Study Title:

The contraceptive knowledge, attitudes and practice among women seeking induced abortion in Mitchell's Plain District Hospital, women's health clinic, Western Cape, South Africa.

By

Samuel Oluwafemi Sobamowo

SBMSAM001

SUBMITTED TO THE UNIVERSITY OF CAPE TOWN

In partial fulfilment of the requirements for the degree

MMED (Fam Med)

Faculty of Health Sciences

UNIVERSITY OF CAPE TOWN

Date of submission

Supervisor : Dr Tasleem Ras

Department of Family Medicine, University of Cape Town

DECLARATION

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

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature: Signed by candidate

Date: 15/05/2020

Acknowledgement

I would like to extend my profound gratitude to my supervisor, Dr Tasleem Ras, for his guidance and support during the study. I appreciate the mentorship, and guidance of the Head of department of Family Medicine, Prof Derek Hellenberg.
Many thanks to the Head of Department of Obstetrics and Gynaecology at Mitchell's Plain District hospital, Dr Tracey Hinkel, for allowing us to conduct the study in her department and for the support of Dr Kaashiefah Adamson.
The study was conducted with the assistance of Ms Anke Salome Theron and Mrs Ntuthu Mvana. I really appreciate your hard work.
I also express my appreciation to Michelle Henry for her help in analysing and interpreting the study data.
I would also say thank you to my wife, Doris Olamide, for her support and encouragement throughout the study. My special thanks goes to the almighty God.

Abstract

Background:
There is an increased awareness among women of child bearing age on the forms of contraceptives in South Africa. Despite this, there has been a steady rise in the number of induced abortions conducted in the country. The objective of this study was to assess the contraceptive knowledge , attitude and practice of women seeking induced abortion in one of the District Hospitals in Western Cape, South Africa.

Methods: This was a cross sectional descriptive study which was conducted in Mitchell's Plain District Hospital, among women seeking induced abortion. Women aged 18 years and older seeking elective Termination of Pregnancy were included in the study. Convenience sampling method was used to select the participants women attending the clinic and who were willing to participate. Researcher-administered questionnaires were used as a data collection tool, and the data analyzed using descriptive statistics to calculate frequencies and percentages. Correlation between socio-demographic factors and contraceptive uptake was made using chi-square and Fisher's tests.

Results: The majority of the participants were between the ages of 26-39 years, single, unemployed and did not have matric education. There was an acceptable knowledge on contraceptives in terms of types, sources and side effects. However, there was low uptake of contraceptives (17%) prior to falling pregnant. The most common barriers to contraceptives use were side effects, no time to visit the clinic and low level of education.

Conclusion: Findings from this study showed that awareness and knowledge of contraceptives does not necessarily translate to practice. In the future, it would be worthwhile to conduct a qualitative in-depth study on decision-making and behavior of all women around contraceptives.

Table of Contents

LIST OF TABLES

Abbreviations

HREC - Human Research Ethics Committee

TOP -Termination of Pregnancy

MPDH -WHC - Mitchell's Plain District Hospital Women's Health Clinic

KAP – Knowledge, Attitudes and Practice.

Chapter 1

Introduction and Background of the study

Globally, it has been estimated that out of the 210 million pregnancies that occur annually, about 80 million (38 %) are unplanned and 46 million (22%) end in abortion(1). In the developing world, unwanted pregnancy poses a social, emotional and economic challenge among women of child-bearing age. A report by Burkman and Sonnenberg from the year 2000, showed that worldwide termination of pregnancy (TOP) related deaths left 220,000 children motherless (2). A study conducted in West Africa precisely Cote d'Ivoire that looked into the burden of unwanted pregnancy among female sex workers reported negative health impact on these women. It also showed that the country has higher maternal mortality ratio (720 deaths per 100000 live births) which is among the highest in the world (3). In addition to this, a cohort study conducted among young Australian women that examined the relationship between depression and termination of pregnancy found out that (30 % of the women were depressed) and violence played an important contributory factor (4)**.** In view of the burden associated with unplanned or unwanted pregnancy, it would be worthwhile to determine and understand the factors responsible for this. Non-usage of contraceptives is the major contributory factor to unwanted pregnancy.

In developing countries, two-thirds of unintended pregnancies occur among women who do not use any form of contraception (5). Increased access to contraceptive use alone could have a very noticeable effect by reducing unintended pregnancies. In the Russian Federation, there was a significant reduction in TOP rates with the introduction of modern contraceptive technologies (6). In South Africa, data shows that 65% of sexually active women between the ages of 15 – 49 years use a modern contraceptive method (7).

Despite the high uptake of contraceptives, the number of women seeking TOP at public hospitals in South Africa is increasing (8). There is a possibility that understanding the perception of women on contraceptives and factors that could prevent its usage will go a long way in averting unintended pregnancies and reducing maternal morbidity and mortality. There has been no local research that have looked into the above problem. Hence, this study is aimed at understanding the reasons for contraceptive choices of the women requesting termination of pregnancy (TOP) at Mitchell's Plain

District Hospital Women's Health Clinic (MPDH – WHC). The study objectives were to determine their knowledge, attitude and practice towards contraceptives.

Literature Review

Termination of pregnancy in South Africa and Internationally

In South Africa, the choice on Termination of Pregnancy Act was enacted in 1997. This Act states that pregnancy may be terminated up to 12 weeks of gestation on request by any female person of any age. Termination from 13 weeks to 20 weeks is only permissible if a medical risk exists, the pregnancy has resulted from rape or incest, or the pregnancy will significantly affect the woman's social or economic circumstances. The Act goes on to describe the requirement that must be met before termination can be conducted after 20 weeks of gestation (9).

In South Africa, there has been a steady rise in the number of terminations of pregnancy conducted in the country. The number has increased from 26,455 in 1997 to 68,736 in 2010(7). Reportedly between 30-50% of women requesting TOP were not using contraceptives at the time of conception and percentages of unplanned pregnancies were similar to this (7).

Implementation of TOP Acts in South Africa

The National Department of Health (South Africa) has put measures in place to ensure that the recommendations outlined in the Acts is followed as closely as possible. This involves ensuring that TOP is free and readily accessible to women of child bearing age at the District hospitals that offers the service, health care personnel (medical practitioner, registered midwife or registered nurse) are adequately trained and equipped to deliver these services, according to the amendment of the Act to perform the required procedures (9).

