of 71.6% is lower than expected but may have been biased by the low follow-up rate. Continuation rates improved with the experience of inserters which highlights the importance of training and supervision.

Conclusion The immediate postpartum period may be the only opportunity to provide long acting reversable contraception to some women. In our study population follow-up rates are poor and therefore conclusions are difficult to accurately gauge. Measures must be taken to improve follow-up.

iii) Acknowledgements and contributions

A sincere thank you to the following people:

- my supervisor Dr. Malika Patel for her time, advice, support and input in the study design and manuscript
- my co-supervisor Professor Gregory Petro for assisting with the statistics and reviewing the document
- the clerks at Mowbray Maternity, New Somerset and Groote Schuur Hospitals for assistance with the collection of patient folders.

iv) List of Tables

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vi) Abbreviations

CI	confidence interval
C/S	caesarean section
FIGO	The International Federation of Gynecology and Obstetrics
F/U	follow-up
GSH	Groote Schuur Hospital
HIV	human immunodeficiency virus
IQR	interquartile range
IUD	intrauterine device
LARC	long-acting reversible contraceptive (or contraception)
LARCs	long-acting reversible contraceptives
max	maximum
min	minimum
MMH	Mowbray Maternity Hospital
n	the sample size
N	the population size
NSH	New Somerset Hospital
P50	50% of estimates exceed the p50 estimate
PPH	postpartum haemorrhage

vii) Dissertation in Publication-format

Chapter 1: Introduction and Literature review

Chapter 2: Publication-ready Manuscript

Chapter 1:

Introduction and Literature Review

The immediate postpartum use of long acting reversable contraception (LARC) such as the intrauterine device (IUD) is an important strategy to increase interpregnancy intervals. It is well known that a pregnancy interval of less than two years contributes to increased perinatal and maternal morbidity and mortality, with complications ranging from preterm rupture of membranes, preterm birth and low birth weight to uterine scar rupture and maternal anaemia. [1] The majority of pregnancies occurring after a short interpregnancy interval are unplanned. [1] Providing reliable contraception in the immediate postpartum period may be the most effective way of preventing unwanted pregnancy and a short interpregnancy interval.

A woman who is not breastfeeding may ovulate by the third week after delivery. Up to 50% of women have resumed sexual activity by 6 weeks postpartum, putting them at risk of unwanted pregnancy by the time they return for the 6 weeks visit. [2] Those who do not return are often socially and economically disadvantaged, and face barriers such as lack of transport and stable housing, and difficulty communicating with their health care providers. [3] In a randomized controlled trial by Levi et al in 2015, women were randomized to either receiving the intrauterine device at caesarean section (C/S) or 6 weeks after delivery. IUD continuation at the 6 months visit was 83% when placed at C/S, versus 64% when placed at the 6 weeks postpartum visit. Of the women randomized to the 6 weeks postpartum insertion, 39% never received an IUD - 25% defaulted follow-up, 9% declined and 5% had failed placement. [3] Women who choose the IUD are up to ten times less likely to having it placed at the 6 weeks visit compared to women receiving it at the time of delivery. [3-5] Follow-up rates for the 6-weeks postpartum visit is poor, ranging between 25 and 62%. [1,2] This could in part be explained by different follow-up locations and dates for mother and baby - a significant barrier to women with new-born babies who just had surgery, and even more

so for someone with socio-economic difficulties. [6] In a systematic review by Goldstuck and Steyn containing 12 studies including 4 randomised controlled trials of delayed versus immediate IUD insertion post-delivery, findings were similar - women randomized to delayed insertion are significantly less likely to receive the device. [7] By not providing LARC at the time of delivery, the most vulnerable women who are most unlikely to return for follow-up are being put at risk of unwanted pregnancy. [2,3] By inserting the IUD at delivery, an important barrier to LARC namely an additional visit for insertion is removed.

Insertion of the IUD during C/S is easier, less time-consuming, less painful and requires less instrumentation than interval insertion. There is no risk of primary perforation as the insertion is performed under direct vision. [7-10] Very few contraindications exist, and most women are eligible for its use. The timing is ideal since the patient is in hospital with adequate counselling and expertise available, and she is motivated for effective family planning. Efficacy of the copper-containing IUD (Pearl index = 0.6) is on par with female sterilization (Pearl index = 0.5), and thus could be offered as a reversable alternative. [11] It is a fit and forget method, since once it is placed its effect is not dependent on any patient action, and even if the patient does not return for her 6 week visit, she will have protection against pregnancy provided that the device stays in place. The IUD is a hormone-free method of contraception, and therefore does not have any effect on breastmilk production or infant growth, with no maternal systemic effects.[12,13] In contrast to some other LARCs, the efficacy of the IUD is not affected by medication such as antiretroviral therapy, antituberculosis treatment and anti-epileptics. In addition, it is immediately effective, its effect can last for up to 10 years, and it requires active discontinuation as compared to most other methods. Insertion at the time of C/S eliminates a 6-week waiting period for contraception, as well as an additional office visit.

In a prospective cohort study by Heller et al, more than one in eight women chose this method of contraception when routinely offered before elective C/S. [14] The study confirmed a low complication rate and an expulsion rate in keeping with that of insertion in women who were not postpartum. Satisfaction rates were high, and continuation rates remained high at 12 months post-insertion. It thus proved to be convenient and cost-effective for both women and health services.

Complications include malpositioning, expulsion, perforation, embedment, infection and failure. Expulsion rates appear to be lower during intra-operative placement (3.9-10.9%) as compared to early insertion after normal delivery (25-30%), but it is slightly higher than the expulsion rate during interval insertions in most studies. [2,3,6,8,9,12,14-16] Expulsion usually occurs within the first 3 weeks post-insertion. [3,15].

The most common immediate postinsertion complication was febrile morbidity (2%) in an observational study by Singal et al, however the majority of these women had a hospital stay of less than 4 days. [6]

Post-insertion infection rates are low, ranging between 0 and 0.8%. [9,10,14] The incidence of a vaginal discharge is around 7%. [10,16] Failure rates are consistently less than 1% in the literature. [6,7,9,16-18]

In a study by Chawla et al, malpositioning after vaginal delivery insertion was 62% versus 28% after operative insertion. Where malpositioning occurred, adverse effects increased, and continuation rates decreased. [15] Gross malpositioning may be detected by a strings check, although this is not always the case. Women may return with side-effects such as menstrual irregularities, pain or unintended pregnancy, or it may be detected by ultrasound. [5] In some situations, malpositioned IUDs may be asymptomatic. Malpositioned IUDs however presents

more commonly with complications than normally placed IUDs. [13,15,16] Identifying a malpositioned IUD presents an opportunity to offer the patient early repositioning or close follow-up, and in this way lower the complication rate and improve compliance. [13;16] Although there is no consensus regarding the threshold measurement that would classify an IUD as being correctly placed, most studies describe a distance less than 15 mm from the fundus as acceptable. It must be positioned linearly in the uterine cavity with the horizontal arms reaching laterally towards the cornua. [9,15] Routine scanning at follow-up is not the norm and may lead to unnecessary anxiety and removal in some instances, but all women who are symptomatic or where the strings cannot be seen, should have an ultrasound to locate the IUD. [13;16;19]

The incidence of lost strings after intra-operative IUD insertion varies, and it can be as high as 50 - 70%. [7,9,14,20] This is increased when compared to interval insertion and can be explained by the method of insertion – the strings usually are not introduced into the cervical canal at the time of caesarean section. It is also dependant on the surgical technique and the type of IUD used – e.g. the Cu380A has short strings, whereas the Nova T has long strings. The majority (91.8%) of lost strings can easily be found in the cervical canal.[17] Anchoring the device, guiding the strings into the cervical canal and using devices with longer strings are all techniques to reduce the incidence of lost strings. In the abovementioned study by Heller et al, the incidence of lost strings in women receiving the IUD at C/S was 50%, and it was recommended by the authors that when intra-caesarean IUD placement is offered, rapid access to ultrasound at follow-up should be considered. [14]

According to the Population Reference Bureau Family Planning Worldwide Data Sheet 2019, 54% of women in South Africa use some form of contraception. [21] Despite this, 62% of

women report that their last pregnancy was unwanted or unplanned. [22] This indicates the still unmet need for the correct method of contraception being used. The lifetime risk of maternal death in South Africa is one in 300, and reliable contraception plays a crucial role in lowering this risk. [21] The reported use of the IUD is 1.2% in South Africa, which correlates with user rates in other less developed countries. [21] Methods more commonly used by women are the injectable contraceptive (23.9%), male condom (8.8%), oral contraceptive pill (8.4%), female sterilization (7.7%) and subdermal implants (3.3%).[21] The use of LARCs is thus much lower compared to other methods, even though the risk of unintended pregnancy is twenty times higher when women are using short-acting methods. This is often due to incorrect and inconsistent use with these methods.[23]

In a South African survey in 2006 about the knowledge, attitudes and practices surrounding the IUD in public sector clinics, barriers to inserting the IUD included concerns regarding pelvic inflammatory disease, misinformation, and lack of sufficient knowledge and training in terms of counselling and insertion. [24] Another finding was that South African women are interested in learning more about the IUD and possibly using it. In a cross-sectional survey of 538 women in the public sector in Cape Town (2009), most women wanted to wait at least 3 years before their next pregnancy, or they were not sure if they wanted another child. Few of them reported having been told about the IUD, and knowledge about the method were lacking. Fear of the procedure of inserting an IUD was another barrier to insertion. [22] The advantage of intra-caesarean insertion in improving the uptake in these women is evident.

