EVALUATION OF THE USE OF BARRIER CONTRACEPTIVES IN WOMEN REQUESTING TERMINATION OF PREGNANCY AT CHBAH.

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A RESEARCH REPORT SUBMITTED TO THE UNIVERSITY OF THE WITWATERSRAND IN FULFILLMENT OF THE MASTER OF MEDICINE DEGREE

Declaration

I Salome Maswime declare that this dissertation is my own work.

It is being submitted to the University of the Witwatersrand in fulfillment for the requirements of a Master of Medicine

Degree.

It was previously submitted to the College of Medicine South Africa
In partial fulfillment of the Fellowship of Obstetrics and
Gynaecology (SA).

Tumishang M Salome Maswime

This 24th day of November 2014

Dedication

For my son Gundo Taurai Maswime

Presentations

- 1. University of the Witwatersrand, Department of Obstetrics and Gynaecology, Research Day. November 2012
- 2. South African Society of Obstetricians and Gynaecologists, Cape Town, May 2014

Abstract

Introduction

South Africa has a high prevalence of unintended pregnancies and HIV. Sixty eight thousand women die due to unsafe abortion annually worldwide, making it a leading cause of maternal mortality. In SA the maternal mortality has decreased from TOP. Maternal mortality from HIV is the leading cause of maternal mortality in South Africa. Unintended pregnancies are mainly a consequence of inconsistent and incorrect contraceptive use. The condom is the only contraceptive method which has the dual ability of preventing HIV and unintended pregnancies. We postulate that the failure of barrier contraception is a risk for both HIV and unwanted pregnancy. This study describes the contraceptive methods used by women at a TOP clinic and evaluates the use of barrier contraceptives amongst women requesting TOP, and the prevalence of HIV.

Methods

CHBAH is tertiary hospital in Southern Gauteng. Women with medical or surgical comorbidities that request a TOP are referred to the hospital. A prospective study using a cross sectional study design was performed at the Chris Hani Baragwanath Academic Hospital TOP clinic between February and October 2011. Data was collected using interviews and medical files.

Results

One hundred and nineteen women were interviewed. Most women 56 (47.06%) did not use any contraception at the time of conception. The most common reason for TOP was financial constraints, followed by relationship conflict. Pregnancy despite condom use was 34.45% (n=41). The percentage of women with condom failure, who were HIV positive was 34.14% (n=14). True condom failure was experienced by 12 women (pregnancy due to breakage/slippage of the condom.

Conclusion

Unintended pregnancy is mainly associated with not using contraceptives. The male condom was the most widely used contraceptive. The HIV prevalence in the group with condom failure was higher than the general antenatal population. There is a need for education regarding correct and consistent use of contraception.

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Table of Contents

Declaration	II
Dedication	III
Presentations	IV
Abstract	V
Acknowledgements	VI
Table of Contents	VII
List of figures	IX
List of tables	X
Abbreviations	XI
Definitions	XIII
Chapter 1	1
Introduction	1
1.1. Problem Statement	2
Chapter 2	4
2.1. Literature Review	4
Condom Use in South Africa	5
Barriers to Contraceptive Use	
Global HIV Statistics	
Reasons for Termination of Pregnancy in Africa	
Abortion and contraceptive use in Sub-Saharan Africa	
Summary	
Chapter 3	
3.1. Objectives	
Primary	
Secondary	
3.2. Methodology	
Study Population:	
Study Design:	
Study Sample:	
Inclusion criteria	17
Exclusion criteria:	17

3.3. Data Management and statistical analysis	17
Data Management	17
Descriptive Statistics	17
3.4. Ethics	18
Chapter 4	19
Results	19
Demographics	19
Pregnancy History	20
Sexual History	21
Contraception	21
Use of Barrier Contraceptives	24
HIV	25
Chapter 5	27
5.1. Discussion	27
Condom use	27
HIV infection	28
Contraceptive use at CHBAH	29
Reasons for requesting TOP	30
5.2. Strengths	32
5.3. Limitations	33
5.4. Conclusion	33
5.5. Recommendations	34
5.6. Future Suggestions for similar studies	34
References	35
Appendix 1: Conceptual Framework	39
Appendix 2: Consent form	40
Appendix 3: Interview	42
Appendix 4: Ethics Clearance Form	47
Annendiy 5: CEO Annroyal form	10

List of figures

Figure 4.1: Highest level of education achieved

List of tables

Table 4.1	Reasons for TOP
Table 4.2:	A description of contraceptives used at the time of conception
Table 4.3:	A description of preferred contraceptives in the future
Table 4.4:	Reason for condom failure in women who were using condoms
Table 5.1:	A comparison of this study with a study done at CHBAH TOP in 2002

Abbreviations

AIDS Acquired Immuno-deficiency Syndrome

CD4 Cluster of Differentiation four

CEO Chief Executive Officer

CHBAH Chris Hani Baragwanath Academic Hospital

GA Gestational Age

HAART Highly Active Anti retroviral therapy

HIV Human Immuno-deficiency Virus

i.e. id est ("that is")

IUCD Intrauterine contraceptive device

KZN Kwazulu Natal

n Number (Statistics)

P Probability value

PMTCT Prevention of mother to child transmission

SA South Africa

SD Standard Deviation

STI Sexually transmitted infection

TOP Termination of pregnancy

UNAIDS Joint United Nations Programme on HIV/AIDS

USA United States of America

WHO World Health Organisation

WITS University of the Witswatersrand

Definitions

Abortion: The ending of pregnancy before 20 weeks (or less

than 500g) (WHO).

True Condom failure: Pregnancy despite use of condom

Induced abortion: See: unsafe abortion

Miscarriage: Spontaneous loss of pregnancy before the fetus

reaches viability (RCOG).

Termination of Pregnancy: The separation of and expulsion, by medical or

surgical means, of the contents of the uterus of a

pregnant woman (CTOP Act 1996).

Unsafe Abortion: A procedure for terminating an unintended

pregnancy either by individuals without the

necessary skills or in an environment that does not conform to minimum medical standards, or both

(WHO)

Unintended pregnancy: A pregnancy that is mistimed, unplanned, or

unwanted at the time of conception (CDC).

Chapter 1

Introduction

An average of 80 000 legal termination of pregnancies (TOP) are performed in South Africa (SA) annually (1). Worldwide, thirty five million induced abortions are performed in developing countries every year (2). Sixty eight thousand women die due to unsafe abortions annually worldwide, making it one of the leading causes of maternal mortality (3).