In order to ensure that this Act is implemented, section 10 of the TOP Act states that anyone who " prevents the lawful termination of pregnancy or obstructs access to a facility for the termination of a pregnancy shall be guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding 10 years " (9).

Operational data (unpublished) at the MPDH – WHC indicate that on average 30 women present for TOP on a weekly basis. It is probably a safe assumption that these TOP requests are because these are unwanted pregnancies. In the context of free access to termination of pregnancy and

effective contraceptive techniques, it would be worthwhile to look into the health-related behaviors that could be driving this phenomenon.

Impact of unwanted or unintended Pregnancy

In developing countries, there has been an increase in the number of unwanted pregnancies. This raises the important question of what is its impact on the women and the general populace?

Unintended pregnancy poses serious public health issue to both the mother and the unborn child. Several studies showed that unintended pregnancies might prevent the mothers from making good use of healthcare services (both prenatal and antenatal care utilization) (10-13). Bearing the above in mind it would be worthwhile to understand the causal factor of unintended pregnancy. A study conducted by Pallitto et al, identified abuse by a partner and family members as the contributory factors to unintended pregnancy (14). An indication of the impact of unwanted pregnancy on the child is suggested by research conducted in Brisbane, Australia, that looked into child mental health and problem behaviors at 14 years of age following unplanned pregnancy. Hayatbakhsh et al discovered an increase in the rates of depression, anxiety and delinquency in children from unwanted pregnancies compared with those in the wanted pregnancy group. An increase in risky behavior such as child smoking and alcohol consumption was self-reported at age 14 years in the unwanted group (15).

The current context in South Africa for contraceptives utilization

There is an increased awareness among women of child bearing age and the general populace on the forms of contraceptive in South Africa (16). In high schools, teaching regarding forms of contraception is incorporated in the school curriculum (17). The media also plays a significant role in educating the general populace on methods of contraception and the need to make good use of it.

In South Africa, regulated Laws are in place to ensure that health care-services is accessible to all. This includes the reproductive health as embodied by, the National Health Acts, the Batho Pele principles, the constitution of South Africa and the patients' Right Charter(7). Reports show that in South Africa, 83% of women obtain their contraceptives from the public sector and 88% of primary health care facilities offers free family planning services five days a week (7).

Contraceptives of various forms are readily and freely available in state hospitals, clinics or mobile units. In Mitchell's Plain district hospital, The South African government and the Department of Health has put measures and policies in place to promote optimal use of contraceptives to the extent that one would expect very high utilization rates of family planning services among women of child bearing age. In terms of contraceptive use, data indicates that 65% of women who are sexually active between the ages of 15 years to 49 years are using a modern contraceptive method(7). This shows that there is a reasonable degree of awareness of contraceptive among women of reproductive age group in South Africa. In Mitchell's Plain district hospital, there is high uptake of hormonal (injectable) form of contraceptives in the facility. Majority of the women are reluctant to use the invasive forms (implanon and intra uterine contraceptive device) as a result of fear of infertility and myths associated with its use. The hospital initiatives includes making the contraceptives accessible to patients, they are also counselled on the importance of family planning irrespective of their ailment. Those undergoing TOP are counselled prior to the procedure on the need to be on effective and acceptable forms of contraceptive post the procedure.

Contraceptives and Termination of Pregnancy

The South African Saving Mothers Report on maternal mortality and morbidity showed that the Maternal Mortality Rate has decreased by 12.6/100 000 from 176/100,000 live births (2008-2010) to 154/100,000 live births (2011-2013). Part of the key recommendations for preventing deaths related to early pregnancy loss includes promoting family planning services in all communities. The other recommendation was making contraceptive more accessible in order to reach all those who would benefit from them (18).

In the developing world, it is estimated that 215 million women have unmet need for modern contraceptives(19). A cross sectional study done in one of the public hospitals in Eastern Cape, South Africa on contraceptives practices among women seeking termination of pregnancy revealed that 85.8% of the participants knew about contraceptives, while only 44.1% used contraceptives before pregnancy (16).

There is relatively low uptake of contraceptives among women seeking termination of pregnancy in some parts of the world. In West Africa, a study conducted by Lamina that looked into the prevalence of abortion and contraceptive practice among women seeking repeat induced TOP in Ogun State, Western part of Nigeria, showed that of the 2934 women who sought TOP during the

one year study period, 675 (23%) had a repeat induced TOP, and of the 675 women seeking repeat induced TOP, non-contraceptive use accounted for 78% of the pregnancies (20). In Nigeria, it is estimated that 1.5 million unplanned pregnancies occur every year, with half of these resulting in elective TOP's as a result of low contraceptive use among women (21).

The literature suggests several reasons for low contraceptive uptake. The following factors could influence contraceptive use: the women level of education, socioeconomic status and the expectation of the family, partner and community around fertility. In addition to this, cultural factors, religion, access to contraceptive services, contraceptive methods, and side effects of contraceptives play an important role (22). A two year cohort study conducted in residential areas near Mthatha in Eastern Cape, South Africa that looked into the risk factors for unplanned and unwanted teenage pregnancies among young women aged 15-26 years showed that high socioeconomic status and hormonal contraceptives were protective while physical abuse was a risk factor (23).

International studies show that family planning is among the most cost effective of all health interventions (2, 24). Reduction in unintended pregnancy as well as sexually transmitted infections including HIV is the end result of contraception. Studies have shown that all contraceptives methods are cost effective in comparison to no method at all(25, 26). Non usage of contraceptives accounts for increase in burden of disease in state hospitals. In 2005, report showed that 8.5 million women annually experience complications from unsafe abortion that require medical attention worldwide, and three million do not receive the care they need (19). Considering the fact that this problem affects large numbers of women every year, a study published in 2012 by the Guttmacher Institute showed that the minimum annual estimated cost of providing post TOP care in the developing world is 341 million US dollars per annum.(19, 27).