Postpartum IUD insertion is a relatively new practice in the Western Cape, with insertion at C/S increasing around 2014, and after vaginal delivery around 2015. With C/S rates still on the

rise in South Africa and worldwide, intra-caesarean IUD insertion provides the ideal opportunity to enable women to achieve healthy inter-pregnancy intervals.

There are currently many IUDs inserted during C/S in the Western Cape, but little is known about the long-term outcomes in these patients in terms of side-effects, continuation rates, patient satisfaction and failure rates. Up till now, there is surprisingly little published data on the factors influencing continuation rates – specifically the indication for the C/S, cervical dilatation, previous uterine surgery, the experience of the inserter and the HIV status of the woman.

Follow-up and self-audit are vital in measuring the success of an IUD program and improving outcomes. Challenges at follow-up include poor attendance rates, varying healthcare provider skills, time, and financial constraints in conducting telephonic interviews, ever-changing patient contact details, and the management of missing strings including availability of thread-retrievers and imaging. Where strings are missing, a second visit may be needed as ultrasound machines and/or operator experience may be lacking. [2;3;5;7;8;10;14;16] In the study by Levi et al, only 48% of women returned for follow-up. Of these women, 72% required an ultrasound, and 26% did not return for their ultrasound appointment. Only 47% of patients were reachable by phone, email or in person by 6 months. [2]

The aim of this study is to assess the practice of placement of IUDs at caesarean section and describe follow-up, with a view to compile best practice guidelines for insertion and follow-up in our clinic setting in the Metro West area of Cape Town. We further aim to investigate factors influencing placement of the IUD and continuation rates. Improving our knowledge about outcomes will help guide us in how to improve counselling and follow-up in these women.

about outcomes will help guide us in how to improve counselling and follow-up in these women.

It is a retrospective descriptive audit of clinical records of all patients who received the IUD at elective and emergency C/S in the 6-month period between January and June 2018 at Mowbray Maternity Hospital (MMH) and New Somerset Hospital (NSH) in Cape Town, South Africa. Women with chorioamnionitis, puerperal sepsis, premature or prolonged rupture of membranes and postpartum haemorrhage (PPH) at the time of insertion were excluded. The available IUD in the state sector at the time was the Nova T 380 (Bayer), which is registered for 5 years of use. Hormone-containing IUDs were not offered in the state sector for the purpose of contraception due to cost.

Theatre registers were used to obtain the names and file numbers of all patients who received the IUD during C/S between 1 January to 30 June 2018. The obstetric records were obtained, and patient demographics and clinical details were recorded (see table I and II p.32-33).

The folder numbers and names were cross checked at GSH and NSH to assess whether the women attended any follow-up visits at the relevant hospitals (Patients who had the IUD inserted at MMH followed up at Groote Schuur Hospital (GSH), and patients who received the IUD at NSH followed up at NSH). Follow-up records were reviewed to assess findings at follow-up, including symptoms, string check findings, whether an ultrasound was performed, ultrasound findings, removal and expulsion rates, and reasons for removal of the IUD. The HIV status, parity, amount of previous C/Ss, cervical dilatation, indication for the C/S and seniority of the IUD inserter and continuation rates were recorded. Information was entered on a data capture instrument (see appendix 1).

The aim was a sample size of 63 patients who attended follow-up at each hospital. This sample size was based on a follow-up rate of 20%, a 95% confidence interval and a power of 80% if 60 IUDs are placed per month at each hospital.

Data was entered on a Microsoft Excel spread sheet (after removal of patient names) and imported into a statistics software package (Stata version 13.1, Copyright 1985-2013 Statacorp, LP, USA) for analysis.

Institutional consent was obtained from all relevant hospitals, as well as the Western Cape Department of Health (Ref no WC_201810_013). Patient consent was not necessary as this was a retrospective chart review. Ethics approval was obtained from the Health Science Faculty Human Research Ethics Committee of the University of Cape Town (Ref no 542/2018).

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Chapter 2:

Publication-ready Manuscript

A review of intrauterine device placement during caesarean section at level two facilities in the Metro West, Cape Town

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Abstract

Background: In the Western Cape there are many intrauterine contraceptive devices (IUDs) inserted during caesarean section (C/S). Little is known about long-term outcomes in the Metro West region of Cape Town.

Objective: To assess placement of IUDs at C/S and describe follow-up, with a view to compile best practice guidelines for insertion and follow-up in our clinic setting.

Method: A retrospective descriptive audit of clinical records was performed of all women who received an IUD at C/S between January and June 2018 at Mowbray Maternity Hospital (MMH) and New Somerset Hospital (NSH) in Cape Town.

Results: There were 2310 and 1376 C/Ss performed at MMH and NSH respectively. The IUD insertion rate was 17.4% (n=402) at MMH and 14.3% (n=197) at NSH. Almost two third of insertions were performed during emergency C/S (59.1%; n=276). The majority of women experienced no immediate complications (84.4%). Only 77 women attended follow-up. The continuation rate at follow-up was 71.6%. The overall expulsion rate in hospital and at follow-up was 3%. Strings were visible in 53.2 % of patients. An ultrasound was performed in 67.5 % of patients. The IUD removal rate at follow-up was 24.7%.

Conclusion: The immediate postpartum period may be the only opportunity to provide long acting contraception to some women. In our study population follow-up rates are poor and therefore conclusions cannot be accurately gauged. Measures must be taken to improve follow-up.

Key words: contraceptive IUDs, caesarean section, best practices, postpartum, outcome

Introduction

The immediate postpartum insertion of long acting reversable contraceptives (LARCs) such as the intrauterine contraceptive device (IUD) is an important strategy to increase interpregnancy intervals. Pregnancy intervals of less than two years significantly contributes to increased perinatal and maternal morbidity and mortality, with complications ranging from preterm rupture of membranes, preterm birth and low birth weight to uterine scar rupture and maternal anaemia. [1] The majority of pregnancies occurring after a short interpregnancy interval are unplanned. [1] Providing reliable contraception in the immediate postpartum period may be the most effective way of preventing unwanted pregnancy and short interpregnancy intervals.

A woman who is not breastfeeding may ovulate by the third week after delivery. Up to 50% of women have resumed sexual activity by 6 weeks postpartum, putting them at risk of unwanted pregnancy by the time they return for the 6 weeks visit. [2] Those who do not return are often socially and economically disadvantaged, and face barriers such as lack of transport and stable housing, and difficulty communicating with their health care providers. [3] Women who choose the IUD are up to ten times less likely to having it placed at the 6 weeks visit compared to women receiving it at the time of delivery. [3-7] Follow-up rates for the 6-weeks postpartum visit is poor, ranging between 25 and 62%. [1,2] This could in part be explained by different follow-up locations and dates for mother and baby - a significant barrier to women with new-born babies who just had surgery, and even more so for someone with socio-economic difficulties. [6] By not providing LARC at the time of delivery, the most vulnerable women who are most unlikely to return for follow-up are being put at risk of

unwanted pregnancy. [2,3] By inserting the IUD at delivery, an important barrier to LARC namely an additional visit for insertion is removed.

Intra-caesarean insertion is easier, less time-consuming, less painful and requires less instrumentation than interval insertion. There is no risk of primary perforation as the insertion is performed under direct vision. [7-10] Few contraindications exist, and timing is ideal since counselling and expertise are available and the patient is motivated for family planning. Efficacy of the copper-containing IUD (Pearl index = 0.6) is on par with female sterilization (Pearl index = 0.5), and thus could be offered as a reversable alternative. [11] Once it is placed its effect is not dependent on any patient action, and even if the patient does not return for her 6-week visit, she is protected against pregnancy provided that the device stays in place.

The hormone-free IUD does not have any effect on breastmilk production or infant growth, and has no maternal systemic effects.[12,13] In contrast to some other LARCs, the efficacy of the IUD is not affected by antiretroviral, antituberculosis or anti-epileptic therapy. In addition, it is immediately effective, can last for up to 10 years, and requires active discontinuation. Insertion at the time of C/S eliminates a 6-week waiting period for contraception and an additional office visit.

In a prospective cohort study by Heller et al, more than one in eight women chose this method of contraception when routinely offered before elective C/S. [14] The study confirmed a low complication rate and an expulsion rate in keeping with that of insertion in women who were not postpartum. Satisfaction and continuation rates remained high at 12 months post-insertion, and it proved to be convenient and cost-effective for both women and health services.

Complications include malpositioning, expulsion, perforation, embedment, infection and failure. Expulsion rates are lower during intra-operative placement (3.9-10.9%) as compared to early insertion after normal delivery (25-30%), but it is slightly higher than the expulsion rate after interval insertions in most studies. [2,3,6,8,9,12,14-16] Expulsion usually occurs within the first 3 weeks post-insertion. [3,15].