The Choice on Termination of Pregnancy Act was passed in 1996 in SA, with the aim of reducing the incidence of unsafe abortions (4). The act could only be implemented in 1997 to allow for training of health workers. South Africa's Termination of the Pregnancy at facility rate was 11.1% in 2009, according to the Department of Health. This is also used as a proxy for 'unmet need for contraception' (5). According to the 2008 – 2011 Saving Mothers report, 186 maternal deaths were early pregnancy losses, and of those, 5% were due to TOP (6). A comparison between maternal deaths due to unsafe abortions between 1994 and 1998-2001, showed a decline of 91.1% (7)

Whilst the maternal mortality from abortion is reduced, maternal mortality from HIV has increased. An estimated 22.4 million people are infected with HIV in Sub-Saharan Africa (9). Despite massive prevention and treatment efforts, the AIDS death toll continues to rise. Prevention of HIV would be the most important measure in controlling the epidemic and condoms are the most important means in sexually active couples.

Although safe TOP is necessary it still has complications, so ideally we should be reducing unintended pregnancy by better contraception. An increase in condom use may result in concomitant reduction in unintended pregnancies and HIV.

We postulate that the failure of barrier contraception is a risk for both HIV and unwanted pregnancy. This study will therefore describe the contraceptive methods used by woman at a TOP clinic and evaluate the use of barrier contraceptives amongst women requesting termination of pregnancy. The prevalence of HIV is also measured in this group of women.

1.1. Problem Statement

Family planning is achieved through education and proper family planning services. Universal access to safe, affordable and effective family planning enables every baby born to be a 'wanted' baby. There are several methods to control fertility. The efficacy of contraceptives can be measured through the Pearl Index, which reflects the number of pregnancies that will occur in 100 sexually active women in one year. With correct use, the male condom has a Pearl Index of 3-15 (9).

Sexual intercourse without the use of a condom poses a risk for HIV, and HIV contributes significantly to maternal mortality. HIV infection contributed to 87.3% of non- pregnancy related infections, which accounted for 40.5% of all maternal deaths in South Africa from 2008-2011 (6).

Barrier contraceptives are the only contraceptives that have the ability to prevent pregnancy and HIV infection.

A study done at the Chris Hani Baragwanath Academic Hospital, Termination of Pregnancy Clinic published in 2008 revealed that 56% of the women requesting TOPs had been using contraceptives prior to falling pregnant. Thirty one and a half percent (31.5%) of the women used condoms as their method of contraception (10). The contraceptive prevalence in South Africa is 64.6% among sexually active women (11). We need to determine the reasons for condom failure in women with unintended pregnancies, by evaluating the use of barrier contraceptives at the time of conception.

The prevalence in HIV is increased in women with unintended pregnancies (12). We therefore associate the failure of barrier contraceptives with a rise in unintended pregnancies and HIV.

The 2010 PMTCT guidelines state that all pregnant women should be routinely offered HIV counseling and testing, as part of the interventions to improve the quality of mothers/women's health and to prevent mortality. The prevalence of HIV in South African women was 12.6% in 2008. The prevalence of HIV in women who attended antenatal clinic in South Africa in 2009 according to the Department of Health study was 29.4% (13). HIV testing has not been routinely offered to women requesting TOP in South Africa (14). It may be that women requesting TOP are at greater risk of HIV and should therefore be tested for HIV routinely. If this study shows that these women are indeed high risk, then HIV testing and treating should be integrated into Reproductive Health and TOP services.

Chapter 2

2.1. Literature Review

The World Health Organisation defines an unsafe abortion as: a procedure for terminating an unintended pregnancy carried out either by persons lacking the necessary skills or in an environment that does not conform to minimal medical standards or both (15).

Unsafe abortions are associated with many complications, such as infection, bleeding, trauma to the pelvic organs and infertility; and it is known that the risk of acquiring HIV is higher in women who have had unplanned pregnancies (16).

The Choice on Termination of Pregnancy Act was passed in 1996 in South Africa, with the aim of reducing the incidence of unsafe abortions (4). The incidence of infection resulting from abortion has since decreased by 52% (2). According to the Termination of pregnancy Act, a 1st trimester pregnancy may be terminated upon request. From week 13 up to and including week 20 a woman can request termination of pregnancy when it poses a risk of injury to the woman's physical and mental health if:

- there is substantial risk to the fetus;
- if it was a result of rape or incest;
- o there are social and economic constraints.

After the twentieth week of gestation pregnancies are terminated when they pose a danger to the woman's life; if there is severe malformation to the fetus; and where there is a risk of injury to the fetus (4). In 2008 the Act was amended. Amendments

include the right to obtain an abortion on demand up to 12 weeks gestation. Other amendments clarify the type of facility, the power of approval of these facilities and that annual statistics need to be submitted by approved facilities. The amendment also allows registered nurses who have undergone the prescribed training to conduct TOP up to 14 weeks of gestation (17).

Condom Use in South Africa

The two key goals in the National Strategic Plan (2007 - 2011) to reduce HIV infection in the age group that is most high risk, are: to influence and change the behaviour of young people; and to encourage correct and consistent condom use (18). Safer sex practices and the promotion of male and female condoms have been identified as key components of HIV prevention and reduction of unintended pregnancy.

The analysis of condom use needs to be expressed in terms of the risk of the group being analysed. It is expected that condom use is generally lower amongst married couples and permanently cohabiting couples. Couples trying to conceive also do not use condoms. In adolescents sexual relationships out of marriage are common, which can also be expressed as high risk sexual behaviour (19).

The South Africa Demographic and Health Survey in 2003 showed that 49% of adolescent girls aged 15 - 19 years who had engaged in high risk sex in the previous twelve months, had used male condoms in their last sexual encounter. Only twenty five percent of the males in the same age group reported condom use (20).

In a study done at the Chris Hani Baragwanath Academic Hospital in 2002 at the TOP Clinic, 31.5% of the 203 women who participated used the male condom as their method of contraception. Fifty percent (50.3%) of the participants had never used a condom before (10).

A study at the University of Kwazulu Natal (KZN) did a study on risk perception and condom use among married or cohabiting couples. Partners in 238 relationships were independently interviewed about condom use and attitudes. The results showed that knowledge of condoms and where to obtain them was very high, but only 15% of men and 18% of women reported consistent or occasional use of the male condom. In the rural setting with less educated couples, the level of use was 8% in men and 11% in women. In the urban setting with more educated couples, the use of condoms was 29% and 34% among men and women respectively (20).

A recent study in rural KZN showed that HIV positive women were more likely to use condoms than younger HIV negative women. Known HIV positive status was a positive determinant of condom use (21).

On paper countries like South Africa and Zimbabwe are believed to have very successful female condom programmes, owing to the support of UNAIDS (22). South Africa's female condom programme is considered to be among the best in the world, but not enough women are empowered to use them. Availability and cost remain a challenge (22). Lack of education about the female condom is a significant reason why it is not widely used.

It appears that initiatives to educate the public about condom use have been successful; however, the barriers to condom use are not being addressed. The low

percentage of condom usage might be one of the reasons why we have such a high prevalence of HIV and unwanted pregnancy.

