

UNIVERSITY OF THE WITWATERSRAND
MASTER'S IN PUBLIC HEALTH (MPH) DEGREE

**EXPERIENCES OF WOMEN USING ETONOGESTREL CONTRACEPTIVE
IMPLANT AND REASONS FOR REMOVAL IN TSHWANE DISTRICT, GAUTENG**

“A Research Report submitted to the School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in Partial Fulfilment of the Requirements for the Master’s degree in Public Health (Maternal and Child Health)”

Researcher: Mrs. Noluthando Bunu

Student Number: 1449059

Research Supervisor: Dr Juliet Nyasulu

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DECLARATION

I declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Public Health at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other university.

A handwritten signature in black ink, appearing to be 'D. P. ...', written in a cursive style.

(Signature of candidate)

30 day of April 2021 at Pretoria

Abstract

Etonogestrel, also called Implanon, is one of the new contraceptive implant methods that is highly effective and convenient. Regardless of several benefits, women still access health facilities to request removal of this contraceptive implant before the expiry date. South Africa reported early removals of Implanon by users after a successful launch in the Public sector in 2014, with high uptake. Tshwane district in Gauteng, specifically, experienced high rates of Implanon removal before expiry date. However, no study has been conducted in Tshwane District to assess implementation of the new contraceptive method and focuses on the experiences of the users and the reasons for early removal. Therefore, the aim of the study was to describe women's experiences of using the etonogestrel contraceptive implant and to determine the reasons for early removal of the implant among women in Tshwane District.

This was a qualitative research study using in depth interviews to collect data from 22 women aged between 18 to 49 years. These women had accessed primary health care services in Tshwane District for removal of the Implanon and voluntarily consented to participate in the study. An interview guide was used to elicit the information and data was analysed using thematic content analysis.

The study revealed that women chose the contraceptive implant because it was convenient and effective. Regardless of the benefits of Implanon, women decided to remove the contraceptive implant before the expiry date due to intolerable side effects such as irregular bleeding, dizziness, headache, weight gain or weight loss. The study also established gaps in counselling services rendered by professional nurses, management of side effects and follow up thereafter, which is similar to what was found in other studies.

There is therefore a need for health care providers to be trained adequately on counselling, management of side effects and further follow up to help improve the sustained use of this contraceptive implant by women. Additionally, clear guidance on the post insertion follow up process, counselling and management of side effects specific to the etonogestrel contraceptive implant should be incorporated in the training. This is currently not outlined in the National Contraceptive Clinical guidelines.

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Definition of Terms

The following terms will be defined to help develop clear understanding and meaning related to this study.

Implanon - A one-rod implant contraceptive inserted under the skin of a woman's upper arm, that is effective for three (3) years to prevent pregnancy, and it contains the hormone etonogestrel (1).

Primary healthcare facility – In this study refers to the health care facility that normally provides first level health care services including sexual reproductive health services operating for eight or more hours a day. It also refers to where the data collection will take place for this study.

Contraceptives methods

In this study, a 'contraceptive' is defined as an agent used by women to prevent conception or impregnation; such as condoms, birth control/hormonal pills and injections, contraceptive loop & diaphragm, contraceptive implant, etc.

Experience - Is a representation and an understanding of a researcher or of a research subject's human experiences, choices, and options, and how these factors influence one's perception of knowledge (2).

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Chapter 1

1.0 Introduction

In this chapter, the researcher introduces the study through the following sections:

Background, the rationale for undertaking this study, the problem statement and the justification for the study. This is followed by the aim and objectives of the study.

1.1 Background

Etonogestrel contraceptive implant is a matchstick sized single rod containing 68 mg of etonogestrel that is inserted sub dermally in the non-dominant arm under local anaesthesia (3-5) It prevents pregnancy by inhibiting ovulation and thickening the cervical mucus. Women using this contraceptive implant are protected from pregnancy for a period of three years (3, 5). It is the most effective reversible contraception method, and is said to be 99% effective (3).