Post-insertion infection is uncommon, ranging between 0 and 0.8%. [9,10,14] The incidence of a vaginal discharge is 7%. [10,16] Failure rates are consistently less than 1%. [6,7,9,16-18]

The commonest postinsertion complication after C/S was febrile morbidity (2%) in an observational study by Singal et al, but most of these women had a hospital stay of less than 4 days. [6]

In a study by Chawla et al, malpositioning after vaginal delivery insertion was 62% versus 28% after operative insertion. Where malpositioning occurred, adverse effects were increased and continuation rates decreased. [15] Gross malpositioning may be detected by a strings check, although this is not always the case. Women may return with side-effects such as menstrual irregularities, pain or unintended pregnancy, or it may be detected by ultrasound. [5] In some situations, malpositioned IUDs may be asymptomatic. Identifying a malpositioned IUD presents an opportunity to offer early repositioning or close follow-up, and thereby lower complication rates and improve compliance. [13;16] Although no consensus exists regarding the threshold measurement that would classify an IUD as being correctly placed, most studies describe a distance less than 15 mm from the fundus as acceptable. It must be positioned linearly in the uterine cavity with the horizontal arms reaching laterally towards the cornua. [9,15] Routine scanning at follow-up is not the norm, but all women who are symptomatic or where the strings cannot be seen, should have an ultrasound to locate the IUD. [13;16;19]

The incidence of lost strings after intra-operative IUD insertion can be as high as 50 - 70%. [7,9,14,20] This can be explained by the method of insertion – the strings usually are not introduced into the cervical canal at the time of C/S. It is also dependant on the surgical technique and the type of IUD used – e.g. the Cu380A has short strings, whereas the Nova T has long strings. The majority (91.8%] of lost strings can easily be found in the cervical canal. [17] Anchoring the device, guiding the strings into the cervical canal and using devices with longer strings are all techniques to reduce the incidence of lost strings. Some authors recommended rapid access to ultrasound at follow-up as an important consideration when offering intra-caesarean IUD placement. [14]

Even though fifty-four percent of women in South Africa use some form of contraception, 62% of their last pregnancies was unwanted or unplanned. [21,22] This indicates the still unmet need for the *correct* method of contraception being used. The reported use of the IUD in South Africa is 1.2%, which correlates with user rates in low-income countries. [21] The use of LARCs is much lower than other methods, even though the risk of unintended pregnancy is twenty times higher when women are using short-acting methods. [23] A South African survey in 2006 found that barriers to IUD insertion included concerns regarding pelvic inflammatory disease, misinformation, and lack of sufficient knowledge and training in terms of counselling and insertion. [24] South African women showed interested in learning more about the IUD and possibly using it. In a cross-sectional survey of 538 women in the public sector in Cape Town (2009), most women want to wait at least 3 years before their next pregnancy or are unsure if they want another child. Few reported having been told about the IUD, and knowledge were lacking. Fear of the insertion procedure was another barrier to using the method. [22] The benefit of intra-caesarean placement in improving uptake in these women is evident.

Postpartum IUD insertion is a relatively new practice in the Western Cape, with insertion at C/S increasing around 2014, and after vaginal delivery around 2015. With rising C/S rates locally and worldwide, intra-caesarean IUD insertion provides the ideal opportunity to enable women to achieve healthy inter-pregnancy intervals.

There are currently many IUDs inserted during C/S, but little is known about the long-term outcomes in the Metro West area. Up till now, surprisingly little data has been published on the factors influencing continuation rates – specifically the indication for the C/S, cervical dilatation, previous uterine surgery, the experience of the inserter and the HIV status of the woman.

Follow-up and self-audit are vital in measuring the success of an IUD program and improving outcomes. Challenges at follow-up include poor attendance rates, varying healthcare provider skills, time and financial constraints in conducting telephonic interviews, ever-changing patient contact details, and the management of missing strings including availability of thread-retrievers and imaging. Where strings are missing, a second visit may be needed as ultrasound machines and/or operator experience may be lacking. [2;3;5;7;8;10;14;16] In the study by Levi et al, only 48% of women returned for follow-up. Of these women, 72% required an ultrasound, and 26% did not return for their ultrasound appointment. Only 47% of patients were reachable by phone, email or in person by 6 months. [2]

The aim of this study is to assess the practice of placement of IUDs at C/S and describe follow-up, with a view to compile best practice guidelines for insertion and follow-up in our clinic setting in the Metro West area of Cape Town.

Methods

A retrospective descriptive audit of clinical records was performed of all women who received an IUD at C/S between January and June 2018 at Mowbray Maternity Hospital (MMH) and New Somerset Hospital (NSH) in Cape Town. Women with chorioamnionitis, puerperal sepsis, premature or prolonged rupture of membranes and postpartum haemorrhage (PPH) at the time of insertion were excluded. The available IUD in the state sector at the time was the Nova T 380 (Bayer).

Theatre registers were used to obtain the names and file numbers of all patients who received the IUD during emergency and elective C/S. Obstetric records were obtained and patient demographics and clinical details identified (see tables I and II).

The folder numbers and names were cross checked at Groote Schuur Hospital (GSH) and NSH to assess whether the women attended any follow-up visits at the relevant hospitals (Patients who had the IUD inserted at MMH followed up at GSH, and patients who received the IUD at NSH followed up at NSH). Follow-up findings were recorded. The aim was a sample size of 63 patients attending follow-up at each hospital. This sample size was based on a follow-up rate of 20%, a 95% confidence interval and a power of 80% if 60 IUDs are placed per month at each hospital.

Data was entered on a Microsoft Excel spread sheet after removal of names and folder numbers and imported into a statistics software package (Stata version 13.1, Copyright 1985-2013 Statacorp, LP, USA) for analysis.

Institutional consent was obtained from all relevant hospitals, as well as the Western Cape Department of Health (Ref no WC_201810_013).

Ethics approval was obtained from the Health Science Faculty Human Research Ethics Committee of the University of Cape Town (Ref no 542/2018).

Results

There were 2310 and 1376 C/S performed at MMH and NSH respectively from January to June 2018. The IUD insertion rate was 17.4% (n=402) at MMH and 14.3% (n=197) at NSH. Of the patients who had an IUD inserted, 132 folders were either lost or excluded due to poor note keeping or exclusion criteria. We could therefore only assess 467 records (figure 1).

The median age at insertion was 27 years (p50=27; IQR=8), and the median parity 2 (p50=2; IQR=1). Most women were unemployed (63.2%; 295/467) and single (60.8%; 284/467) (table I). Almost two third of insertions were done at the time of emergency C/S (59.1%; 276/467). In 7 cases it was unclear if the C/S was an elective or emergency (table II). A family planning discussion was documented in the antenatal period with 84% (392/467) of patients, during labour in 2% (7/467) and at the time of C/S in 13% (61/467). The commonest indications for the emergency C/S were fetal distress (49.7%), one previous C/S (12.76%) and failure to progress (10.3%).

Of patients choosing the IUD, 40% (187/467) had no previous C/S, 41.8% (195/467) had one previous C/S, and 18% (84/467) had more than one. The HIV positive rate amongst the study population was 27.8% (130/467), with 85.4% (111/467) of these women having a viral load of less than a thousand (table II).

Immediate complications (figure 2) were defined as complications occurring whilst still in hospital and which could *possibly* have been attributed to the IUD. Most women experienced no immediate side-effects (84.4%, 394/467). Complications included unexplained tachycardia

(10.7%, 50/467), unexplained temperature (3%, 14/467), PPH (1.3%, 6/467), expulsion (1.1%, 5/467), minor wound sepsis (0.6%, 3/467), and endomyometritis (0.4%, 2/467). One of the women with endomyometritis (0.2%) had a hysterectomy. She had an evacuation of her uterus 6 weeks post-delivery for secondary PPH. Three days later she had a hysterectomy and histology confirmed endomyometritis.

The mean amount of days spent in hospital post-delivery were 3.27 (min 2, max 12, 95% CI 3.19-3.35).

Only 16.5% (77/467) of women attended follow up of whom 68 (88.3%) attended at the designated appointment and 9 (11.6%) attended elsewhere. The follow-up rate at NSH (18.4%, 25/136) was slightly better than at GSH (13%, 43/331). There was no difference in the mean age and parity between patients who attended follow up (27.4; 2.3) and those who did not attend (27.2; 2.3). The continuation rate at follow up was 71.6% (53/74), specifically 60.5% (23/38) after emergency C/S, and 82.8% (24/29) after elective C/S (p=0.049) (figure 3, table VII). Of the 49 MMH patients who followed up, 34 (69.4%) continued with their IUD, and of the 28 NSH patients who followed up, 19 continued (67.9%) (p=0.889) (figure 4). In 3 of the women attending follow up it was not clear from the case notes whether they continued with their IUD or not (table III). The commonest symptoms at follow up were vaginal discharge (26%; 20/77), pain (11.7%; 9/77), expulsion (11.7%; 9/77), abnormal bleeding (6.5%; 5/77), and protruding strings (6.5%; 5/77). There were no perforations. Patients were asymptomatic in 51.9% (40/77) of cases (figure 5). In most patients complaining of a discharge no antibiotic was prescribed and reassurance was adequate.

One woman fell pregnant post-insertion. She was a 27-year old para 4 who defaulted follow-up after IUD-insertion at emergency C/S. She returned three months later pregnant with

twins. No IUD was seen on ultrasound. She had a negative laparoscopy for abdominal pain in the second trimester, and subsequently had a C/S and tubal ligation early in 2019. The total expulsion rate after emergency C/S was 3.26% (9/276) and after elective C/S 2.17% (4/184) (p=0.576 table VI, fig.7). In one case it was unsure if it was an emergency or elective C/S).

Strings were visible at follow up in 53.2 % (41/77) of patients. An ultrasound was performed in 67.5 % (52/77) of patients - 79.6% (39/49) of patients at GSH and 46.4% (13/28) at NSH. The IUD was normally placed in 63.5 % (33/52) of cases where ultrasound was performed. Malpositioning (IUD distance of more than 20 mm from fundus and/or abnormally positioned in the cavity) occurred in 23% (12/52) of cases, and no IUD was seen in 5.8% (3/52) (figure 7).