From observation at the MPDH-WHC, a significant number of women are requesting termination of unwanted pregnancies. In view of the above, a better understanding of their knowledge, attitudes and practice towards contraceptives, is vital in the effort to prevent unwanted pregnancies in Mitchell's Plain community.

Usefulness of Knowledge, Attitudes and Practice (KAP) studies.

Regarding health-seeking behavior, KAP surveys are used to determine changes in human knowledge, attitudes and practices in response to a specific intervention. " KAP studies tell us what people know about certain things, how they feel, and how they behave. In addition it brings to light the social, cultural and economic factors that may influence health and the implementation of public health initiatives." (28) Usefulness of KAP studies in determining factors that may promote health is in conformity with the outcome of the study conducted in Malawi that looked into the socio cultural factors that affect treatment and prevention of malaria in pregnancy in rural Malawi, southern Africa(28).

Chapter 2: Publication-ready manuscript

Introduction and Background

Worldwide, there has been a tremendous rise in the number of unwanted or unplanned pregnancies with resultant high rates of termination of pregnancy (TOP) among women of child bearing age (1, 20). In South Africa, the rate at which TOP is conducted in public hospitals and in the country as a whole since the TOP Act was enacted in 1997 is increasing at an alarming rate (8) (7).

The impact of unwanted or unintended pregnancy is felt mostly among women and their families in developing countries compared to their counterparts in developed countries (2). These include psychological and behavioral problems such as depression, anxiety disorder and delinquency in unwanted children (15). It also makes the mother vulnerable to risky behaviors by influencing their health seeking behavior, in particular prenatal and antenatal care utilization(10, 11, 13).

Non-usage of contraceptives with subsequent unplanned pregnancies also accounts for an increase in the burden of disease in state hospitals (19). Local South African data indicates that 65% of women of reproductive age group are using some sort of contraception (7). Of the remaining 35%, it is not known how many are sexually active, and at risk of unplanned pregnancies.

In view of the above, a review of the major contributory factors to unwanted pregnancy could shed some light on this phenomenon. Several studies conducted in developed and developing countries have identified non usage of contraceptives as the leading contributory factor to the prevalence of unwanted pregnancies (5-7, 16, 20). In addition, certain factors that increase the risk of non-utilization of available contraceptives have been identified. These includes women's level of education, socioeconomic status, place of residence (rural or urban areas) partner, family and community expectations around fertility. In addition to this, access to contraceptive services, contraceptive methods and side effects of contraceptive are the other factors. Studies have shown that family planning is among the most cost effective of all health interventions(2). The resultant effect of intervention is reduction in unintended pregnancy, as well as sexually transmitted

infections including HIV. This shows that all contraceptives methods are cost effective compared to no method at all(2).

With the high number of requests for first trimester TOP's at the MPH-WHC, it was hypothesized that there were behavioral reasons for this phenomenon. In the absence of any studies done locally that have looked into the factors responsible for these unintended pregnancies, the aim of this study was to uncover the reasons for contraceptive choices of the women requesting TOP at this site.

Aim and objectives

Aim:

To better understand the reasons for contraceptive choices of the women requesting termination of pregnancy (TOP) at Mitchells Plain Women Health Clinic.

Objectives:

(1) To evaluate their level of knowledge on contraceptives.

(2) To determine their attitude towards contraceptive use.

(3) To determine their practice with regards to contraceptive.

Methods

This was a cross sectional quantitative study that made use of researcher-administered a questionnaire as a data collection tool.

The study was conducted at Mitchells Plain District Hospital Women's Health Clinic (MPDH – WHC). The clinic is staffed with 3 professional nurses trained in performing TOP procedures,2 enrolled nursing assistant, the hospital ARV counselor consults with patients prior to the procedure. The gynecologist and doctors working in obstetrics and gynecology department in the hospital provides assistance in the management of difficult cases. The clinic is opened 5 times in a week from 7am to 16.00pm. It is a district hospital located in Mitchell's Plain, a township which is about 32 km from the City of Cape Town. It is one of South Africa's largest townships located

on the Cape Flats on the False Bay coast between Muizenberg and Khayelitsha. According to 2011 census data compiled by statistics South Africa, it is estimated that about 310,485 people reside in the community. MPDH -WHC provides termination of pregnancy (TOP) services to women who reside in Mitchell's Plain and other neighboring townships which include Nyanga, Cross Road, Gugulethu and Phillipi. Mitchells Plain is home to 85 schools and it comprises the following demographics: Black Africans 7.32 %, Coloured 90.77 % , Indian/Asian 0.62 %, White 0.19 % (29).

Population and Sampling

The population being studied was women seeking first trimester TOP at MPDH-WHC. Inclusion criteria was age over 18yrs, current attendance at the clinic requesting TOP, mental competence, and willingness to enroll in the study (by signing an informed consent form). Exclusion criteria were age less than 18yrs, intellectual impairment, and pregnancy as a result of rape (implying non-consensual sexual activity).

Convenience sampling was used to select prospective participants from the study population due to limited time available to the research team to collect data. All those women who attended the MPDH-WHC on a day that the researcher was able to also attend the clinic, were invited to participate in the study. In a private space, the research assistant introduced the study to potential participants in a language of the participant's choice (English, Afrikaans or isiXhosa), explained the consent form in this language, and obtained voluntary consent. A distress protocol had been discussed and implemented with the clinic staff to address any distress that arose as a result of the interview. The questionnaire was administered prior to undergoing the procedure.

Given an estimated headcount over 2 months of 330 patients, a sample size of 178 was calculated to give a confidence level of 95%, and precision (d) of 0.05.

Data collection and analysis

Using factors known to influence contraceptive decisions as described in the literature, a questionnaire was developed by the research team. The questionnaire was validated in the following manner: face and content validity was achieved by incorporating findings from the literature review into the questionnaire and asking senior members of the clinical team (Consultant

Family Physician, Obstetrician, and Senior Professional Nurse) to review and comment on it. The resulting tool was further validated by conducting a pilot study among 5 women seeking Termination of Pregnancy. This pilot study helped us to identify potential problem areas and deficiencies of our research instruments and protocol before administering it to our study population. It also helped us to understand the most suitable way to administer our questionnaire. We did not analyze these preliminary results to measure construct validity. The final questionnaire was translated into isiXhosa and Afrikaans.