Etonogestrel might be highly effective but like any other contraceptive method, it has its advantages and disadvantages. An advantage of etonogestrel is the convenience of not having to remember the next date for the injection or dose of oral contraceptives (depending on which the women has selected) for three years after implantation (3, 5, 6), Additional advantages include significant reduction of dysmenorrhea, the fact that it can be safely used during breastfeeding, and the quick return to fertility after removal of the implant (3, 5).

The side effects of etonogestrel include irregular bleeding (which is usually resolved within six months), weight gain, breast tenderness, headaches, mood changes, gastrointestinal difficulties, acne and vaginitis (7, 8). Etonogestrel is also known to be less effective in women taking certain medications due to drug interactions, for example anti-retroviral and tuberculosis drugs (5). It is therefore important that healthcare professionals are trained, not only in counselling skills, but also on how to insert and remove an implant (4, 9). They should also be trained on how to counsel women properly about the advantages and possible side effects, so that they are empowered to make an informed decision (10).

Popularity of contraceptive implants varies in different parts of the world. In Great Britain, only 2.6% of women of child bearing age use an implant compared to 1% -2% in France (11). A number of studies conducted in Europe, United States, and Australia showed that the contraceptive implant is acceptable to young women, with continuation rates ranging from 80% to 86% after 12 months (11, 12).

In Sub Saharan Africa, the picture is different. The uptake of implants has increased in countries like Tanzania, Rwanda, Ethiopia and Malawi (which doubled its uptake) (3). In Zimbabwe, implant use increased from less than 1% in 1994 to 10 % by 2015 (3).

Studies conducted in African countries like Nigeria and Ethiopia showed a discontinuation rate of 8.1% and 54% respectively, within one year of contraceptive implant use (4, 10, 11). Side effects of the contraceptive implant were the main contributing factors of early removal of contraceptive implant (4, 12, 13).

In February 2014, etonogestrel was launched in South Africa and made available in public health facilities. Training was conducted throughout the country during this time (14). Three years after a successful launch with good uptake, there were concerns about the declining number of women using etonogestrel as a method of contraception (14). The decline in etonogestrel implant use was accompanied by media reports of early removals of the implants (14). Not many studies have been conducted to evaluate the experiences of women using the contraceptive implant in South Africa. Mgobhozi (2017) explored women's experiences and perceptions on the use of Implanon as a contraceptive method in KwaZulu -Natal and found that 58.1% of the participants were still happy with the method, and 40.9% had stopped using the method because of the side effects (which included heavy menstrual bleeding and low sex drive) (15).

A study conducted by Pillay *et al* (2017) in the City of Johannesburg and North-West Province showed that etonogestrel is acceptable to women of child bearing age, although the concern in this study was that only 15% of users were less than 25 years (14). Eighty-two percent of users had their contraceptive implant removed within 12 months, which is concerning, especially when the use of contraceptive implant is in its early stages in the public sector. The reasons for early removal of the implant were in line with studies conducted in other countries, these included side effects such as changes in bleeding patterns. Rumours and misinformation were also reported as factors contributing to removals (3).

1.2 Rationale

Studies conducted globally and in South Africa have shown high rates of contraceptive implant removals. Studies conducted in Nigeria and Ethiopia showed a discontinuation

rate of 8.1% and 54% respectively, within one year of contraceptive implant use (4, 16, 17). This is supported by a cross sectional quantitative study conducted by Asaye (2018) in North west Ethiopia which showed that the early discontinuation rate was 65%, which was high.

In a cross sectional quantitative study conducted by Mrwebi *et al* (2018) in Eastern Cape, 67.3% discontinued within the 1st year of Implanon use.

The reports submitted by the facilities on Implanon removals in Tshwane District showed a rise in removal rate. Not much is known about the individual experiences of using the contraceptive implant beyond the common discontinuation rate. The reasons for early removal are also not well understood. No study has been conducted in Tshwane district to explore the experiences of women using the etonogestrel contraceptive implant. Therefore, this study will focus on exploring the experiences of women using the etonogestrel contraceptive implant as well as reasons for removal in Tshwane District.