Barriers to Contraceptive Use

One-third of young South African women become pregnant before the age of twenty despite contraception being free (23).

A study done in Limpopo with nurses and teenagers revealed that nurses were not comfortable with giving teenagers contraception as they felt that they should not be having sex, and left the girls feeling harassed (23). Inaccurate information about reproduction prevented the girls from using contraception, like "Fear that condoms would be left inside the vagina", thoughts such as "injections causes infertility" and misconceptions such as "I only need to take pills on days when I have sex".

Efforts to promote condom use are often aimed at high risk groups, and thus married and cohabiting couples are often neglected. Research has shown that condoms are often regarded as inappropriate in marital relationships. The association between lack of trust with condom use, has barred many couples from using condoms mainly in African countries. Many couples in Sub-Saharan Africa want to have large families, and thus the use of condoms is found to be unacceptable (20).

Studies done in the United States have found that the major barrier for the use of the female condom is: ridicule of the femidom by the press, limited advertising, limited distribution, limited promotion, higher prices than the male condom and inadequate training of health care providers (22). It appears that we face the same challenges in South Africa.

Reasons for condom failure are either due to inconsistent or incorrect use. Incorrect use involves the storage of the condom (e.g. exposure to heat), the use of certain types of lubricants, time of insertion, slippage and breakage. Less than 2 in every 100 condoms slip. Slippage is also associated with using the incorrect size of condom (24).

Global HIV Statistics

HIV/AIDS is a burden socially and medically. The latest statistics of the global HIV and AIDS were published by UNAIDS in November 2009. They refer to the end of 2008.

The estimated number of people living with HIV/AIDS worldwide in 2008 was 33.4 million. 31.3 million were adults and 2.1 million were children. Of these, 15.7 million were women. In 2008 there were 2.7 million new infections, and 2 million people died of AIDS (8).

At the end of 2008, women accounted for 50% of all adults living with HIV worldwide.

Africa has over 14 million AIDS orphans (8).

Of the 9.5 million people in developing countries who are in need of anti-retrovirals, only 4 million are receiving them (8).

Sub-Saharan Africa has the highest number of people living with HIV. An estimated 22.4 million adults and 1.9 million children are living with the disease (8).

In 2009 an estimated 5.7 million South Africans were living with HIV, which is more than any country in the world. We have a prevalence of 11%. Almost one in three women aged 25 - 29 are living with HIV (8).

In 2007, 256 million male condoms were distributed countrywide and 3.5 million female condoms were distributed between 2006 and 2007 in efforts to reduce the rate of transmission of HIV (8).

The present situation in South Africa is that most women requesting termination of pregnancy in this country are not being routinely tested for HIV (25). Furthermore the majority of women who are HIV positive are tested during antenatal pregnancy visits. In 2009 of all the South Africans who were tested for HIV in the 15 to 24 age group only 31.8% were males, the rest (71.2%) were female (13).

Reasons for Termination of Pregnancy in Africa

The annual number of TOPs rose in Africa between 1995 and 2003. Of the 5.6 million abortions performed in Africa in 2003, only 100,000 were performed under safe conditions. Most safe abortions occurred in Tunisia, SA and Cape Verde, where abortion had been legalised (26).

TOP is not permitted for any reason in 14 African countries. In 9 countries abortion is only permitted to save lives, but in two of these it is also permitted in cases of rape and, in one, in cases of incest. Seventeen other countries permit TOP to preserve a woman's physical health as well as to save her life, 8 of these also do so on the grounds of fetal impairment. In 9 countries TOP is permitted to preserve a woman's

mental health, they also allow the procedure on grounds of rape, incest or fetal impairment (26).

Zambia permits TOP on socioeconomic grounds. Cape Verde, South Africa and Tunisia allow pregnancy termination without restriction before 12 weeks.

The WHO suggests that one in seven maternal deaths result from unsafe abortion.

Studies showed that nearly three in ten post-abortion patients in Kenya experienced severe complications, whereas in South Africa severe complications declined considerably after the legalisation in 1996 (26).

The pregnancy rate in Africa in 2008 was 222 per 1000 women aged 15 – 44. The rate of unintended pregnancies was 86 per 1000 in 2008, one third of these, result in abortion. Many African women who do not want to fall pregnant are not using contraception, because they are limited in their knowledge of contraceptives (26).

The reasons for TOP in African were classified into: saving lives, preserving physical health, preserving mental health, fetal impairment, rape, incest and socioeconomic reasons (26). The percentage of women having unsafe abortions is alarming, but what is even more concerning, is the fact that this population of woman are also not using contraception; and they also have a very high incidence of HIV (26).

The majority of first and second trimester legal TOPs are performed for socioeconomic reasons (25). In a study conducted in Ghana the reasons which women gave for requesting an abortion were as follows (15):

- Not to disrupt work or education (35.6%)
- Could not afford baby expenses (14.9%)

- Partner rejected pregnancy (9.2%)
- Too young (28,7%)
- Other (11,5%):To increase interval between childbirth

Low income

To postpone childbearing

Abortion and contraceptive use in Sub-Saharan Africa

Historically women have always controlled births by abortion and contraception (27). Available evidence suggests that Sub-Saharan Africa often substitutes modern contraceptives with abortion (27). There is an indication that this happens in adolescents as well as older groups. In certain Sub-Saharan countries, where the availability of contraceptives is low, abortion (usually illegal) tends to be the preferred method for spacing out and limiting births (27).

Even though there is little data, it shows that high rates of abortion correlate with low access to modern contraception, low status of women, strong sanctions against premarital pregnancy, traditional tolerance of abortion and availability of legal abortion services (27).

Through modernisation the world has seen greater access to reliable and safe birth control. Internationally there has been a birth decline, but high fertility persists in Sub-Saharan Africa. The National Committee of Science sites the "African social organisation" as the cause of the high fertility rate in Sub-Saharan Africa. The value attached to perpetuation of lineage; the importance of children as a means to gain resources; and the use of kinship networks to share the costs and benefits of

children, all inhibit the adaptation to contraceptive use and prevent a decline in fertility (27).

Other factors which have contributed to the slower adaptation of contraception are:

- o Lower levels of development and governance
- Less international investment for family planning
- Less urbanisation
- o Lower education levels amongst married women
- Traditional and economic practices which place high values on having many children

Only South Africa has legalised TOP in Sub-Saharan Africa. In recent years Benin, Chad, Guinea, Mali, Niger, Swaziland, Togo and Ethiopia have expanded the reasons for women to procure an abortion legally.

The continuous ethical debate on abortion versus contraception versus abstinence versus infanticide and child neglect, has led to the conclusion that many societies in Sub-Saharan Africa use abortion as the first and last resort to control fertility (27).