Those participants who provided informed consent, were interviewed by a research assistant in their preferred language. The data were entered onto a Microsoft Excel spread sheet, then imported into EPI – INFO software and analyzed by a bio-statistician using SPSS version 25 analysis package. The results of the analysis was presented as means with confidence intervals, while the correlation between socio-demographic factors and contraceptive uptake was made using chi-square test and Fishers test.

Ethical Consideration

As per the Declaration of Helsinki, participant wellbeing and risk minimization were key principles in managing the data collection, analysis and storage processes. Informed consent was voluntary, procured in the participant's preferred language, and all participants were informed that they could withdraw from the study at any stage, without compromising the standard of clinical care they received. Each participant was allocated a study number, and hardcopies of the questionnaire did not contain any personal patient identification. Filled questionnaires were stored in a locked office, that only the researchers had access to. The digital data was entered onto a password-protected computer. All data will be stored for ten years after the study is published(30).

Permission was obtained from relevant authorities at Department of Health Western Cape and Mitchells Plain District Hospital prior to commencement of the study. Ethical clearance for the study protocol was obtained from the University of Cape Town Human Research Ethics Committee (Ref: 844/2017).

The findings of the study and recommendations were made available to the relevant stakeholders.

Results

Demographics

Of the 178 women who participated in the study, 38% were between the ages of 18-25, 57% were 26-39 years, and 5% were older than 40 years. The majority were single (93%), Christian religion (92%), and unemployed (74%). Just under half had less than a matric education (47%), 4% were still in school, and 10% had a tertiary education (see Table 1 for full socio-demographic characteristics).

Table 1. Socio-demographic Characteristics of Sample.

	N	**%**
Age		
18 – 25	68	38.2
26 – 39	102	57.3
> 40	8	4.5
Marital Status		
Single	165	92.7
Married	12	6.7
Separated	1	0.6
Level Education		
In school	7	3.9
Did not finish matric	84	47.2
Matric	69	38.8
Tertiary	17	9.6
No formal education	1	0.6
Religion		
Christian	164	92.1
Muslim	5	2.8
Other	9	5.1
Employment status		
Employed	47	26.4
Unemployed	131	73.6

Knowledge

All participants had heard of contraceptives. The majority had heard about them from a health facility (85%), from their school (69%) or friends (61%), and just over half from family (54%). Nearly all had heard of condoms and the injection (both 97%) and Implanon (85%) as a form of contraception. Approximately two-thirds knew about the oral contraceptive pill (65%) and

Intrauterine Contraceptive Device (IUCD, 64%). Only less than a quarter knew about the rhythm method or lactational amenorrhea (23%) as a form of contraception (see Table 2).

The figures presented above show that all the participants knew that contraceptives prevent pregnancy. Additionally, 10% thought contraceptives prevent weight gain and 2% thought they prevented high blood pressure. The majority thought that contraceptives cause abnormal menstruation (88%) and weight gain (86%), and just over half thought they cause headaches (53%). Most of them knew they can get contraceptives from hospitals/clinics (99%), doctors (84%) and pharmacies (82%), while less than half know they can get them from schools (46%) or shopping malls (41%).

Table 2. Knowledge of Contraceptives.

	N	**%**
Have you heard about contraceptives?		
Yes	178	100
No	0	0
Where did you hear about it? [a]		
Family	95	53.7
Friends	108	61
Media	71	40.1
Partner	29	16.4
Health Facility	151	85.3
School	122	68.9
Which forms of contraceptives do you know?		
Condom	173	97.2
Oral Contraceptive Pill	115	64.6
2- or 3-Month Injections	172	96.6
Intrauterine Contraceptive Device	114	64
Calendar (Rhythm) Method	40	22.5
Implanon	151	84.8
Lactational Amenorrhea	40	22.5
Contraceptives can prevent		
HIV	49	27.5
Pregnancy	178	100
High blood pressure	4	2.2
Weight gain	17	9.6

The common side effects of contraceptives are?		
Abnormal menstruation	156	87.6
Weight gain	153	86
Abdominal pain	77	43.3
Headaches	94	52.8
Diabetes	6	3.4
Blood clot formation	54	30.3
Causes cancer	9	5.1
Don't know	2	1.1
Where can you get contraceptives?		
Hospitals / Clinics	177	99.4
Pharmacy	146	82
Schools	81	45.5
Shopping Mall	73	41
Private Doctors	150	84.3

[a] Data based on 177 participants – one participant did not respond to this question.

Attitude

Nearly all participants believed that contraceptive use is a personal decision (98%), that it is important to plan when to get pregnant (97%), that it is safe to use contraceptives (96%), and plan on using contraceptive in the future (94%) (see Table 3). Three-quarters believed that contraceptives can cause weight gain (75%), whereas less than a quarter believe they cause permanent infertility (21%), damage the womb (20%) or cause abnormal babies (14%).

Table 3. Attitude Towards Contraceptives.

	N	**%**
Contraceptive use is a personal decision		
Yes	174	97.8
No	2	1.1
Don't know	2	1.1
It is important to plan when to get pregnant		
Yes	172	96.6
No	5	2.8
Don't know	1	0.6
It is safe for me to use contraceptives		
Yes	170	95.5
No	6	3.4
Don't know	2	1.1
My religion forbids me to use contraceptives		

Yes	20	11.2
No	153	86
Don't know	5	2.8
I plan on using contraceptives in the future		
Yes	167	93.8
No	5	2.8
Don't know	6	3.4
Contraceptives can:		
Damage of womb	35	19.7
Cause cancer	13	7.3
Cause permanent infertility	38	21.3
Give you abnormal babies	25	14
Cause weight gain	133	74.7
Don't know	27	15.2

Contraceptive Practice

Out of a total of 178 women, 128 women (71.9%) stated that they had previously used contraceptives but stopped, 30 (16.9%) used them previously and currently. Eighteen (10.1%) had never used contraceptives, and 2 (1.1%) started using contraceptives but had never used them before. Of the 128 women who stopped using contraceptives, the most common reasons were negative side effects (49.2%), no time to visit the clinic (47.7%), and other reasons not specified (46.1%). Of the 160 who had used contraceptives, the most reported types before falling pregnant were the injection (81.3%) and condoms (50%). The majority reported that their partner (75%) and family (87%) supported their use of contraceptives.