1.3 Problem Statement

The department of health introduced the etonogestrel contraceptive implant as part of their strategy to expand on methods available to the public to reduce unplanned pregnancies (18).

According to the Tshwane District Health Information System (DHIS) (unpublished data), 4827 etonogestrel contraceptive implants were inserted from April 2015 to March 2016. There were 2888 implants inserted from April 2016 to February 2017. The DHIS only started capturing data on the etonogestrel contraceptive implant removals in April 2016 and the data showed that 2523 implants were removed from April 2016 to January 2017. This shows that a number of implants were removed

before the expiry date, however, it was expected that a number of users would start removing their implants mostly from February 2017, when they expire. Only 412 were removed during the month of February due to expiry. No study has been conducted in Tshwane District to explore the reasons for early removal of the contraceptive implant.

This study aims to investigate women's experiences of using the etonogestrel contraceptive implant. It also aims to determine the reasons for early removal of the implant among women attending primary health clinics in Tshwane District.

1.4 Justification for the study

The National Department of Health introduced the etonogestrel contraceptive implant as part of a strategy to expand the contraceptive methods available in the public sector, in an attempt to reduce unplanned pregnancies (5). This contraceptive method has been available in the public sector for four years. However, it has already shown a decline in its uptake as well as early removal of the implant by users. It is important that this is investigated to identify and address gaps so that the Department of Health's strategy succeeds (5).

As indicated above, few studies have been conducted in South Africa to assess the implementation of the new contraceptive method, specifically pertaining to the experiences of the users and the reasons for early removal. Therefore, establishing women's experiences, successes, gaps and recommendations in the etonogestrel

contraceptive implant services at district level is critical to improve the quality of contraceptive services rendered in the district.

Furthermore, this study will contribute to the knowledge base and assist in improving the implementation of contraceptive and fertility services in Primary Health Care facilities, using research-based findings.

1.5 Aim of the study

The aim of the study was to explore women's experiences of using the etonogestrel contraceptive implant during January 2016 to December 2018 in Tshwane District, South Africa.

1.6 Study objectives

The objectives of the study were to:

- 1 Describe women's experiences of using the etonogestrel contraceptive implant in Tshwane District from January 2016 to December 2018.
- 2 Explore reasons for early removal of the etonogestrel contraceptive implant among the women of Tshwane District.
- 3 Suggest possible facilitators to the use of the etonogestrel contraceptive implant among women in Tshwane District.

Chapter 2: Literature Review

2.0 Introduction

This chapter provides a description of etonogestrel and a review of the literature on this contraceptive implant. Findings of the literature review relating to the uptake of contraceptive implants, including factors associated with early removal of contraceptive implants and the theoretical framework applied in analysing this topic is outlined.

2.1 Etonogestrel contraceptive implant

The etonogestrel contraceptive implant is a matchstick sized single rod containing 68 mg of etonogestrel that is inserted sub dermally in the non- dominant arm under local anaesthesia (3-5). It prevents pregnancy by inhibiting ovulation and thickening the cervical mucus. Women using the etonogestrel contraceptive implant are protected from pregnancy for a period of three years (3, 5). The etonogestrel contraceptive implant is the most effective method of long acting reversible contraception, it is said to be 99% effective (3).

The etonogestrel contraceptive implant might be highly effective but, like any other contraceptive method, it has its advantages and disadvantages. The advantages of etonogestrel include convenience, which means that after insertion of the implant, the woman does not have to worry about remembering the next date of injection or the next dose of oral contraception for the next three years (3, 6). Significant reduction of dysmenorrhea, ability to be safely used during breastfeeding, quick return to fertility after removal of the implant are also some advantages of the etonogestrel contraceptive implant (3, 5).