Summary

South Africa has a high prevalence of unintended pregnancies and HIV. There are specific barriers to condom usage which are not being addressed in condom promotion campaigns. The percentage of condom usage in various studies ranges between 8 to 49%, with rural communities and cohabiting couples ranking at the lowest.

Although the National Strategic plan is to encourage correct and consistent condom use, the attitudes of health workers and incorrect information about contraceptives appear to be the main barriers to condom usage.

Studies on true condom failure are very few and give a poor reflection of the true rate in South Africa. True condom failure refers to pregnancy despite consistent and proper use. More studies are needed in Sub-Saharan Africa, as HIV has the highest prevalence in this region.

Thirty three million people are living with HIV worldwide, as per global statistics in 2008. More than 50% of these are women. Of the 33 million, over 24 million are found in Sub-Saharan Africa. One in 3 South African women aged 25-29 in South Africa are living with HIV.

Only three African countries permit termination of pregnancy without restriction.

Alarmingly unsafe abortion is the 7th cause of maternal death (WHO). Unlike the rest of the world fertility is on an increase in Sub-Saharan Africa because of the failure to adapt to modern practices of contraception. Traditional norms still play a big role in preventing modern techniques. Unfortunately the shame of an unwanted pregnancy is best curbed by an abortion in many of the African communities.

By preventing unintended pregnancies, we decrease maternal mortality. The failure to drive the use of barrier contraceptives correctly and consistently is probably one of the most important reason why Sub-Saharan Africa has the burden of HIV. By properly educating on the use of barrier contraceptives, in a non-judgmental way, we will significantly curb the plight of HIV, and reduce the need for termination of pregnancy.

Chapter 3

3.1. Objectives

Primary

To evaluate the use of barrier methods (male and female condom) in women with unintended pregnancy requesting TOP at CHBAH.

To assess prevalence of HIV in women requesting TOP

Secondary

To determine the proportion of women using contraception and the type of method used

To find reasons for TOP

To establish the reasons for condom failure. Establish true condom failure in those who say their contraceptive method is the condom. (True condom failure being defined as pregnancy despite consistent and proper use)

To establish what proportion of women are using condoms to prevent STI's including HIV, pregnancy or both

To assess consistency of barrier method use

3.2. Methodology

Study Population: CHBAH is a tertiary hospital serving the community of Soweto and Southern Gauteng. Women who request a first trimester TOP: who have had a previous caesarian section or those who have medical conditions, are referred to

CHBAH for termination of pregnancy; as well as women who request a TOP in the 2nd trimester. Approximately 2200 TOPs were done in 2010 CHBAH, according to the TOP register.

Study Design: A prospective study using a cross sectional study design was performed. We interviewed women who had been referred to CHBAH for TOP, after obtaining consent (refer appendix no 3). Some data was retrieved from patients records. The interviews (refer appendix no 4) were conducted by the researcher or the medical officer assigned to TOP clinic for that month. All the women were referrals from local TOP clinics, and the interviews were conducted on the first day that the woman attended TOP clinic in a private room.

Study Sample: A convenience sample of women attending TOP clinic at CHBAH were interviewed. Selection of patients would normally be the first 4 patients in the TOP queue on a day, depending on the availability of the researcher. The interviews were conducted between 1 February 2011 and 31 October 2011. The women were recruited from the TOP queue, and were interviewed in a private room thereafter.

Sonars for gestational age were done on every woman requesting TOP. For those who did not know their HIV status or were negative prior to this pregnancy, an HIV test was offered, as is the standard of care since January 2011. Pre and post-test counseling was done. For those who consented, blood tests were done for HIV.

Protocol for TOP at CHBAH: (26)

Stable first trimester patients are treated as outpatients

All second trimester admissions are treated as inpatients. Failed Day 3 outpatient TOPs and patients with co-morbidities are also considered for admission.

At the first visit, an ultrasound is performed for gestational age, assessment for co-morbidities, HIV counseling and testing is undertaken. The first visit is concluded with a group counseling session on future contraception.

1st trimester TOP: 2 doses of 600 micrograms of misoprostol administeredPV at home, 6 hours apart.

If patient has aborted the foetus a Manual Vacuum Aspiration is performed the following day

2nd trimester TOP: Day 1: Admission to hospital

600ug of misoprostol is inserted vaginally and repeated 6 hours later, up to 3 doses.

Day 2: Evacuation is done if abortion has occurred and is incomplete. If abortion has not occurred 800ug misoprostol is inserted PV.

Day 3: Evacuation if abortion has occurred and is incomplete. If not, Dinoprostone 0,5mg is inserted vaginally.

Day4: Evacuation, if aborted and is incomplete. If the woman has not aborted a hysterotomy or dilatation and extraction is performed.

Inclusion criteria: Women over the age of 18 requesting TOP.

Exclusion criteria: Women who refuse to be part of this study

3.3. Data Management and statistical analysis

Data Management

The data was entered into a database using Epi-info, was then exported into an

excel spreadsheet for cleaning. We checked all the outliers. Data was then analysed

using Statatm 10 statistical software (Stata Corp., Texas, USA).

Descriptive Statistics

A description of categorical variables was made using frequencies and continuous

variables using mean and medians.

We described:

1. Demographic factors (age, level of education, socio-economic status and

religion)

2. Pregnancy history (past and present)

3. Contraceptive use

4. Sexual history and condom use in more detail.

The number of women who were HIV infected and their degree of immune-

suppression was assessed. We describe the time that the diagnosis was made in

17

relation to the request for TOP. Reasons for TOP for the whole group was analysed and compared in HIV positive versus HIV negative women using either chi-squared or Fischers Exact test.

3.4. Ethics

The study was approved by the Human Research Ethics Committee (WITS). Ethics Clearance Certificate:M101130 (refer appendix no 5),

Permission to perform the study at CHBAH was obtained from the CEO (refer appendix no 6).

Women were given an information sheet and a consent form to sign prior to the interview. The interviews were performed in a private room at the time that the woman was first seen at this hospital. We excluded women under the age of 18 for ethical reasons.

Chapter 4

Results

One hundred and twenty three women were interviewed, 2 data sheets were excluded because of missing data, and another 2 data sheets were excluded because they did not meet the inclusion criteria. In this chapter, a description of the demographics, pregnancy history, sexual history, reason for TOP, HIV and contraception usage in 119 women, is presented.

Demographics

The mean age of women used for this study was 27.37 (SD \pm 6.36). The range was 18-42.

Residence: 74 (62.18%) women were from Soweto, the rest were from other districts.

Religion: We had 5 Atheist participants, 1 Muslim, 9 women did not disclose their religion, and the rest were Christian. The Christians were subdivided into Zionist churches (n=29, 24.37%), Traditional churches (e.g. Catholic church, n=25, 21.01%) and Charismatic churches (n=50, 42.02%).