The IUD removal rate at follow up was 24.7% (19/77). Reasons for removal included symptoms (6/19; 31.6%), symptoms and ultrasound (5/19; 26.3%), ultrasound alone (5/19; 26.3%), clinical malpositioning (IUD stem visible on speculum) (1/19; 5.3%), and patient request (1/19; 5.3%). In one case the reason for removal was unclear in the notes (figure 9). Two women opted for IUD reinsertion at the same visit, the others chose a different contraceptive method (table III).

Surgeons with the best continuation rates were the registrars (67.6%; 23/34), followed by the medical officers (59.3%; 16/27), the community service doctors (57.1%; 4/7), and interns (33.3%; 1/3) In 8 women who attended follow-up it was unclear from the notes who the inserter was (figure 10; table 4).

The amount of previous caesarean sections (p=0.053), degree of cervical dilatation (p=0.249) and HIV status (p=0.474) had no statistically significant effect on continuation rates.

Tables:

Demographics	n (%)
Age	n = 467
15-19	33 (7.1)
20-24	120 (25.7)
25-29	165 (35,3)
30-34	102 (21.8)
35-39	43 (9.2)
40+	4 (0.9)
Employment	
Unknown	17 (3.6)
Employed	155 (33.2)
Unemployed	295 (63.2)
Income	
Unknown	2 (0.43)
< R70 000 p/a	415 (88.9)
R 70 0000 - R250 000 p/a	33 (7.1)
> R250 000 p/a	13 (2.8)
Private	4 (0.9)
Marital status	
Unknown	4 (0.9)
Single	284 (60.8)
Married	137 (29.3)
Partner	42 (9)

Table I. Patient demographics

CLINICAL PATIENT DATA	
	n (%)
Parity post-delivery	n=467
1	107 (22.9)
2	176 (37.7)
3	139 (29.8)
4	36 (7.7)
5	4 (0.9)
6	1 (0.2)
Unknown	4 (0.9)
Caesarean section	
Elective	184 (39.4)
Emergency	276 (59.1)
Unknown	7 (1.5)
Previous CS	
None	187 (40.0)
1	195 (41.8)
2	73 (15.6)
more than 2	4 (0.9)
Unknown	7 (1.5)
Booking	
Unbooked	2 (0.4)
Booked	458 (98.1)
Unknown	7 (1.5)
HIV status	
Unknown	2 (0.4)
Positive	130 (27.8)
Negative	335 (71.7)
Viral load	
Unknown	9 (6.9)
<1000	111 (85.4)
>1000	10 (7.7)

Table II: Clinical patient data

Findings at Follow-up	77
Complete expulsions found at F/U appointment	4
Removals (partial expulsions + other)	19
Re-insertions	2
Unknown (whether patient continues or not)	3
Total continuation	**53**

Table III: Continuation rates

Seniority of surgeon	Number* (n=79)**	%
Registrar	23/34	67.6
Medical Officer	16/27	59.3
Community Service doctor	4/7	57.1
Intern	1/3	33.3
Inserter unknown	7/8	87.5
*Number of patients		
**In-hospital expulsions/removals(5) + pts at F/U(77) minus unknown outcomes at F/U(3) = 79		

Table IV: Continuation rate by seniority/experience of surgeon performing insertion

Type of expulsion	n=467
Expulsions/removals in hospital	5
Partial expulsions* at F/U	5
Complete expulsions at F/U	4
Total	14
Overall expulsions = immediate(5) + at follow-up(9) = 14/467 = 3%	

*IUD stem visible on speculum exam or partial expulsion on ultrasound

Table V: Expulsions

Column1	IUD inserted	In-hospital Expulsion	Expulsion detected @ F/U	Total
Emergency C/S	276	4	5	9
Elective C/S	184	1	3	4
Unknown	7	0	1	1
Total	467	5	9	14

Table VI: Expulsion vs C/S type

Column1	Column2	Column3	Column4	Column5
	Emergency C/S	Elective C/S	Unknown	**Total**
Continued	22	23	6	51
Discontinued	15	5	1	21
Unknown	2	1	0	3
Reinserted	1	1	0	2
Total	**40**	**30**	**7**	**77**

Table VII: Continuation vs C/S type

Figures:

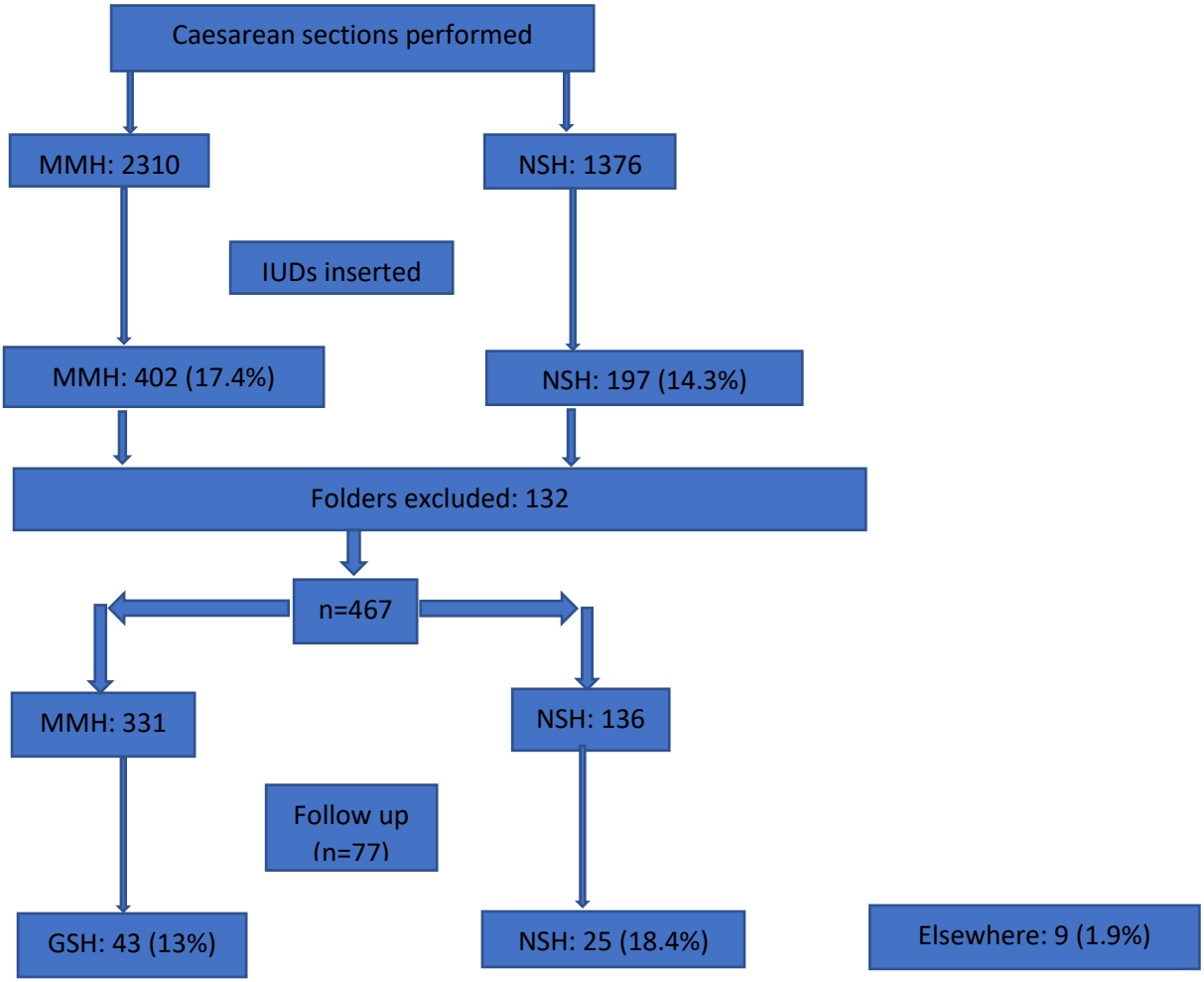


Figure 1: Data collection summary

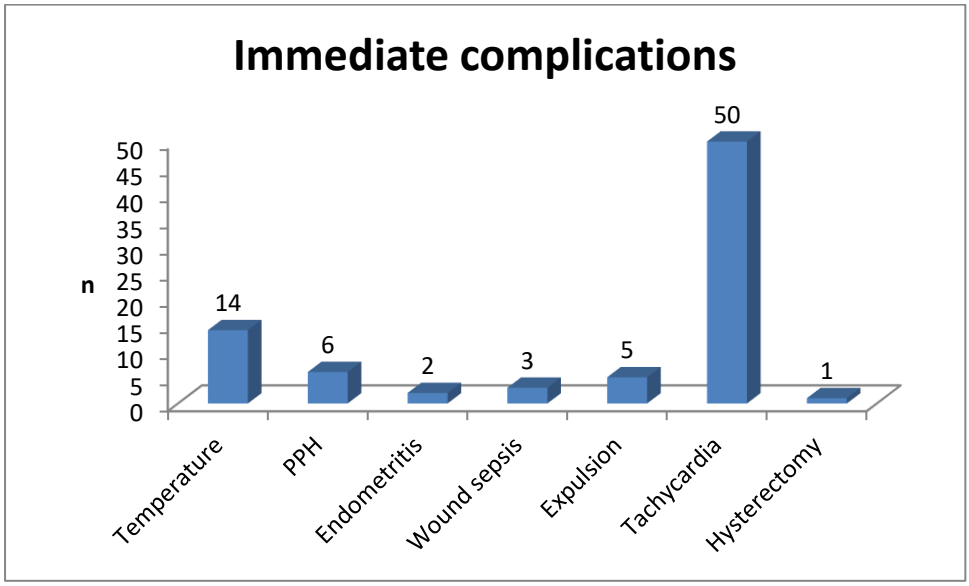


Figure 2: Immediate complications that could possibly be attributed to the IUD.