The side effects of the etonogestrel contraceptive implant include irregular bleeding (which usually subsides within six months), weight gain, breast tenderness, headaches, mood changes, gastrointestinal difficulties, acne and vaginitis (7, 8). The etonogestrel contraceptive implant is also known to be less effective in women taking certain medication due to drug interaction, for example anti-retroviral and tuberculosis drugs (5). Health care professionals who administer the implant need training on counselling skills and skills on how to insert and remove the implant (4, 9, 10). Before insertion of the etonogestrel contraceptive implant, women need to be counselled properly about the advantages and possible side effects so they can make an informed decision (10).

2.2 Uptake of contraceptive implant

Long acting reversible contraceptives which include contraceptive implants are known to be effective and safe, but irrespective of that, they are underutilised worldwide. About 5% of women use progesterone injectables, 14% use an intra uterine device and only 3.4% use contraceptive implants (19). Popularity of the implant as a method of contraception varies in different parts of the world, in other areas slower whereas in others, the use is increasing at a faster rate.

In Great Britain, only 2.6% of women of child bearing age were using an implant compared to 1% -2% in France, indicating a low uptake (11). However, in Sub Saharan Africa the picture is different as the uptake of implants is increasing in countries like Tanzania, Rwanda, Ethiopia and Malawi, which doubled its uptake. In Zimbabwe, implant use increased from <1% in 1994 to 10 % by 2015 (3). In countries as diverse

as Burkina Faso, Ethiopia, the Democratic Republic of Congo, Ghana, Kenya and Senegal, implant use now accounts for one-fourth to one-half of all modern contraceptive method use (20).

Regardless of the benefits of long-acting reversible hormonal contraceptive methods, the uptake of these methods, which include contraceptive implants, is still low in South Africa. An increase in the uptake of these methods can reduce the number of unplanned pregnancies in South Africa (19). In February 2014, the etonogestrel contraceptive implant was launched in South Africa and it was made available in public health facilities. Training was conducted throughout the country (14). Three years after a successful launch with good uptake, there were concerns about the declining number of women using etonogestrel as a method of contraception (14).

Moodley and Mahomed (2018) conducted a study on the prevalence and predictors of the Implanon uptake in Ugu, Kwa Zulu-Natal. The results showed that participants were not willing to use the Implanon due to fear of side effects and the invasive insertion procedure. This was despite them having adequate knowledge about the implant (65,7%) (21).

In contrast to the study by Moodley and Mahomed (2018), the findings from the study conducted by Pillay *et al* (2017) in North West and City of Johannesburg showed that about 90% of the removals of the contraceptive implants were requested by the users and not initiated by the providers (14).

A qualitative study by Rabopape *et al* (2019) showed that health professionals lacked training and were not competent in inserting and removing the implant. Furthermore, their lack of adequate counselling skills resulted in fear amongst the adolescent girls, which lead to a poor uptake of the Implanon amongst them (22).

2.3 Factors associated with early removal of contraceptive implant

Most women opt for the contraceptive implant as a method of contraception because of its convenience and one does not have to visit the health facility often. Regardless of the advantages of the contraceptive implant, other users discontinue its use before the expiry date due to various reasons. Quantitative and qualitative studies were conducted globally and nationally to explore reasons for early removal of the Implanon.

In a study conducted by Mastor *et al* (2011) in Malaysia by collecting data from medical records and telephonic interviews, most of the participants (70%) complained about irregular menses which, was the main reason for discontinuation of the implant (23). The results from the qualitative study by Flore *et al* (2016) in Australia were not different from other studies as the findings showed that the main reason for early removal was bleeding. Other side effects included mood swings, skin changes and weight gain (6).

Hoggart and Newton (2013) in Eltham, UK conducted a qualitative study on young women's experiences of the side effects of implants and found that the reason why some young women have them removed is due to intolerable side effects (24). They further stated that they were not warned about the possible side effects.

A descriptive cross-sectional study conducted by Burusie (2013) to determine the reasons for premature removal of the Implanon in Arsi Zone in revealed that heavy bleeding, planning pregnancy, planned trips abroad and pain on the insertion arm were the main reasons why participants decided to remove the implant (10).