Employment: On enquiring about employment we found that 81 women (68.07%) of the women were unemployed. It must be noted that more than 70% of the population did not proceed beyond high school.

Pictoral presentation in Figure 4.1.

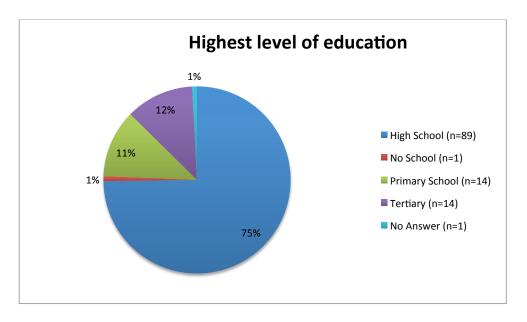


Fig 4.1: Highest level of education achieved

Pregnancy History

The median parity in this group of women was 1, IQR 1-4, Range=0-5.

The gestational age was calculated using the date of last menstrual period but all the patients had a sonar to confirm the gestational age on their first clinic visit. The mean gestational age was 15.01 weeks (SD±2.19), calculated on sonar assessments.

Primary Reason for TOP

The most common reason given by women was lack of finances, followed by relationship conflict. One of the woman said 'I broke up with the father of the child', another said, 'this child is a product of infidelity, and I am engaged to someone else'. We also had a woman who said, 'I want this abortion because I am unsure of the father of this baby.' All the women who requested TOP because of medical conditions, referred to HIV as the medical condition (4.13%). Some of the other reasons had to do with child spacing, i.e. 'Have a very young baby at home', and one women stated that her husband had died.

Reasons are presented in the table.

Table 4.1. Reasons for TOP

Reason for TOP	Number	Percent
	n=119	100%
Financial	43	36.13
Medical Condition	5	4.20
Relationship conflict	30	25.21
Studies	9	7.56
Too many children	19	15.97
Too old to have children	1	0.84
Too young to have children	5	4.20
Work	1	0.84
Other	6	5.04

Nine woman (7.56) reported that they had a TOP in a previous pregnancy.

Sexual History

The mean age at sexual debut 17.53 years [(SD \pm 1.93) Range 14 – 24].

The mean number of sexual partners over the past six months was 1.13 [(SD \pm 0.36); the median was 1 [(IQR 1-3)] Range=1-3.

The mean number of lifetime partners was 3.39 [(SD \pm 2.49) range 1 – 16].

Contraception

Women were asked what type of contraceptive they used at the time of conception: the male condom was found to be the most widely used contraceptive, tabulated below (Table 4.1). Almost half of this population did not use any contraceptives at all

prior to becoming pregnant. One woman said she had used "a band around her waist" to prevent pregnancy.

Table 4.2: A description of contraceptives used at the time of conception

Contraceptive	Number	<u>Percentage</u>	
	n=119	100%	
Combined oral contraceptive	10	8.40	
Progesterone only pill	1	0.84	
Depo Provera	4	3.36	
Nur Isterate	5	4.20	
Male Condom	41	34.45	
No method	56	47.06	
Traditional method	1	0.84	
Did not answer question	1	0.84	

None of the women had a condition preventing them from using contraception. Six of the women (5.04%) complained of side effects with past use of contraceptives, such as headaches and palpitations which had required them to change their method of contraception.

Concerning future contraception, 67 woman opted for injectibles, represented in the table 4.3.

Table 4.3: A description of preferred contraceptives in the future

Method	Number	Percentage
	n=119	n=100%
Injectible	68	57.14
Injectible and male condom	2	1.68
Injectible and female condom	1	0.84
Male condom	8	6.73
Female condom	1	0.84
Loop	4	3.36
Oral contraceptives	14	11.76
Sterilisation	11	9.24
Unsure	8	6.73
No answer	2	1.68

Condom failure and HIV Status

Pregnancy despite condom use was 34.45%, based on the fact that 41 women were using the male condom as their contraceptive method at the time of conception.

The HIV status of these women: 14 women were HIV positive, 25 (69.98) were negative and 2 were unknown. The HIV rate was 34.14% in the group of women with condom failure.

On exploring reasons why women believed the condom failed, 22 women blamed themselves for not using the condom consistently, represented in Table 4.3 below.

Table 4.4: Reason for condom failure in women who were using condoms

Why condom failed	Number	<u>Percentage</u>
	n=41	100%
Condoms fault	12	29.27
(breakage/slippage)		
Did not know	3	7.31
Inconsistent use	22	53.66
Partners fault	2	4.88
Did not respond	2	4.88

Use of Barrier Contraceptives

Seventy five (63.02%) women reported ever using barrier contraceptives as a contraceptive method. None of these women used the female condom. It is noted that the number of women using the condom at the time of the interview (n=75) was almost double the number of women who used the condom at the time of conception (n=75).

The women were asked further questions to evaluate the consistency of use, availability of condoms, condom accidents, and their attitude towards condoms.

Female condom: Reasons that women gave for not using the female condom: "did not know enough about it", "didn't know how to use it" and "didn't know where to find it".

Dual contraception: Thirteen women (17.33%) said they had previously used the condom with another method of contraception.

Accessibility of condoms: 70 of the women (93.33%) said condoms were easily accessible for them.

A third of the women said they rely on their partner to bring the condoms, a third said they themselves find their own condoms and the rest said that, they, together with their partners obtain the condoms.

Reasons for the condom as their choice of contraception included: 'Safety' of the condom compared to other methods. 'Simplicity' of the method, 'side effects' from other methods and the 'easy access' of the condom, were the reasons given.

Almost all the women said they use condoms to prevent both HIV and/or pregnancy (n=55, 73.33%), 4 (5.33%) women said they use the condom mainly to prevent HIV. Fourteen women (18.67) said they only use the condom to prevent pregnancy.

Condom accidents: 31 women (41.33%) reported ever having a condom accident. The mean number of times was $1.77 \text{ SD} \pm 1.3591$, Range 1-8. Type of accidents: 22 women (70.96%) reported broken/burst condoms, 3 reported slippages (9.68%), The rest were unsure.

Knowledge of emergency contraceptives: In this group 21 women (28.00%) said they knew about emergency contraceptives.

Condom use at last sexual encounter: Of the 75 women who said they used the condom as their method of contraception at present: 34 women (45.33%) said they used the condom at their last sexual encounter, 40 women (53.33%) did not use a condom and one woman did not respond.

Of the 16 women in this group, who knew they were HIV positive prior to the interview, 11 had used a condom in their last sexual encounter. Which means that women who are HIV positive are more likely to use a condom (Fischer Exact = 0.01).

HIV

We were able to record the HIV status of 112 (94.12%) women, 50 (43.75%) women knew their HIV status prior to this interview, and the rest were tested on the day of the interview. Twenty seven (22.68%) women were HIV positive.