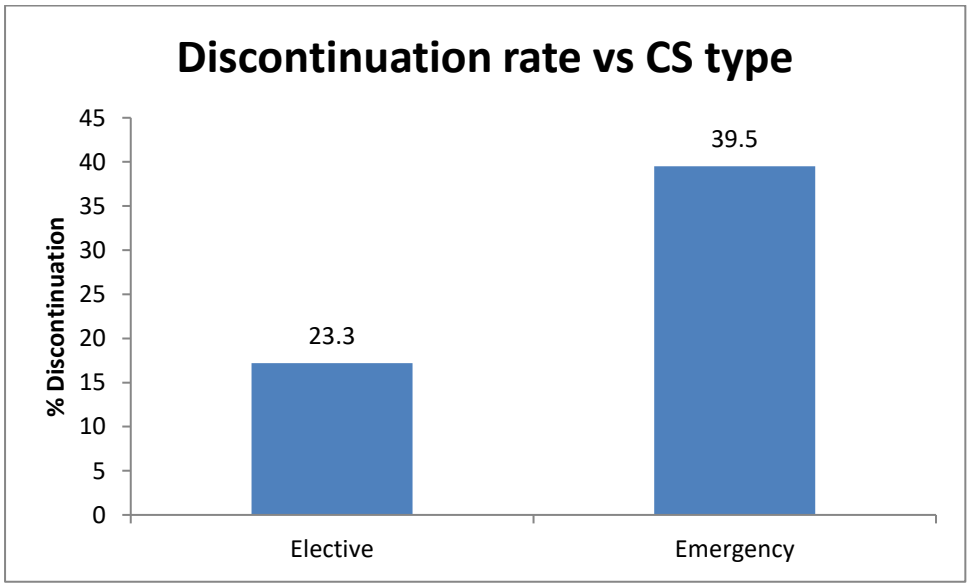


Figure 3: Discontinuation rate vs CS type

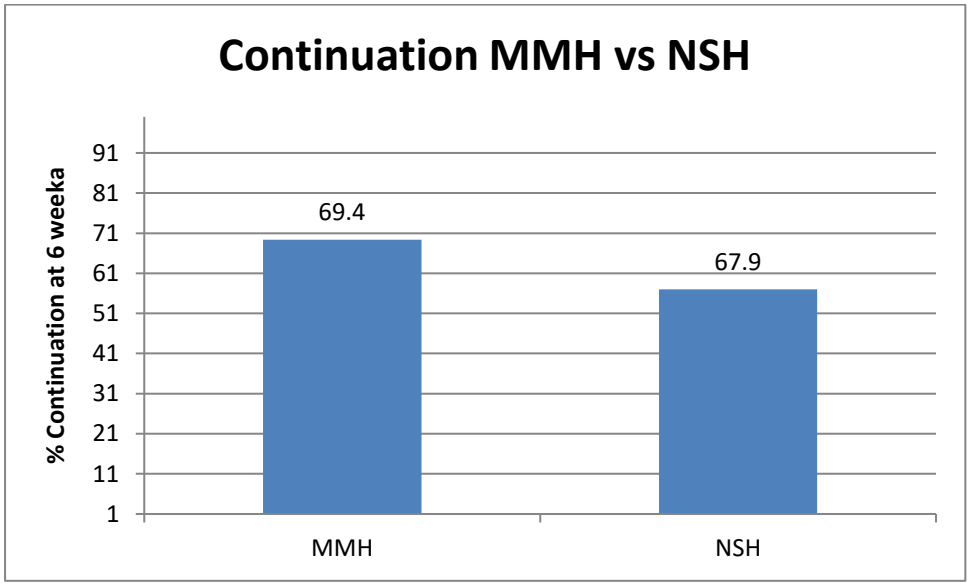


Figure 4: Continuation rate at 6 weeks follow-up.

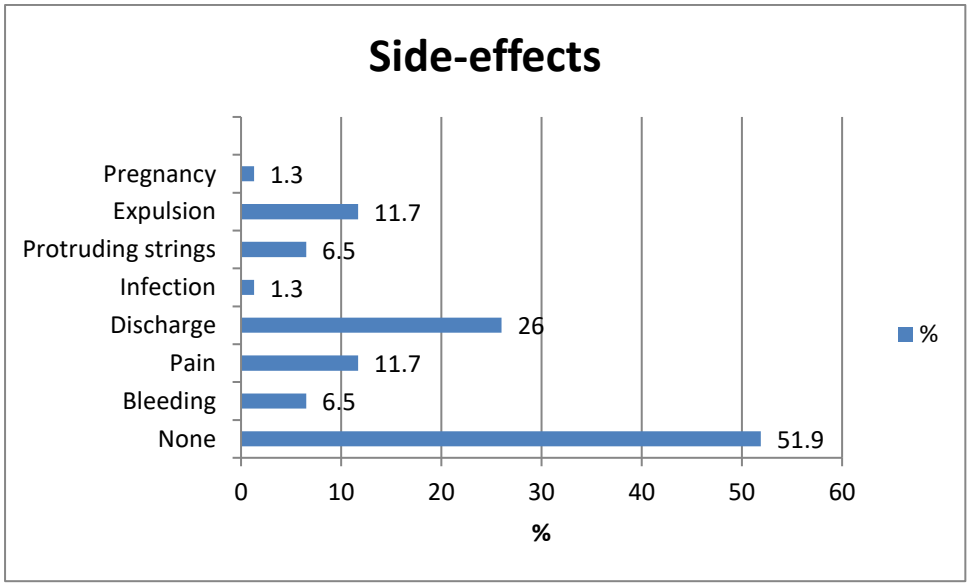
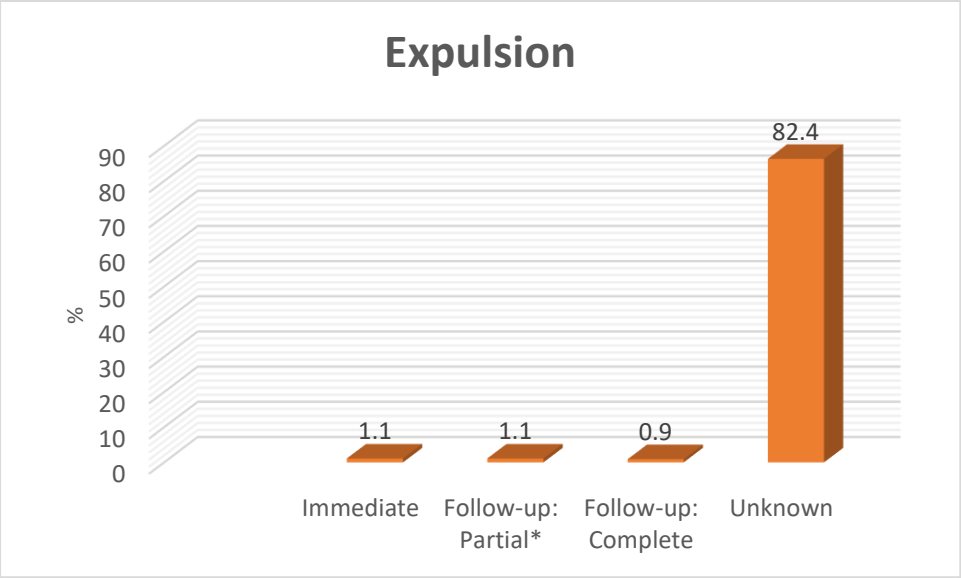


Figure 5: Side-effects at follow-up



*Partial expulsion: expulsion identified by IUD stem visible on speculum or by ultrasound