A facility based cross-sectional study conducted by Asaye (2018) in North west Ethiopia showed that the early discontinuation rate was high at 65%. The factors

contributing to early removal of the Implant included planned pregnancy, and side effects experienced by users. The study also showed that women who did not receive adequate counselling about the possible side effects were more likely to remove the contraceptive implant earlier than those who were adequately counselled. Also, failure by health care workers to provide follow up dates after the insertion of the contraceptive implant contributed to early removals (25).

The findings in a quantitative study conducted by Birhane *et al* (2015) are similar to those in the study by Asaye (2018), although the overall early discontinuation rate was 16%, reasons for early removal of the implant were planned pregnancy, side effects experienced and failure to set follow up dates after the insertion (7).

Madugu *et al* (2015) conducted across-sectional study involving the reviewing of client records in Nigeria, the major side effects of the implant were menstrual irregularities which were also the major reason for early removal. Other reasons for removal included headache, weight gain, mood swings, abdominal bloating and desire for pregnancy (13).

A South African cross-sectional quantitative study conducted by Mrwebi *et al* (2018) showed that the median duration for Implanon use was 10 months, with the majority of the participants removing it because of side effects such as heavy bleeding, severe headaches and pain in the insertion arm. Wrong positioning, planned pregnancy, and receiving other medication such as anti-retroviral drugs, antipsychotic and antituberculosis drugs also contributed to early removal of the implant (26).

Removal of the Implanon for women on antiretroviral treatment still needs to be clarified for health professionals, according to the study by Payra *et al* (2015). Although the effectiveness of the etonogestrel is decreased by efavirenz, pregnancy rates were still lower than those amongst women using other contraceptive methods like

injectables (27). The emergence of dolutegravir in the new antiretroviral guidelines has brought hope that women will be able to use the contraceptive implant freely as there is no drug interaction between dolutegravir and etonogestrel (28).

A qualitative study conducted by Adeagbo *et al* (2017) on the uptake and early removals of the Implanon NXT in South Africa revealed that the highest contributing factor for early removals was side effects, especially irregular bleeding as well as the lack of support from the partners of implant users. Furthermore, the findings showed that there was still a need for providers to receive training on counselling skills and on the standardised guidelines used for managing side effects (29).

In South Africa, the rate of unplanned pregnancies is still high amongst HIV positive women and adolescent girls. Furthermore, the number of women accessing termination of pregnancy services is also on the rise (5). It is therefore imperative that long acting reversible methods which include contraceptive implants are promoted in the public health facilities. The environment in the public health facilities should also be conducive to an increase in the uptake of these methods through adequate training of health professionals, both nurses and doctors with, emphasis on counselling and mentoring until one is competent.

2.4 Theoretical framework of guiding the study

The theory of planned behaviour (TPB) is the most widely used theory in the environmental psychology and it is referred to in literature where contraceptive use and decision making are concerned (Ajzen, 1991 in Conner 2010). The theory provides a comprehensive framework for understanding the determinants of specific intentions and behaviours. According to the TPB, human behaviour is guided by three kinds of considerations:

- Perceived behavioural control,

- Behavioural beliefs and,
- Subjective norms

Perceived behavioural control is a person's anticipation that the performance of the behaviour is in their control. Behavioural beliefs are beliefs about the probable consequences of the practiced behaviour which normally result in a favourable or unfavourable attitude towards that behaviour. Subjective norms refer specifically to how others will perceive the action (30)

Application of TPB in this study:

Perceived behavioural control would be the woman's capacity to make a decision to insert and/or remove the contraceptive implant.

Subjective norms refer to the belief about whether most people approve or disapprove of the behaviour. These could be family members, friends or health care workers. In this study, the subjective norms would be the women's perception of whether her decision to remove the contraceptive implant would be socially acceptable or not.

Attitudes is an individual 's evaluation of performing a particular behaviour, it can be favourable or unfavourable. It refers to a women's perception of whether removing the contraceptive implant was a good decision or not.