Eighteen women knew their CD4 prior to this interview. The median CD4 was 316.78: SD±183.73 [(IQR), Range: 29 – 766]. CD4 results in those women who did not have tests in the last 6 months were performed and women were asked to collect their results at their clinics – we did not have access to their results.

We asked all the women if they had discussed HIV with their partners prior to the interview, 77 women (64.71) had discussed with their partners. Sixty two women (52.10%) said they 'knew' their partners HIV status.

Of the 27 women who were HIV positive, 18 (66.67%) knew their status prior to requesting TOP, and 9 (33.33%) were tested during this consultation. This meant that women who knew their HIV status, were more likely to request TOP (Fischer exact = 0.008)

Chapter 5

5.1. Discussion

Condom use

<u>Condom failure</u> is a legitimate health risk, as it results in pregnancy, HIV and other STI's (29). The challenge of measuring condom failure, and condom consistency lies in the different definitions of these terms.

Condom failure is defined as incorrect condom use and misuse. Other definitions include inconsistent use, which would mean that, in the time period that women said that they used the condom as their method of contraception, there were encounters of unprotected sex (29).

Condom failure in this study was assessed according to the number of women who said they were using a condom as their method of contraception at the time of conception. Those who reported condom failure (breakage/slippage) as the reason for pregnancy were considered to be true condom failure. Twelve out of the 41 (29.27%) woman reported true condom failure.

Studies on condom failure, estimate a lifetime prevalence of 1 - 33% of experiencing at least one breakage or slippage during penetrative sex (11). We had a prevalence of condom accidents of 41.33%, in all the women who had used a condom before.

In a study that was done in South Africa, condom failure was measured in a study of a high risk population of women attending STI services: 37% of women had experienced condom failure (11)

Condom consistency is defined as:

- condom use at last sex
- always using condoms with most recent sex partner
- always using condom since first sexual encounter
- always using condom in the 12 months prior to this interview

These definitions are not standardised, and therefore condom failure, the measure of condom failure, will differ, according to the definition used. The accuracy also depends on the person responding. Some women answer according to what they think they are expected to say (11).

Condom use at last sex in this study was 45.33%. Condom use at last sex is considered to be a key indicator towards combating HIV/AIDS. A South African study reported that women between age of 14 and 24yrs had a condom at last sex rate of 46.1 – 73.1%. Our findings are consistent with this.

<u>Barriers:</u> Female gender was associated with inconsistent condom use in an African Study. The observation that females didn't use condoms in relationships where they felt emotionally attached was made. Social status and level of education played a role in determining likelihood to use contraceptives consistently. Africa being a patriarchal society also meant that negotiation for condom use gave the man a superior advantage over the woman's desire to use a condom (30).

Studies have shown that a wide gap exists between the knowledge and usage of the female condom, primarily due to lack of support and programmes by government (22). Fundamentally the lack of knowledge about female condoms is due to policy makers, donors and providers. The female condom has an efficacy of more than 90% and has the advantage of giving the women the upper hand when it comes to preventing HIV. Ultimately, the failure of the female condom is not due to failure of the product, but failure to initiate well established programmes (22). The reasons women gave for not using the femidom in our study reflected this well.

HIV infection

The prevalence of HIV in the entire population was lower than the prevalence of the South African antenatal population of 29.4% (13). We do not test for HIV routinely in TOP clinics (25). Furthermore, women in South Africa requesting abortion are not required to disclose their HIV status beforehand (31).

The prevalence of HIV1 infection was higher among women undergoing termination of pregnancy than amongst the normal antenatal population in a study that was done in Rome (32).

It may be that with the roll-out of HAART, that women were more confident about having a pregnancy It is unlikely that HIV infected women had better access and use of contraceptive services as these are the same for HIV positive and negative women in our setting. An American study showed that women were more likely to fall pregnant in the era of HAART. A study done in India also revealed that with the availability of PMTCT services women were becoming more confident in deciding to have children (33).

The combination of pregnancy and HIV can be challenging and may require difficult decisions. Influences on whether to terminate or continue with the pregnancy are: present clinical illness, risk of infection to the child and general knowledge about the disease (34). Fears about dying and leaving an orphaned HIV positive child are also factors that lead to TOP.

Sexual debut: the average age in South Africa is 17 years (35). Interestingly a study done in Uzbekistan amongst sex workers also showed sexual debut to be 17.2 years (35). Our study also found the mean age for coitarche to be the age of 17. Early sexual debut is linked to increase in HIV. Women who lose their virginity before the age of 15 are more likely to get HIV. Part of the national strategic plan is to delay the age of first sexual encounter, in order to prevent HIV (18).

Contraceptive use at CHBAH

More than 350 million male condoms were distributed in South Africa by the national department of health in 2008/2009. This is equivalent to 12.3 male condoms per male 15 years and older.

A study done at CHBAH in 2002, assessed contraceptive practices of women requesting TOP (10).

Comparisons outlined in table 5.1:

Table 5.1: A comparison of this study, with a study done at CHBAH in 2002.

	2002 (10)	2011
Contraceptive use	56%	52.94%
Repeat TOP	2.5%	7.56%
Condom use at conception	31.5%	34.45%
Primary reason for TOP	Economic 35%	Economic 36.13%
HIV	-	23.38%
Knowledge of Emergency	12%	28%
contraceptives		
Ever used dual	-	17.33%
contraceptives		
Women who have ever	-	41.33%
had a condom accident		

The contraceptive prevalence rate is below the national one, which is 64.6% among sexually active women.

Condom use has increased, but does not reflect the massive campaigns and the rise in condom distribution over the 9 years.

This is a population comprised of low to middle income earners. Economic difficulties continue to be the main reason for TOP. Lack of education and unemployment are reflected in both studies.

Reasons for requesting TOP

There is a difference between reasons for TOP in first world and in third world countries. In countries like USA, socioeconomic reasons are listed often, but the most common reason why TOPs are requested is: Not ready for the responsibility (32%). These were the findings from studies of women who requested TOP in the USA (from different states), from studies conducted between 1996 and 2005 (35).

<u>Socio-economic factors:</u> Our findings of socio-economic hardships and relationship conflict were found to be consistent with findings of other African studies. Women

from African communities such as in the Ghanaian study are most likely to request TOP for socioeconomic reasons and not to disrupt education or employment (15).

<u>Abuse:</u> Abortion is also sought in pregnancies occurring through rape and abusive relationships. Social stigmas such as with women having children with married partners; and advanced maternal age are other reasons for TOP (25). Our study did not explore intimate partner violence or abuse, but relationship conflict was one of the main reasons for requesting TOP.

<u>HIV:</u> Women who knew they were HIV positive, were more likely to request TOP. In a Vietnam study, two thirds of women who became pregnant after testing HIV positive terminated their pregnancies (33).