Figure 6: Expulsion

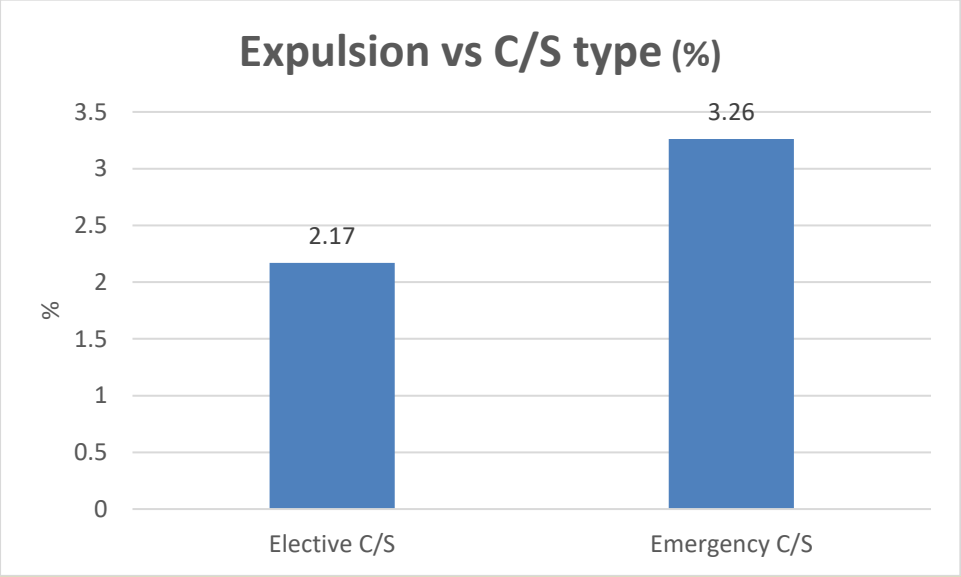


Figure 7: Expulsion vs C/S type

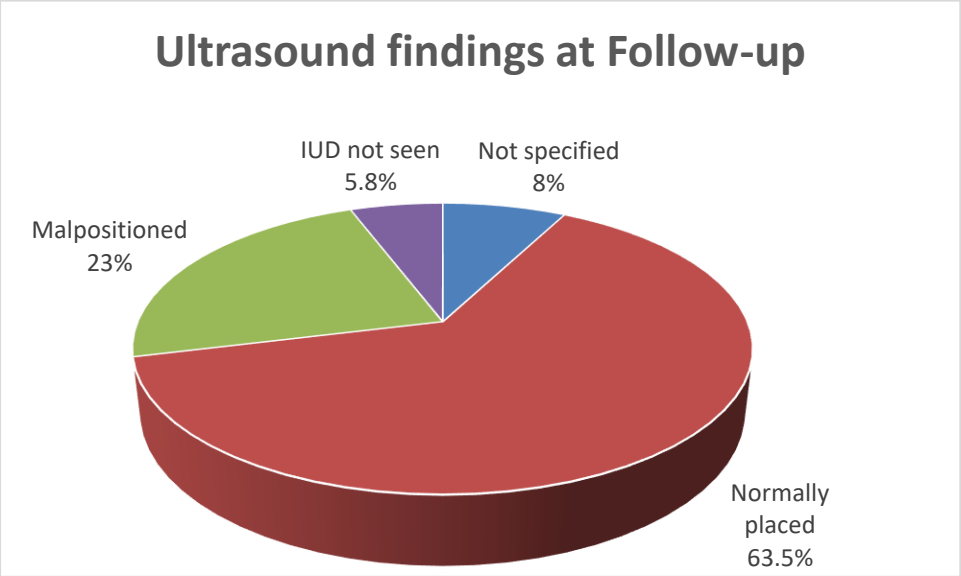


Figure 8: Ultrasound findings at follow-up

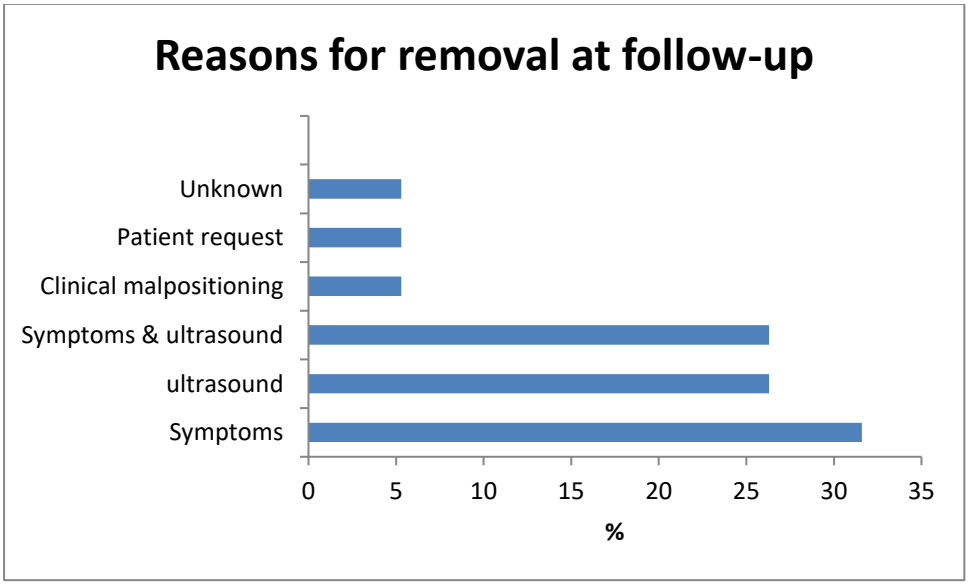


Figure 9: Reasons for removal of IUD at follow-up

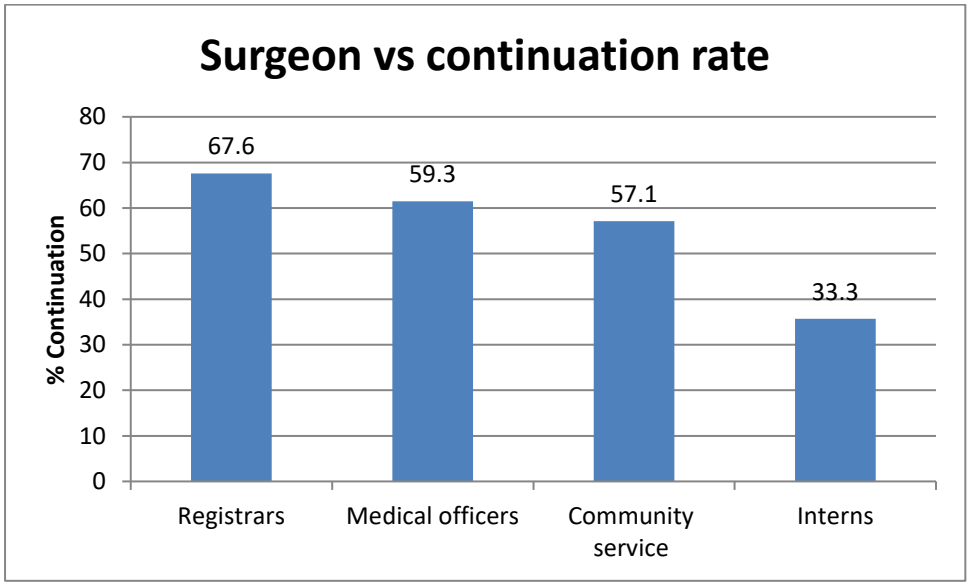


Figure 10: Inserter experience vs continuation rate

Discussion

Patients who opted for intra-caesarean placement were mostly between the age of 20 and 34, with the highest uptake in the 25-29 years age group. The uptake (14.3 – 17.4%) is similar in other studies. [21] The high proportion of single, unemployed women choosing the IUD confirm the need for LARCs in these women. The low rate (0,4%) of unbooked women is encouraging, and we can assume that contraceptive methods would have been discussed with most women at some stage during their pregnancy.

The high percentage of patients who did not attend follow-up (83.5%) is concerning. The slightly better follow-up rate at NSH might be because patients could follow up at the place of insertion and thus were familiar with the setup, whereas MMH patients attend follow-up at GSH. The employed proportion of women who followed up was almost double that of the unemployed. This underscores the financial barrier to follow-up, and rates might improve if patients could follow up closer to their homes. Follow-up rates in the literature ranges between 48 and 88.5%, but this was in prospective studies where patients were counselled extensively and may have received remuneration for transport. [8;21;22;24] Some of our patients may have attended in the private sector or at their local clinic, in which case we cannot see it on the hospital computer system. A study exploring reasons for the poor follow-up rates and whether women attend elsewhere may be insightful. The continuation rate of 71.6% is slightly lower than expected. In the literature it ranges between 80 and 91%. [2;8;9;13;21;23] One could postulate that women would be more likely to attend follow-up if they experienced side-effects or wanted the IUD removed, which would make the complication and removal rate higher in the follow-up than in the lost-to-follow-up group. However, this is our opinion and cannot be accurately ascertained.

Most women (84.4%) experienced no immediate side-effects, which is reassuring. Many of the side-effects could also be attributed to the normal inflammatory response to surgery or pain, e.g. a transient tachycardia (10.7%) and/or unexplained temperature (3%). The immediate expulsion rate was 1.1 %. Four out of five immediate expulsions were after emergency C/S – some directly post-operative in the theatre or recovery room and some during the hospital stay. It may be postulated that cervices often are dilated in the case of emergency C/S, and that may explain the increased rate of expulsion thereafter. The incidence of endomyometritis (0.4%) and minor wound sepsis (0.6%) were low. Major complications were rare – only one woman (0.2%) had a hysterectomy secondary to endomyometritis. It is difficult to prove that the IUD caused the endomyometritis although it may have been a contributing factor. Hysterectomy does not appear to be increased after intra-caesarean IUD insertion and there were no maternal deaths in our patient sample. Immediate complications or side-effects did not prolong hospital stay, which is important if cost, resources, and patient satisfaction are considered.

The commonest side-effect at follow-up was a vaginal discharge (26%), with pain the second most common symptom (11.7%). In the literature pain and bleeding are the most common symptoms, with an incidence of up to 55%. [8] The high incidence of vaginal discharge could be physiological, since very few patients required antibiotics.