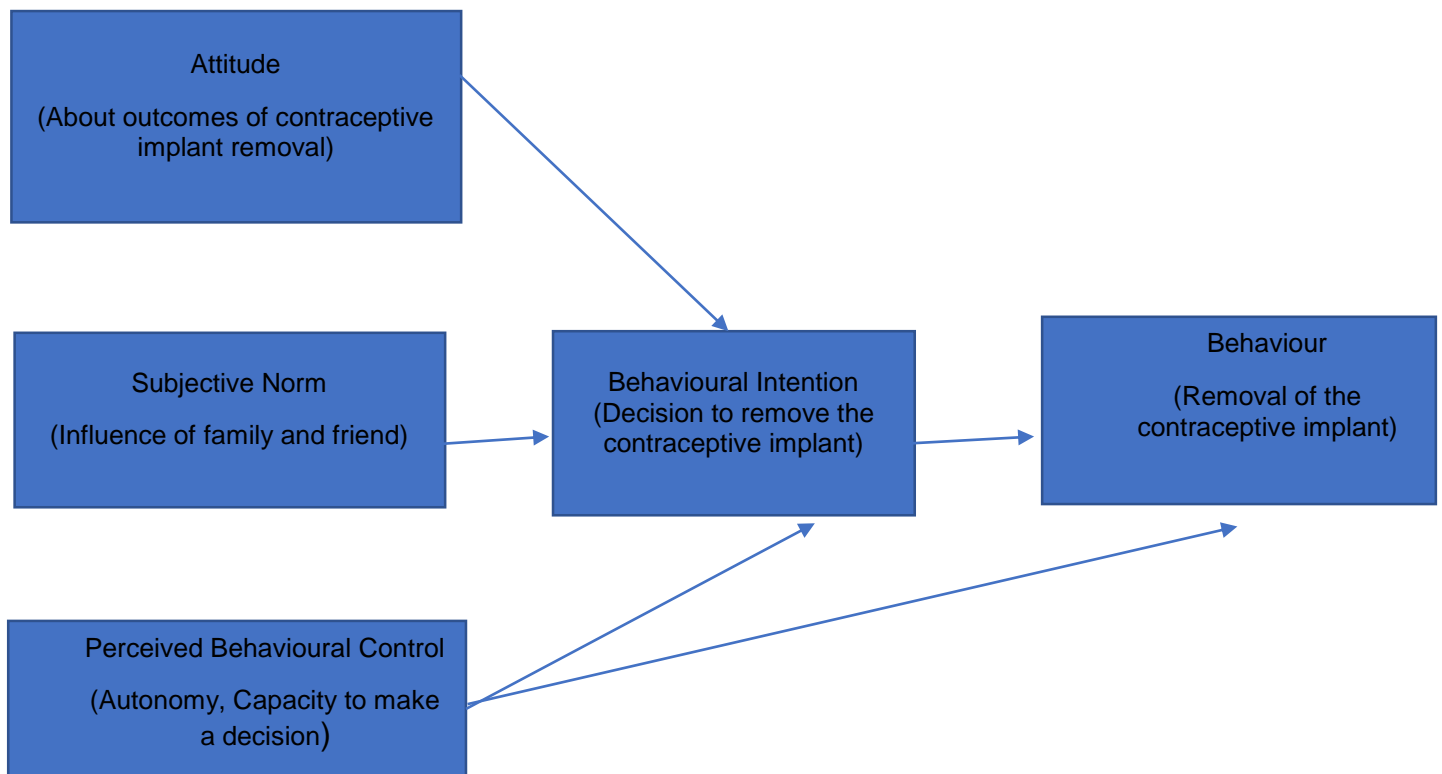


Figure 1: Theoretical framework adapted from the TPB (Ajzen ,1991, in Conner 2010)

2.5 Conclusion

In this chapter, overview of Implanon, its benefits and disadvantages, women's experiences and the reasons for removal were discussed. Research studies that were conducted globally and nationally on women's experiences including reasons for early removal of Implanon were explored and various reasons were identified. The theoretical framework guiding the study was also discussed. In the next chapter, the research methodology of the study will be discussed.