Most of the women that were sampled had never had a previous TOP (88%), 11% had one previous TOP, and 1% had two previous TOPs. Of the 22 women who had previous TOP, 67% reported it being due to unwanted pregnancy, 48% due to being unemployed, and 38% reported other reasons. It is also important to note that some of these women gave multiple reasons for their previous TOP. For the current TOP, 71% reported it being due to unwanted pregnancy, 35% due to being unemployed, and 40% reported other reasons – patients were allowed to list more than one reason.

Table 4. Contraceptive Practice of Sample.

	N	**%**
Currently use contraceptives		
Yes	32	18
No	146	82
Previously used contraceptives		
Yes	158	88.8
No	20	11.2
Partner supports my use of contraceptives		
Yes	134	75.3
No	34	19.1
Don't know	10	5.6
Family supports my use of contraceptives		
Yes	154	86.5
No	15	8.4
Don't know	9	5.1
Found the nurses helpful		
Yes	162	91
No	8	4.5
Don't know	8	4.5
Why they stopped using contraceptives (*n* = 128)		
Side effects	63	49.2
I want to have a baby	2	1.6
No time to visit clinic	61	47.7
Partner's negative attitude	6	4.7
I fell pregnant while on it	22	17.2
Other reasons	59	46.1
Not applicable	9	7
Contraceptive used before falling pregnant (*n* = 160)		
Condom	80	50
Oral Contraceptive Pill	15	9.4
2- or 3-Month Injections	130	81.3
Intrauterine Contraceptive Device	3	1.9
Implanon	11	6.9
None	16	10
Previous TOP		
None	156	87.6
One	20	11.2
Two	2	1.1
Reason for previous TOP [a] (*n* = 21)		
Unemployed	10	47.6
Unwanted pregnancy	14	66.7
Used as a form of contraceptive	0	0
Other	8	38.1

Reason for current TOP		
Unemployed	63	35.4
Unwanted pregnancy	126	70.8
Used as a form of contraceptive	0	0
Other	71	39.9

[a] Data based on 21 participants – one of the 22 women who had a previous TOP did not respond to this question.

Employment was not associated with planning to use contraceptives in the future (p = .183), current use of contraceptives (p = .521), previous use of contraceptives (p = .355), or with change in contraceptive use (p = .569).

Table 5: Patient's responses to questions regarding contraceptive practices 9 proportions reported below).

	Q 16 – Plan to use contraceptives in future			Q18 – Current use of contraceptives		Q19 – Previous use of contraceptives		Change in contraceptive use			
	Y	N	D/K	Y	N	Y	N	No previous or current use	Previous use but stopped	No previous use but started	Previous use and continuing
Employment											
Employed	93.6	0	6.4	85.1	14.9	85.1	14.9	14.9	70.2	0	14.9
Unemployed	93.9	3.8	2.3	80.9	19.1	90.1	9.9	8.4	72.5	1.5	17.6
Education											
Currently in school	100	0	0	28.6	71.4	85.7	14.3	0	71.4	14.3	14.3
Never finished matric	94	3.6	2.4	20.2	79.8	88.1	11.9	11.9	67.9	0	20.2
Matric	92.8	1.4	5.8	13	87	89.9	10.1	10.1	76.8	0	13
Tertiary	94.1	5.9	0	17.6	82.4	88.2	11.8	5.9	76.5	5.9	11.8

Note – removed 1 person because only one person had no education and it was interfering with the stats to have n=1 in a group

Education was not associated with planning to use contraceptives in the future (p = .683), current use of contraceptives (p = .489), or previous use of contraceptives (p = .927). However, education was associated with change in contraceptive use (p = .009), with a significantly higher proportion of those still in school not having previously used contraceptives but currently using.

Discussion

The results of this study revealed that most women requesting TOP were between the ages of 26 to 39 years (57.3%). This is surprising, as it was expected that the majority of women seeking TOP would be younger. The possible explanation for this might be the women in this age group (26 - 39 years) might have had 2 or more children and not willing to have more. The other reason might be due to the fact that more than half of the study population (57 %) were in that age group. However, this finding is consistent with the result of other studies(16).

The findings of the study point to an adequate knowledge about contraceptives. All our participants had heard of contraceptives, with most of them getting information from a variety of sources. Our results showed that most women got their knowledge from a health facility or from schools. It is interesting to note that apart from health facilities and schools, family and friends played an important role in acquiring contraceptives knowledge. The study findings indicated that 87% of the participants reported that their families support their use of contraceptives. Regarding source of information on contraceptives, our finding is different from the other studies(31, 32) that identified media as the major source of information on contraceptives. From our study, only 40% mentioned the media as their source of information compared to 85% and 61% that mentioned health facility and friends respectively. The other positive findings from this study were nearly all participants believed that contraceptive use is a personal decision. Majority of the respondents reported that they found the nurses at the family planning clinic very helpful. Seventy five percent of women and 87% of women said their partner or their family supported their use of contraceptives, respectively. Most of the women (88%) had never had a previous TOP.

Against this backdrop of high knowledge levels, 82% of the respondents were not using contraceptives prior to falling pregnant. This raises questions of what the contributory factors are that guided these participants in their decision–making. It would be worthwhile to involve the partners of these women in order to understand their views on the matter and see if they would be

able to effect a change. This is crucial, since there has been some studies that reinforces the need to engage men as clients, treating them as equal partners and advocates of change (33, 34).

Our study showed that education was associated with change in contraceptive use (p=0.009), with a significantly higher proportion of those still in school not having previously used contraceptives but currently using contraceptives. This may be a reflection of the age of school-going women becoming sexually active for the first time, or that current educational efforts are producing this behaviour change. The latter is in line with a study that examined the impact of a school-based program on adolescent sexual behaviour, finding that the programme helped to increase contraceptive use, decrease pregnancy and childbearing (35).