In 40.3% of cases IUD strings were not visible at follow-up which was expected. Visibility of strings can be as low as 28% after caesarean insertion. [8] In a large observational trial by FIGO conducted in 6 low-income countries (2018), missing strings were 2.88 times more common following insertion at C/S as compared to vaginal delivery. [10]

An ultrasound was performed in 67.5% of women. The GSH family planning unit scan most women at the 6 weeks visit, whereas an ultrasound was only performed in the instance of lost strings or symptoms at NSH. The continuation rate between the two hospitals was not significantly different even though the scan rate was higher at GSH. Our follow-up groups were however too small to draw any definitive conclusions regarding this. Three patients (3/52) in whom ultrasounds were performed were found to have had undetected expulsions. The absence of visible strings is an important clue to this, and availability of ultrasound is important in these patients. One patient presented with a twin pregnancy three months after insertion due to undetected expulsion. The importance of follow-up must be emphasised in our patient population, since they may experience pregnancy as failure of the device, whereas it was actually failure of attending F/U leading to undetected expulsion.

The IUD was normally positioned in 63.5% of women where ultrasound was performed. The removal rate due to ultrasound findings alone was 26.3%. This confirms that patients may be asymptomatic in some cases of malpositioning. With our high removal rate due to asymptomatic malpositioning, routine ultrasound at the 6-weeks visit should be considered in all women after intra-caesarean IUD insertion.

An important finding is the significantly decreased continuation rate after emergency C/S (60.5%). Many factors could contribute – prolonged labour and multiple vaginal examinations increasing the risk of endomyometritis, the degree of cervical dilatation at the time of insertion, and the inflammatory response characteristic of labour triggering contractions. To our knowledge no studies have specifically looked at this variable yet and it may need further investigation.

The expulsion rate was 11.7% (9/77) if we only look at the patients who attended follow-up. The partial (5/9) and complete (4/9) expulsion rates were similar. This is slightly higher than the expulsion rates in the literature (3.9-10.9%). This may be explained by our small follow-up group, as well as the possibility of patients with complications or symptoms being more likely to attend. Expulsions were increased after emergency C/S, even though not statistically significant (p=0.576). Clinician experience at follow-up may play a role in the partial expulsion rate – some doctors may be more experienced in performing ultrasound for IUD positioning, and may have more strict criteria for the IUD being correctly positioned. Their IUD removal rate may be higher where ultrasound is performed. Some may scan everyone at follow-up, whereas others may have a higher threshold for performing ultrasound. A standardized protocol for follow-up may give more reliable results.

Continuation rates improved with the experience of the inserters in our study. This highlights the importance of training and adequate supervision of junior doctors. Previous uterine surgery, cervical dilatation and HIV status did not significantly affect continuation and should not be a contraindication to insertion.

Limitations of the study

This is a retrospective study relying on information from notes made in hospital folders, therefore information is not standardized and is dependent on the nature of the clinical note keeping. Some folders were excluded due to poor note keeping as it could not be established whether the patients ultimately received the IUD or not. Lost folders may also have contributed to the poor F/U rate. The number of patients who attended follow-up were exceptionally low, which make findings from the population who followed up less reliable due to the small group. Findings between the two hospitals were similar though, which is

reassuring. We could not assess patient satisfaction since this was rarely documented in the notes. This important outcome will best be measured in a prospective study.

Conclusion

The immediate postpartum period may be the only opportunity we have to provide LARC in some women. In our patient population follow-up rates are poor, and therefore the side-effects, expulsion rate, malpositioning and acceptability of the method cannot be accurately gauged. Measures must be taken to improve this. A prospective study with a different location or method of follow-up may give more information regarding these factors. Where the IUD is considered at the time of *emergency* C/S, patients must be informed about the possible lower continuation rate. However, it should still be offered as many patients may default follow-up, and the IUD is safe, effective and long-acting.

Recommendations

1) Revision and standardization of follow-up protocols. Follow-up at Primary Health Care Clinics where the patient will attend for her and her baby's 6 weeks visit may improve attendance rates.
2) Adequate training of Primary Health Care staff to ensure that they are familiar with the follow-up care.
3) Ultrasound access at the follow-up facility to efficiently manage patients with symptoms or lost strings. Where ultrasound is readily available, routine scanning at the first visit should be considered. Effective referral pathways must be ensured.

4) Adequate counselling before discharge including:
    - possible side-effects (specifically leucorrhoea, spotting, pain and protruding strings)
    - the small risk of unnoticed expulsion and unwanted pregnancy
    - the importance of follow-up and what it entails
    - an open-door policy for the trimming of strings and management of side-effects.
5) Information leaflets with contact numbers and appointment slips
6) Note keeping about insertion of IUDs and counselling before *and* after IUD insertion are medicolegal pitfalls and should receive more attention.
7) Adequate training of junior doctors in the correct insertion techniques. IUD placement techniques should be standardised – particularly strings should be fed into the cervical canal and not trimmed based on the high rate of missing strings.
8) More data is needed regarding the decreased continuation rate after insertion at the time of emergency C/S. Patients should be informed about this risk.
9) A follow-up visit tool to improve data collection and encourage standardized follow-up practices.

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viii) Appendices

- Appendix 1: Data capture instrument
- Appendix 2: Ethics approval letter
- Appendix 3: Provincial Government approval letter
- Appendix 4: Mowbray Maternity Hospital approval letter
- Appendix 5: New Somerset Hospital approval letter
- Appendix 6: Groote Schuur Hospital approval letter
- Appendix 7: Instruction to Authors *Obstetrics and Gynaecology Forum*

Appendix 1:

Data Capture Instrument

Study number	
Placement Hospital 1=MMH 2=NSH	
Folder number	
First name	
Surname	
Age	
Parity (post-delivery)	
Employment 0=unknown 1=yes 2=no	
Income 0=unknown 1=h1 2=h2 3=h3 4=private	
Marital status 0=unknown 1=single 2=married 3=partner	
Contraceptive counselling time 0=none 1=antenatal 2=labour 3=at C/S 4=unknown	
Caesar type 1=elective 2=emergency 3=unknown	
Emergency indication 0=unknown 1=fetal distress 2=malpresentation 3=FTP 4=twins 5=failed IOL 6=PET 7=c/sx1 8=c/s>1 9=post-term 10=macrosomia 11=labour 12=APH 13=prev 3rd deg tear	
Emergency indication 0=unknown 1=fetal distress 2=malpresentation 3=FTP 4=twins 5=failed IOL 6=PET 7=c/sx1 8=c/s>1 9=post-term 10=macrosomia 11=labour 12=APH 13=prev 3rd deg tear	
Previous cs 0=0 1=1 2=2 3=>2 4=unknown	
Number of vaginal examinations in labour.	
Booking 0=unknown 1=booked 2=unbooked	
HIV status 0=unknown 1=positive 2=negative	
Viral load 0=unknown 1=<1000 2=>1000	
Cervical dilatation at time of delivery (cm).	
IUD inserted by: 0=unknown 1=consultant 2=senior registrar 3=junior registrar 4= medical officer 5=COSMO 6=intern	
Immediate complications (1) 0=none 1=fever 2=PPH 3=endometritis 4=wound sepsis 5=expulsion 6=removal 7=death 8=tachycardia 9=hysterectomy 10=unknown	
Immediate complications (2) 0=none 1=fever 2=PPH 3=endometritis 4=wound sepsis 5=expulsion 6=removal 7=death 8=tachycardia 9=hysterectomy 10=unknown	
Days in hospital post-caesarean section	

A review of IUD placement during caesarean section at level two facilities in the Metro West area.

University of Cape Town

MMED: Dr. Marcelle Schutte

SCHMAR 170

Placement date: _____

Data collection date:

_____

Data Collection site:

- MMH
- NSH

Follow up at 6 weeks 1=attended 2=not attended 3=attended elsewhere in system 4=IUCD removed earlier 5=demised	
Timing of attendance post-insertion: 1=<2 months 2=2-3 months 3=>3 months 4=unknown 5=expelled earlier	
Side effects at follow-up(1) 0=none 1=bleeding 2=pain 3=discharge 4=infection 5=pregnancy 6=unknown 7=expulsion 8=protruding strings	
Side effects at follow-up(2) 0=none 1=bleeding 2=pain 3=discharge 4=infection 5=pregnancy 6=unknown 7=expulsion 8=protruding strings	
Side effects at follow-up(3) 0=none 1=bleeding 2=pain 3=discharge 4=infection 5=pregnancy 6=unknown 7=expulsion 8=protruding strings	
Expulsion 0=none 1=partial 2=complete 3=unknown	
Strings 1=visible 2=not visible 3=unknown	
Ultrasound 1=done 2=not done 3=unknown	
Ultrasound distance from fundus: 0=not specified 1=fundal 2=>20mm from fundus 3=not seen	
Ultrasound position 0=not specified 1=normal 2=rotated 3=oblique/inverted 4=lateral 5=not seen	
Continuation at week 6 0=unknown 1=yes 2=no	
Removal at 6 week visit 0=unknown 1=yes 2=no 3=expelled earlier	
Reason for removal 0=not removed 1=ultrasound 2=symptoms 3=ultrasound and symptoms 4=pt request 5=other 6=unknown 7=clinical findings 8=expelled	
Specific indication for removal(1) 0=not removed 1=pain 2=bleeding 3=infection 4=pt request 5=failure 6=malposition 7=not specified 8=unknown 9=expelled	
Specific indication for removal(2) 0=not removed 1=pain 2=bleeding 3=infection 4=pt request 5=failure 6=malposition 7=not specified 8=unknown 9=expelled	

Appendix 2:

Ethics Approval Letter

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

Room E53•48 Old Main Buildins
Groote Schuur Hospita
Observatory 7925
Telephone [021] 406 6492
Email: symayah.adefdleo@uct.ac.ze
Website: www.health.uct.oc.za/fhs/research/humanethics/sitocm!