Age: Has been found to be a significant factor in the decision to terminate pregnancy in some studies. In our study we found that only 4.96% requested TOP primarily because of their age. A study conducted in Vietnam revealed that women over 30 were 5 times more likely to induce abortion than younger women (33).

<u>Parity</u>: Sixteen percent of women said they were requesting TOP because they have too many children. The number of children a woman has in relation to their socio-economic circumstances and their age is usually a determinant in their decision to terminate. Common reasons such as: "I am not ready to have a child"; "I have the number of children I desire"; "I am too poor to support another child", were cited in a Cape Town study (25).

The fact that mostly parous women request TOPS could suggest there may be a gap in our postpartum contraceptive education, also evidenced by the fact that almost 8% of the women said they had had a previous abortion.

Religion: We still find that more than 90% of women requesting TOPs are Christian. Most religions do not permit abortion. South African history on abortion is characterised by opposition mostly from Christian groups and churches. The pro-life campaign was driven mostly by churches at the time that the bill was passed. Doctors for Life, which traditionally is made up of Christian doctors also contested the bill. The Christian Lawyers Association took the Minister of Health to court to

contest the Right to Life (36). A number of churches have openly criticized abortion, including the Dutch Reformed Church, when the first abortion act was passed in 1975 (37). We do not know what role religion plays when one decides to perform a TOP and whether the stigma of pregnancy contributes or not.

Education and employment: Although almost 8% of women in this study gave studies or employment as a reason for the TOP, most women had a high school education. The reasons why so many of these women were not using contraception is worrying and needs to be explored. It has been shown that factors such as literacy levels determine the likelihood of using contraceptives. In fact, it has been established by the United Nations Population Fund that seven years of education is the threshold to decrease total fertility rate. In Brazil it was found that women with no education had an average of 6,5 children, whereas educated women had an average of 2.5 children (38).

A study conducted in Cape Town, published in 2011, found that women without jobs or earning irregular or little income felt compelled to consider termination of pregnancy. These challenges seemed to be heightened when coupled with HIV infection (25). Financial reasons were higher in HIV positive women.

In our population with a high unemployment rate, findings were more consistent with studies that showed that unemployment was a significant predictor for termination of pregnancy.

5.2. Strengths

We looked at condom failure in a population considered to be high risk for HIV infection, and could therefore see the importance of HIV testing in TOP services.

This was a prospective study.

Data was complete, only 4 exclusions.

5.3. Limitations

We could not look at contraceptive failure adequately because we were looking at a group with 100% contraceptive failure.

We excluded women under the age of 18, for ethical reasons, because, even though they can consent for TOP, they would still need their parents to consent for their interviews. Our annual statistics show a small number of women under the age of 18 (10%).

Recall bias, we could not verify if we were being told the truth in our interviews.

We did not ask how long women had been using condoms as their method of contraception.

There may be referral bias, we are a referral centre seeing high risk women which could have given us a different representation of the community. The mean gestational age was 15 weeks beacause 2nd trimester TOPs cannot be done at clinics.

The numbers were sufficient to determine our primary outcomes, but too small to stratify into different groups, like age, HIV status, parity etc, It was however not the aim of this study to look at special groups.

5.4. Conclusion

The number of unintended pregnancies, is a reflection of the unmet need for contraceptives. More than 50% of the women with an unintended pregnancy used contraceptives at the time of conception, albeit inconsistently.

The male condom was the most widely used contraceptive method in women requesting TOP; the female condom was not a contraceptive method for any of the woman. Condom failure and consistent condom use are associated with both pregnancy and HIV infection. Women with condom failure were found to have a higher HIV prevalence rate. HIV testing and contraceptive education is important for

reduction of unintended pregnancies, and also need to be incorporated to all TOP facilities.

5.5. Recommendations

HIV testing should be integrated into TOP services.

Education on contraceptives should focus on the importance of consistency and continuation.

There should be more awareness on emergency contraceptives.

More money and effort should be aimed on educating women on the femidom.

5.6. Future Suggestions for similar studies

One of the most important causes for unwanted pregnancy in this study was women who were not using any contraception- further studies in this group to understand the barriers to contraception use in the South African population.

Evaluating condom use may be better understood if we also added a control group of women who were successfully using condoms.

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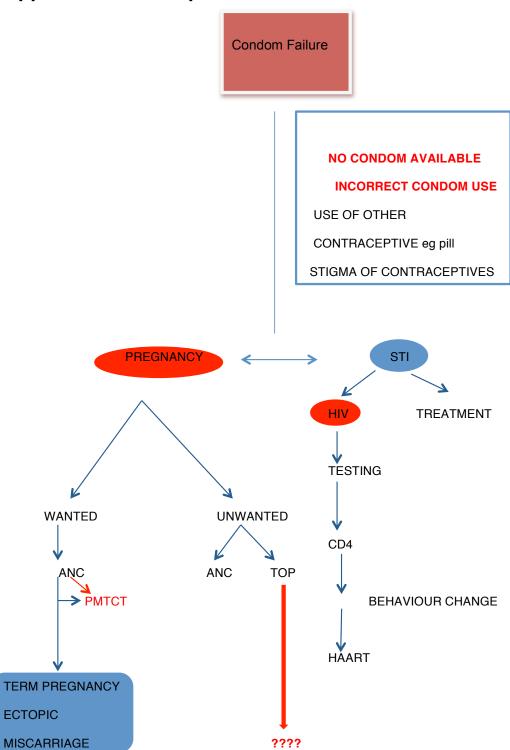
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Appendix 1: Conceptual Framework



Appendix 2: Consent form

STUDY: AN EVALUATION OF THE USE OF BARRIER
CONTRACEPTIVES IN WOMEN REQUESTING TERMINATION OF
PREGNANCY AT CHBH.

Good-day

My name is Dr S. Maswime. I am a doctor in the gynaecology department at Chris Hani Baragwanath Hospital.

We are doing a study where we are exploring the reasons for termination of pregnancy, and we are particularly interested in finding out why contraceptives fail. As part of the study I would like to interview you about your use of contraceptives prior to falling pregnant.

The study will require you to have a 20 minute interview with us. We would also like to offer you a test you for HIV, as part of the new HIV Testing guidelines.

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits.

You may discontinue the study at any time without penalty. There will be no benefit to you participating in the study, however the information may help us medically in informing women on the use of barrier contraceptives.

Your answers will be completely confidential. We will not use any of your personal information. We will use this information for teaching, and we may present the findings at conferences and publish in Medical Journals.

For further information please contact me at 076 470 1169. To report complaints or ethical concerns you may contact the University of Witswaterand Ethics Committee 0117171000 Ext 71234

Please fill out the following and give it to your interviewer:

[Type text]		
Iof this study.		give consent to being part
Signature:	Date:	
Witness:		
Signature:	Date:	
Thank you!		