The demographic data indicates that this cohort of women were largely unemployed (74%), 93% of them were single, only 10% progressed to tertiary level while majority did not finish or stopped at matric. The outcome of this study is consistent with the series of studies that found that poverty and low level of education is a major contributory factor to low uptake of contraceptives (16, 36-39). However, this study was limited to this population (those with low level of education and socio-economic income) and comparisons with more educated and affluent populations were not made, so it is not possible to use this data to reach a definitive conclusion in this regard.

The reasons for stopping contraceptive use were lack of access to services (timing), unpleasant experiences due to adverse effects, and previous failed contraceptives. This is evident from our study that showed that 50% of the women that stopped using contraceptives attributed it to intolerable side effects. All of these suggest active decisions to omit contraceptive use despite clear knowledge of the benefits, based on factors rooted in context or past experience. This finding supports existing evidence that unpleasant side effects and adverse reactions which includes weight gain, disruption of menstrual cycle, headaches and lack of sexual desires were common reasons for non-use or contraceptive discontinuation (13, 40-43).

Limitations

The study was conducted on women who attended a clinic of a district hospital in a specific geographic location, and the findings cannot be generalised to the whole community. In addition, while the desired sample size was reached, the important aspect of randomisation could not be implemented due to resource limitations. To ensure generalisability to the general population, the

sample would have to be collected over multiple sites and be of sufficient size to be regarded as representative of the population being studied.

Although face and content validity was achieved in the process of validating the questionnaires, analysis to measure construct validity was not done. This would have been important to strengthen the case for the findings being deemed reliable.

Recommendations

Future studies should look at construct validation for this questionnaire and broadening the scope beyond this facility to ensure that data is generated that can be useful for policy-makers, service planners, clinicians and counsellors.

In addition, research should explore the contextual and personal factors that impact on decision-making around using contraceptives, and in particular, the role that family, partners, peer groups and formal educational programmes can play in effecting behaviour change.

Conclusion

This single-centre study, using a newly developed tool, suggests that awareness and knowledge of contraceptives does not necessarily translate to practice in terms of patient behaviour. Although some methodological aspects will need attention should this study be replicated elsewhere, the findings offer some evidence that psychosocial dimensions impacting decision-making should be a focus in public health campaigns.

Competing Interest:

The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.

References

1. Singh S, Wulf D, Hussain R, Bankole A, Sedgh G. Abortion worldwide: a decade of uneven progress. Guttmacher Institute; 2009.
2. Burkman RT, Sonnenberg FA. Health economics of contraception. Obstetrics and gynecology clinics of North America. 2000;27(4):917-31.
3. Schwartz S, Papworth E, Thiam-Niangoin M, Abo K, Drame F, Diouf D, et al. An urgent need for integration of family planning services into HIV care: the high burden of unplanned pregnancy, termination of pregnancy, and limited contraception use among female sex workers in Côte d'Ivoire. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2015;68:S91-S8.
4. Taft AJ, Watson LF. Depression and termination of pregnancy (induced abortion) in a national cohort of young Australian women: the confounding effect of women's experience of violence. BMC Public Health. 2008;8(1):75.
5. Singh S, Darroch JE, Ashford LS. Adding it up: The costs and benefits of investing in sexual and reproductive health 2014. 2014.
6. Westoff CF. Recent trends in abortion and contraception in 12 countries.DHS analytical Studie No. 8. Calverton, Maryland:ORC Macro 2005.
7. Motsoaledi A. National Contraception and Fertility Planning Policy and Service Delivery Guidelines A companion to the National Contraception Clinical Guidelines. 2012. SA; 2015.
8. Trust HS. Health statistics: TOPs (terminations of pregnancy). Health Systems Trust Durban; 2009.
9. Gazette RoSAG. Choice on Termination of Pregnancy Act No. 92 of 1996. 1996;377(17602).
10. Abosse Z, Woldie M, Ololo S. Factors influencing antenatal care service utilization in hadiya zone. Ethiopian Journal of Health Sciences. 2010;20(2).
11. Guliani H, Sepehri A, Serieux J. Determinants of prenatal care use: evidence from 32 low-income countries across Asia, Sub-Saharan Africa and Latin America. Health policy and planning. 2013;29(5):589-602.
12. Amo-Adjei J, Anamaale Tuoyire D. Effects of planned, mistimed and unwanted pregnancies on the use of prenatal health services in sub-Saharan Africa: a multicountry analysis of Demographic and Health Survey data. Tropical Medicine International Health. 2016;21(12):1552-61.

13. Ochako R, Mbondo M, Aloo S, Kaimenyi S, Thompson R, Temmerman M, et al. Barriers to modern contraceptive methods uptake among young women in Kenya: a qualitative study. BMC public health. 2015;15(1):118.
14. Pallitto CC, Campbell JC, O'Campo P. Is intimate partner violence associated with unintended pregnancy? A review of the literature. Trauma, Violence, Abuse. 2005;6(3):217-35.
15. Hayatbakhsh MR, Najman JM, Khatun M, Al Mamun A, Bor W, Clavarino A. A longitudinal study of child mental health and problem behaviours at 14 years of age following unplanned pregnancy. Psychiatry research Journal. 2011;185(1-2):200-4.
16. Oluwole EO, Skaal L. Contraceptive practices among women seeking termination of pregnancy in one public hospital in Eastern Cape, South Africa. African journal of primary health care. 2016;8(1):1-6.
17. Adams Tucker L, George G, Reardon C, Panday S. 'Learning the basics': young people's engagement with sexuality education at secondary schools. Sex Education. 2016;16(4):337-52.
18. Pattinson RP, South Africa: DoH. National Committee for Confidential Enquiry into Maternal Deaths Saving Mothers 2011–2013: Sixth Report on Confidential Enquiries into Maternal Deaths in South Africa. 2013.
19. Organisation WH. Facts on induced abortion worldwide. Guttmacher Institute; 2012.
20. Lamina MA. Prevalence of abortion and contraceptive practice among women seeking repeat induced abortion in Western Nigeria. Journal of pregnancy. 2015;2015.
21. Abiodun OM, Balogun OR. Sexual activity and contraceptive use among young female students of tertiary educational institutions in Ilorin, Nigeria. Contraception journal. 2009;79(2):146-9.
22. Carr D, Khan M. The unfinished agenda: meeting the need for family planning in less developed countries. 2004.
23. Christofides NJ, Jewkes RK, Dunkle KL, McCarty F, Shai NJ, Nduna M, et al. Risk factors for unplanned and unwanted teenage pregnancies occurring over two years of follow-up among a cohort of young South African women. Journal Global health action. 2014;7(1):23719.
24. Smith R, Ashford L, Gribble J, Clifton D. Family planning saves lives. 2009.
25. Trussell J, Leveque JA, Koenig JD, London R, Borden S, Henneberry J, et al. The economic value of contraception: a comparison of 15 methods. American journal of public health. 1995;85(4):494-503.