24 August 2018

HREC REF: 542/2018

Dr M Patel
Head: Reproductive Medicine& Fertillty Regulation
Obstetrics & Gynaecology
H-Floor
OMB

Dear Dr Patel

PROJECT TITLE: A REVIEW OF INTRA-UTERINE DEVICE PLACEMENT DURING CAESAREAN SECTION IN THE METRO WEST AREA (MMED CANDIDATE • DR MSCHUTTE)

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 i granted for one year untll the 30 August 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/humanethlcs/forms)

We acknowledge that the student: Dr Marcelle Schutte will also be *Involved In this .tudy.*

Please quote the HR!C REF In all your corre pondence.

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 JDJ1B obtain appropriate Institutional approval, where necessary, before the research may occur.

Yours slncerely

Signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON,fHS.HUMAN.RESEARCHLETHICS.COMMM!E

Federal Wide Assurance Number: FWA00001637.
Instltutlonal Review Board (IRB) number: IRB00001938

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 Convention on Harmonisation Good Cllnical Practice (ICH GCP), South African Good Cllnlcal 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 SO, 56 and 312.

Appendix 3:

Provincial Government Approval Letter

Western Cape Government
Health

Health impact assessment
Health research sub-directorate
Healfh.Research@wesferncape.gov.za
Tel: +27 21 483 0866: fax: +27 21 483 9895
5th Floor, Norfon Rose House, 8 Riebeek S1ree1, Cape Town, 800 l
www.capeqafeway.gov.za)

REFERENCE:WC_201810_013
ENQUIRIES: Dr Sabela Petros

University of Cape Town

Anzio Road

Observatory

Cape Town

7925

For attention: Dr Marcelle Schutte, Dr Malika Patel, Dr Gregory Petro

Re: A Review of Intra-Uterine Contraceptive Device Placement During Cesarean Section At Level Two Facilities In The Metro West Area.

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 following people to assist you with any further enquiries in accessing the following sites:

New Somerset Hospital	**Dr Donna Stokes**	**0214026448**

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. By being granted access to provincial health facilities, you are expressing consent to provide the department with an electronic copy of the final feedback **(annexure 9)** within six months of completion of your project. 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

Signature Removed

MS A VAN DEN B

ACTING DIRECTOR: HEALTH IMPACT

ASSESSMENT DATE:

Appendix 4:

Mowbray Maternity Hospital Approval Letter

Western Cape Government
Health

Health impact assessment
Health research sub-directorate
Heal1h.Research@wes1erncape.gov.za
Tel: +27 21 483 0866: fax: +27 21 483 9895
5th Floor, Norton Rose House, 8 Riebeek Stree1, Cape Town, 8001
www.capega1eway.gov.za)

REFERENCE:WC_201810_013
ENQUIRIES: Dr Sabela Petros

University of Cape Town

Anzio Road

Observatory

CapeTown

7925

For attention: Dr Marcelle Schutte, Dr Malika Patel, Dr Gregory Petro

Re: A Review of Intra-Uterine Contraceptive Device Placement During Cesarean Section At Level Two Facilities In The Metro West Area.

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 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. By being granted access to provincial health facilities, you are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of your project. 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

Signature Removed

DRM MOODLEY

DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE:

Appendix 5:

New Somerset Hospital Approval Letter

Western Cape Government
Health

Health impact assessment
Health research sub-directorate
Healfh.Research@wesferncape.gov.za
Tel: +27 21 483 0866: fax: +27 21 483 9895
5th Floor, Norfon Rose House, 8 Riebeek S1ree1, Cape Town, 800 l
www.capeqafeway.gov.za)

REFERENCE:WC_201810_013
ENQUIRIES: Dr Sabela Petros

University of Cape Town

Anzio Road

Observatory

Cape Town

7925

For attention: Dr Marcelle Schutte, Dr Malika Patel, Dr Gregory Petro

Re: A Review of Intra-Uterine Contraceptive Device Placement During Cesarean Section At Level Two Facilities In The Metro West Area.

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 following people to assist you with any further enquiries in accessing the following sites:

New Somerset Hospital	**Dr Donna Stokes**	**0214026448**

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. By being granted access to provincial health facilities, you are expressing consent to provide the department with an electronic copy of the final feedback **(annexure 9)** within six months of completion of your project. 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

Signature Removed

MS A VAN DEN B

ACTING DIRECTOR: HEALTH IMPACT

ASSESSMENT DATE:

Appendix 6:

Groote Schuur Hospital Approval Letter

Western Cape Government
Health

GROOTE SCHUUR HOSPITAL
Enquiries: Dr Bernadette Eick
E-mail : *Bernadette.Eick@westerncape.gov.za*

Dr M. Patel
OBSTETRIC & GYNAECOLOGY

E-mail: m.patel@uct.ac.za / marcelleschutte@gmail.com / Gregory.Petro@westerncape.gov.za

Dear Dr Patel

RESEARCH PROJECT: A Review of IUCD Placement During Caesarean Section At Level Two Facilities In The Metro West Area

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 August 2019.**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) No additional costs to the hospital should be incurred i.e. Lab, consumables or stationary.
d) **No patient folders may be removed from the premises or be inaccessible.**
e) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
f) Confidentiality must be maintained at all times.
g) Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).
h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
i) Please discuss the study with the HOD before commencing.
j) Please introduce yourself to the person in charge of an area before commencing.
k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
l) Kindly submit a copy of the publication or report to this office on completion of the research.

I would like to wish you every success with the project.

Yours sincerely

Signature Removed

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 26 September 2018

C.C. Mr L. Naidoo
Professor E. Weimann
Professor L. Denny

Appendix 7:

Instructions For Authors *O&G Forum*

Instructions for Authors

Obstetrics & Gynaecology Forum (O&G Forum)

Material submitted for publication in the O&G Forum is accepted on condition that it meets the requirement of the editor in chief. The publisher reserves the copyright of the material published. All authors must give consent to publication, and the O&G Forum does not hold itself responsible for statements made by contributors.

The Journals primary aim is the publication of review and original articles, case reports and letters to the editor aimed at specialist obstetricians and gynaecologists and other professionals working as primary care practitioners. All material will be sent for peer review.

Manuscript preparation

1. Copies should be neatly typewritten, with double spacing and wide margins. The manuscript should be submitted electronically. Authors are required to state that their material is original and not previously published or currently submitted elsewhere.
2. **All abbreviations** should be spelt out when first used in the text and thereafter used consistently.
3. Scientific measurements should be expressed in SI units throughout, with two exceptions: blood pressure should be given in mmHg and haemoglobin values in g/dl.
4. Author's full name & surname, affiliation & correspondence address (including email address) to be set out in full on title page of article.
5. All articles (review, original research etc) are to have an **abstract**, giving a brief succinct overview of the article. The abstract should reflect the essence of the paper and be 200 to 250 words. For **Original Research** articles, the abstract should be structured as follows:- Objective, Method, Results and Conclusion.
6. **Authors must give a minimum of three key words, and should use the MeSH (Medical subject headings list of index medicus) cataloque.**
7. A clear statement on ethical issues in clinical and animal research must be provided; conflict of interests and patient confidentiality issues must be indicated.
8. For multi authored papers, the International Committee of Medical Journal Editors (ICMJE) states that, there are three necessary conditions one must meet in order to claim (co) authorship:
    1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretations of data.
    2. Drafting the article or revising it critically for important intellectual content.
    3. Final approval of the version to be published.

Those, and only those who meet all three of the above stipulations, can be named authors, while those who meet only some of the requirements or otherwise facilitate the research by contributing to funding, data collection, editorial work, etc. should be named in the 'Acknowledged' section.

Accordingly, multi-authored papers need a declaration of relative contribution.

Illustrations

1. Figures consist of all material which cannot be set in type, such as photographs and line drawings. Photographs should be forwarded electronically.
2. Tables and legends for illustrations should be typed on separate sheets and should be clearly identified. Tables should carry Roman numerals, thus I, II, III, etc, and illustrations Arabic numerals, thus: 1, 2, 3, etc.
3. Where identification of a patient is possible from a photograph the author must submit a consent to publication signed by the patient, or by the parent or guardian in the case of a minor.
4. If any tables or illustrations submitted have been published elsewhere, written consent to republication should be obtained by the author from the copyright holder and the author(s).

References

1. References should be inserted at the end of the sentence, outside the full stop, as superior numbers, and should be listed at the end of the article in numerical order.
   Do not list them alphabetically.
2. It is the author's responsibility to verify references from the original sources.
3. References should be set out in the **Vancouver style**, and only approved abbreviations of journal titles should be used; consult the List of Journals Indexed in Index Medicus for these details. Names and initials of all authors should be given unless there are more than six, in which case the six names should be given followed by ''et al''. First and last page numbers should be given.

   Journal references should appear as follows:

   a. Peter S. Acute hamstring injuries. Am J Sports Med 1994; 12(7):395-400.

   Book references should be set out as follows:

   a. Williams G. Textbook of Sports Medicine. 2nd Edition: Butterworth, 1989: 101-104.
   b. Vandermere P, Russel P. Biomechanics of the hip joint. In:Nordien PE. Jeffcoat A, eds, Clinical Biomechanics. Philadelphia: WB Saunders, 1990:472-479.

4. ''Unpublished observations'' and ''personal communications'' may be cited in the text, but not in the reference list. Manuscripts accepted but not yet published can be included as references followed by ''(in press)''.

All manuscripts and correspondence should be emailed to: inhouse@iafrica.com