Appendix 3: Interview

1. HOW OLD ARE YO	U?	
2. WHERE DO YOU L	IVE e.g. diepkloof?	
3. WHAT LEVEL OF E	DUCATION DID YO	OU ACHIEVE?
No School		
Primary School		
High School		
Tertiary		
Other		
4. PLEASE CHOOSE	ONE OF THE FOLL	.OWING:
I AM UNEMPLOYED		
I AM LOOKING FOR JO	OB	
I HAVE A TEMPORAR		
I HAVE A PERMANEN	T JOB	
OTHER (EXPLAIN)		
5. WHAT IS YOUR RE	ELIGION?	
If Christian) WHAT CH	URCH DO YOU AT	TEND?
6. HOW MANY TIMES		
VEAD 1	MEEKS	OUTCOME

YEAR	WEEKS	OUTCOME
		(T/A/M/E)
E.g. 1999	5	A * IF A, answer
		question 7
Abbreviations: T=term A=abortion M=miscarriage E=ectopic		

[Type text]	
This Pregnancy	
LMP	
Gestational Age (Sonar)	
7. IF YOU HAD A TERMINATION PREVIO	USLY WHAT WAS THE REASON?
8. WHAT MADE YOU DECIDE TO HAVE PREGNANCY?	A TERMINATION IN THIS
FINANCIAL RELATIONSHIP CONFLICT TOO MANY CHILDREN TOO YOUNG TOO OLD SEXUAL ABUSE MEDICAL CONDITION STUDIES WORK OTHER (EXPLAIN ABOVE)	
9. ARE YOU IN A PERMANENT RELATION IF YES: MARRIED COHABITING OTHER (EXPLAIN) 10. DOES YOUR PARTNER LIVE WITH Y	
ALWAYS	
MOST NIGHTS	
NEVER	

PLEASE TELL PATIENT: **WE WOULD LIKE TO ASK YOU SOME QUESTIONS ABOUT SEX, YOU DON'T HAVE TO ANSWER IF YOU DON'T WANT TO.**

11. AT WHAT AGE DID YOU BECOME SEXUALLY

OTHER (EXPLAIN)

[Type text]				
ACTIVE?				
12. HOW MANY SE	XUAL PARTN	ERS DO YOU HA	VE?	
13. HOW MANY LIF	ETIME PARTI	NERS HAVE YOU	J HAD?	
14. IN THE LAST 6 I	MONTHS HO	W MANY PARTNE	ERS HAVE YO	U HAD?
15. WERE YOU USI	NG PREVENT	ΓΙΟΝ BEFORE YO	OU BECAME F	PREGNANT?
	Present	Time of Conception	Past	
Male Condom				
Female Condom				
Nuristerate				
Depo Provera				
Progesterone Only Pill				
COC				
Mirana				_
Mirena Dual (specify)				_
WHY WERE YOU US	SING THE ME	THOD YOU WER	E USING?	
16. DO YOU USE P	REVENTION /	ALL THE TIME, S	OME TIMES C	PR NEVER?
17. HAVE YOU EVEI	R BEEN TEST	ED FOR HIV?		
IF YES, WHEN:				
WHAT IS YOUR HIV	STATUS:			
WHAT IS YOUR MO	ST RECENT (DD4:		
WHEN WAS IT TAKE	=N·			

[Type text]
18. HAVE YOU DISCUSSED HIV WITH YOUR PARTNER?
19. DO YOU KNOW YOUR PARTNERS HIV STATUS?
20. WOULD YOU LIKE US TO TO TEST YOU FOR HIV?
21. WHAT METHOD OF PREVENTION DO YOU INTEND TO USE IN THE FUTURE?
22. HAVE YOU HAD ANY ILLNESS THAT PREVENTED YOU FROM USING ANY METHOD OF CONTRACEPTION?
THE FOLLOWING SECTION APPLIES TO THOSE WHO USED THE CONDOM AS THEIR METHOD
1. WHAT TYPE OF BARRIER METHOD DO YOU USE?
FEMALE CONDOM
MALE CONDOM OTHER, SPECIFY
2. DO YOU USE THE CONDOM SOME TIMES, ALL THE TIME, ONCE IN A WHILE:
3. DID YOU USE A CONDOM IN YOUR LAST SEXUAL ENCOUNTER(Y/N):
4. HAVE YOU EVER HAD CONDOM BREAKAGE/ SLIPPAGE - DESCRIBE.
HOW MANY TIMES?
WHAT DID YOU DO?
WERE YOU AWARE OF EMERGENCY CONTRACEPTIVE PILLS?

HAS IT CHANGED YOUR PREFERED METHOD OF CONTRACEPTION, IF YES HOW:
5. DO YOU USE THE CONDOM ALONG WITH OTHER METHODS, SPECIFY?
6. ARE CONDOMS EASILY ACCESSIBLE FOR YOU:
7. DO YOU GET THEM OR DO YOU RELY ON YOUR PARTNER TO FIND THEM:
8. HAVE YOU USED THE FEMIDOM (WHY/ WHY NOT):
9. WHY DO YOU USE THE CONDOM AS YOUR METHOD?
10. DO YOU USE PREVENTION MOSTLY TO PREVENT PREGNANCY/HIV OR BOTH?
11. WHY DO YOU THINK THE CONDOM DIDN'T WORK FOR YOU?
Thank you for your time!!!

Appendix 4: Ethics Clearance Form

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

R14/49 Dr Salome Maswime

CLEARANCE CERTIFICATE M10M101130

Evaluation of the Use of Barrier Contraceptives in **PROJECT**

Women Requesting Termination of Pregnancy at **CHBH**

INVESTIGATORS Dr Salome Maswime.

DEPARTMENT Department of Obstetrics & Gynaecology

26/11/2010 DATE CONSIDERED

DECISION OF THE COMMITTEE* Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon

application.

DATE

CHAIRPERSON (Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor: Dr Y Adam

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix 5: CEO Approval form

MEDICAL ADVISORY COMMITTEE CHRIS HANI BARAGWANATH HOSPITAL PERMISSION TO CONDUCT RESEARCH

Date: 16 November 2010

TITLE OF PROJECT:

An evaluation of the use of barrier contraceptives among women requesting termination of pregnancy at CHBH

UNIVERSITY:

Principal Investigator: Dr S Maswime

Department: Obstetrics and Gynaecology

Supervisor (If relevant):. Dr Y Adam

Permission Head Department (where research conducted) Yes

Date of start of proposed study: January 2011 Date of completion of data collection: May 2011

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur

permission is granted for the duration of the Ethics Committee approval.

PROF JOHN PETTIFOR MBBCh, FCP (S.A.)

Recommended

CHIEF PAEDIATRICIAN

(On behalf of the MAC)

Date: 16 November 2010

Approved/Net Approved

Hospital Management

Date: 19 Now 2010