26. Trussell J, Lalla AM, Doan QV, Reyes E, Pinto L, Gricar J. Cost effectiveness of contraceptives in the United States. Journal Contraception. 2009;79(1):5-14.

27. Organization WH. Unsafe abortion incidence and mortality: global and regional levels in 2008 and trends during 1990-2008. World Health Organization; 2012.

28. Launiala A. How much can a KAP survey tell us about people's knowledge, attitudes and practices? Some observations from medical anthropology research on malaria in pregnancy in Malawi. Anthropology Matters. 2009;11(1).

29. Smith K. The status of Cape Town: development overview. Isandala Institute. 2005.

30. General Assembly of the World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. J Am Coll Dent. 2014 Summer;81(3):14-8. PMID:25951678.

31. Aderibigbe M, Basebang M. Contraceptive awareness among adolescents in Lagos, Nigeria.Bachelor's Thesis; 2011[cited 2014 Feb 8]. Available from:http://www.theseus.fi/bitstream/handle/10024/32673/Basebang_Aderibigbe.pdf?sequence=1

32. Onwasigwe C. Contraceptives knowledge and practice among married women in Enugu metropolis. Orient Journal of Medicine. 2001;13(3):63-5.

33. Stern E, Pascoe L, Shand T, Richmond S. Lessons learned from engaging men in sexual and reproductive health as clients, partners and advocates of change in the Hoima district of Uganda. Culture, health & sexuality. 2015;17(sup2):190-205.

34. Peacock D, Khumalo B, McNab E. Men and gender activism in South Africa: observations, critique and recommendations for the future. Agenda. 2006;20(69):71-81.

35. Kirby D. The impact of schools and school programs upon adolescent sexual behavior. Journal of sex research. 2002;39(1):27-33.

36. Bassey E, Abasiattai A, Asuquo E, Udoma E, Oyo-lta A. Awareness, attitude and practice of contraception among secondary school girls in Calabar, Nigeria. Nigerian journal of medicine: journal of the National Association of Resident Doctors of Nigeria2005;14(2):146-50.

37. Oye-Adeniran BA, Adewole IF, Umoh AV, Ekanem EE, Gbadegesin A, Iwere N. Community-based survey of unwanted pregnancy in southwestern Nigeria. African Journal of Reproductive Health. 2004.

38. Obwoya JG, Wulifan JK, Kalolo A. Factors influencing contraceptives use among women in the Juba city of South Sudan. International Journal of Population Research. 2018;2018.

39. James E, Finlay J, editors. Barriers to Contraceptive Use: Examination of Contraceptive Laws and Contraceptive Use in Sub-Saharan Africa. PAA 2017 Annual Meeting; 2017: PAA.

40. Burke H, Ambasa-Shisanya C. Qualitative study of reasons for discontinuation of injectable contraceptives among users and salient reference groups in Kenya. African journal of reproductive health 2011;15(2).

41. Mustafa R, Afreen U, Hashmi HA. Contraceptive knowledge, attitude and practice among rural women. Coll Physicians Surg Pak. 2008;18(9):542-5.

42. Apanga PA, Adam MA. Factors influencing the uptake of family planning services in the Talensi District, Ghana. Pan African Medical Journal. 2015;20(1).

43. Pleaner M, Morroni C, Smit J, Lince-Deroche N, Chersich M, Mullick S, et al. Lessons learnt from the introduction of the contraceptive implant in South Africa. South African Medical Journal. 2017;107(11):933-8.

Appendix A

INFORMED CONSENT FORM

Study Title: **The family planning knowledge , attitudes and practice among women seeking induced abortion in Mitchell's Plain Women Health Clinic Western Cape, South Africa.**

Investigators: Dr Tasleem Ras and Dr Sobamowo Samuel.

Research Assistant: Anke Salome Theron and Ntuthu Mvana

Department: School of Public Health and Family Medicine, University of Cape Town, South Africa.

INFORMATION

The doctors in this study are trying to understand the health seeking behavior of women attending the Mitchell's Plain Women Health clinic to Family Planning.

Unwanted and unplanned pregnancy poses a social, emotional and economic challenge among women of child bearing age.

Understanding the knowledge, attitude and practice of women towards family planning will allow doctors to set up programs to address the issue.

Those who choose not to participate in the study will not be treated unfairly, they will still receive the standard quality care in the clinic.

What will happen?

The researchers and assistant will introduce the study, the benefit and inconvenience that may occur while participating in the research to you. Questionnaire will be given to you.

Is there any benefit to me?

By knowing your health seeking behavior to family planning will assist us in providing effective measures to reduce unplanned pregnancy and induced abortion.

Is there any potential harm to me?

There is no potential harm to you. The only inconvenience is the time used in filling the questionnaire.

The findings of the study will be published in a medical journal and made available to relevant stakeholders.

Please read this form carefully and ask the investigators to explain any unclear words or information to you before giving your consent.

CONSENT STATEMENT.

I therefore certify that:

- I have read the above information and understand that the study involves research.
- I have had the opportunity to ask questions. All my questions have been answered to my satisfaction.
- I understand that the information on the questionnaire will be confidential (participants will not be identified)

Participant Name: Signature: Date:

Person obtaining consent: Signature: Date:

APPENDIX B.

Questionnaire

		Socio-Demographic Characteristics				
Items	**Questions**	**Answers**				
1	**Age group in years**	(a) 18-25 years	(b) 26-39 years		(c) 40 years and above	
2	**Marital Status**	(a)Single	(b) Married	(c) Separated	(d) Divorced	(e) Widowed
3	**Level of Education**	(a) In Grade….	(b) Did not finish Matric		(c) Finished Matric	
		(d) Tertiary	(d) No formal education			
4	**What is your Religion**	(a) Christian	(b) Muslim	(c) Hindu	(d) Others	
5	**Employment Status**	(a) Employed	(b) Unemployed			
		Knowledge on Contraceptives				
6	**Have you heard about Contraceptives?**	**(a) Yes**	**No**		**I don't know**	
7	**Where did you hear about it?**	(a) Family	(b) Friends		(c) Media	
		(d) Partner	(e) Health Facility		(f) School	
8	**Which forms of Contraceptives do you know?**	(a) Condom	**Yes**	**No**	**I don't know**	
		(b) Oral contraceptive pills	**Yes**	**No**	**I don't know**	
		(c) 2 or 3 Months - Injections	**Yes**	**No**	**I don't know**	
		(d) Intrauterine contraceptive device	**Yes**	**No**	**I don't know**	
		(e) Calendar (Rhythm) Method	**Yes**	**No**	**I don't know**	
		(f) Implanon	**Yes**	**No**	**I don't know**	
		(g) Lactational Amenorrhoea	**Yes**	**No**	**I don't know**	

9	**Contraceptives can prevent?**	(a) Prevents HIV	**Yes**	**No**	**I don't know**
		(b) Prevents Pregnancy	**Yes**	**No**	**I don't know**
		(c) Prevents High blood pressure	**Yes**	**No**	**I don't know**
		(d) Prevents weight gain	**Yes**	**No**	**I don't know**
10	**The common side effects of contraceptives are?**	(a) Abnormal Menstruation	**Yes**	**No**	**I don't know**
		(b) Weight gain	**Yes**	**No**	**I don't know**
		(c) Abdominal pain	**Yes**	**No**	**I don't know**
		(d) Headaches	**Yes**	**No**	**I don't know**
		(e) Diabetes	**Yes**	**No**	**I don't know**
		(f) Blood clot formation	**Yes**	**No**	**I don't know**
		(g) Causes Cancer	**Yes**	**No**	**I don't know**
11	**Where can you get contraceptives?**	(a) Hospitals / clinics	**Yes**	**No**	**I don't know**
		(b) Pharmacy	**Yes**	**No**	**I don't know**
		(c) Schools	**Yes**	**No**	**I don't know**
		(d) Shopping Mall	**Yes**	**No**	**I don't know**
		(e) Private Doctors	**Yes**	**No**	**I don't know**
		Attitude Towards Contraceptives			
12	**I think contraceptive use is a personal Decision**	**Yes**	**No**		**I don't know**
13	**It is important to plan when to fall pregnant**	**Yes**	**No**		**I don't know**
14	**It is safe for me to use contraceptives**	**Yes**	**No**		**I don't know**
15	**My religion forbids me from using contraceptives**	**Yes**	**No**		**I don't know**
16	**Do you plan to use contraceptives in the future?**	**Yes**	**No**		**I don't know**

17	**Do you belief that contraceptives can**	(a) Damage the womb	**Yes**	**No**	**I don't know**
		(b) Cause cancer	**Yes**	**No**	**I don't know**
		(c) Cause permanent infertility	**Yes**	**No**	**I don't know**
		(d) Give you abnormal babies	**Yes**	**No**	**I don't know**
		(e) Cause weight gain	**Yes**	**No**	**I don't know**
		Contraceptive Practice			
18	**Do you currently use contraceptives?**	**Yes**	**No**	**I don't know**	
19	**Have you previously used contraceptives?**	**Yes**	**No**	**I don't know**	
20	**My partner support my use of contraceptives**	**Yes**	**No**	**I don't know**	
21	**My family support my use of contraceptives**	**Yes**	**No**	**I don't know**	
22	**I found the nurses to be quite helpful**	**Yes**	**No**	**I don't know**	
23	**Why did you stop using contraceptives?**	(a) Side effects	**Yes**	**No**	**I don't know**
		(b) I want to have a baby	**Yes**	**No**	**I don't know**
		(c) No time to visit clinic	**Yes**	**No**	**I don't know**
		(d) My partner's negative attitude	**Yes**	**No**	**I don't know**
		(e) I fell pregnant while on it	**Yes**	**No**	**I don't know**
		(f) Other reasons	**Yes**	**No**	**I don't know**
24	**Which contraceptive did you use before you fell pregnant?**	(a) Oral contraceptive pills	**Yes**	**No**	**I don't know**
		(b) Condoms	**Yes**	**No**	**I don't know**
		(c) 2 or 3 months -injection	**Yes**	**No**	**I don't know**

		(d) Intrauterine Contraceptive device		**Yes**		**No**	**I don't know**
		(e) Implanon		**Yes**		**No**	**I don't know**
		(f) None		**Yes**		**No**	**I don't know**
25	**How many previous TOP have you had?**	(a) None	(b) 1	(c) 2	(d) 3 and above		
26	**What was the reason for the previous TOP?**	(a) Unemployed		(b) Used as form of Contraceptives			
		(c) Pregnancy Unwanted		(d) Other reasons			
27	**What is the reason for wanting TOP now?**	(a) Unemployed		(b) Used as form of Contraceptives			
		(c) Pregnancy Unwanted		(d) Other reasons			

Appendix c : Ethical Approval

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

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

11 January 2018

HREC REF: 844/2017

Dr T Ras
Division of Family Medicine
School of Public Health & Family Medicine
Falmouth Building-FHS

Dear Dr Ras

PROJECT TITLE: THE FAMILY PLANNING KNOWLEDGE, ATTITUDES AND PRACTICE AMONG WOMEN SEEKING INDUCED ABORTION IN MITCHELL'S PLAIN DISTRICT HOSPITAL, WOMEN HEALTH CLINIC, WESTERN CAPE SOUTH AFRICA (MMED CANDIDATE - DR S SOBAMOWO)

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

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

Approval is granted for one year until the 30 January 2019.

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

We acknowledge that the student: Dr S Sobamowo will also be involved in this study.

Please quote the HREC REF in all your correspondence.

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

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

Yours sincerely

Signature removed to avoid exposure online

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

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

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies 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 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.