CHAPTER 3: Research Methodology

3.1 Introduction

This chapter provides an outline of the research methods that were implemented in this study. The research design, study site, study population, sampling technique, data collection procedure, data analysis and ethical considerations are discussed. In addition, methods used to ensure trustworthiness are explained.

3.2 Study design

The study design refers to a plan that guides the researcher in the process of data collection, its analysis and the interpretation of the findings (31, 32). This was a cross-sectional qualitative research study done through interviews with women using the etonogestrel contraceptive implant. Qualitative research emphasises the dynamic, holistic and individual aspects of the human experience, and it attempts to capture those experiences in their entirety, within the context of those experiencing them (32). Therefore, the qualitative design was found to be particularly useful in exploring and describing the experiences of women using the etonogestrel contraceptive implant as a method of contraception, in Tshwane District from January 2016 to December 2018.

3.3 Study site

The study was conducted in the Primary Health Care facilities of Tshwane District, Gauteng Province. These facilities form part of the Tshwane District Health Services. Three facilities operate in sub-district three and four facilities operate in sub-district six, giving total of seven facilities as shown in Table 1 below.

Table 1: Names of Primary Health Care Facilities: the sample facilities of study site

| Sub-district | Name of facility |
|---------------------|-------------------------|
| Sub-district three | Skinner Clinic |
| | Bophelong Clinic |
| | Laudium CHC |
| Sub-district six | Stanza Bopape CHC |
| | Eersterust CHC |
| | Holani Clinic |
| | Ubuntu Clinic |

3.4 Study Population

The target population for this study was all women of child bearing age between 18 to 49 years who accessed contraception services for contraceptive implant removal in Tshwane district.

3.5 Study Sample

Sampling of facilities

Tshwane consist of seven sub-districts of which, two were purposively selected for this study (sub-districts three and six). Sub-district three has one community health centre and three clinics, with sub-district six having two community health centres and two clinics. Facilities that took part in the study are those which form part of sub-district three and sub-district six, in which the researcher coordinates maternal and women's health services under Provincial administration.

Sampling of participants

Participants for this study were selected through purposive sampling. Nurses who are working in the participating facilities assisted with the identification of potential study participants. The inclusion criteria for participating in the study was as follows:

- Participants had to be women between the ages of 18 and 49 years who have experienced the removal of the contraceptive implant.

- Participants had to be clients who accessed contraception services for contraceptive implant removal in one of the seven facilities in sub-districts three and six. Both booked and walk in clients were eligible to participate in the study.

3.6 Data collection

3.6.1 Data collection tool

The researcher collected data using semi-structured interviews. The interview guide (Appendix 4) included questions about the participant's demographics, their reasons for opting for implant as a method of contraception, concerns about the implant, reasons for deciding to remove the implant, reasons for keeping the implant (for the women who kept the implant until expiry date) and the overall experience of using the implant. The researcher arranged with the facility manager and the professional nurse working in sexual reproductive health for a private room where the interviews could be conducted prior to going to the facilities for data collection. Booked and walk in clients meeting inclusion criteria for the study were recruited by the professional nurses working in sexual reproductive health services and potential participants were shown the consulting room where the briefing about the study was going to take place.

3.6.2 Pilot study

The study tools were piloted at Stanza Bopape Community Health Centre before commencing with data collection for the study. A pilot study was conducted to determine whether the methodology, sampling, instruments and analysis were adequate and appropriate (33). The interview guide was piloted using two participants. The participants were identified according to the criteria set out in the study. The interviews were transcribed and analysed. This assisted the researcher in identifying

potential problems that may have occurred during the research process. Questions that were not clearly understood by the participants were clarified and amended in the data collection tool. The pilot study gave the researcher an opportunity to test the effectiveness of the audio recorder and to modify the data collection tool. The process also provided insight in determining the time it might take to complete the interview. Data from the pilot study was not included in the final report of the study.

3.6.3 Data collection process

The nurses from the participating facilities alerted the researcher on the women booked for Implanon removal in their facilities. These women were interviewed by the researcher after the removal of the contraceptive implant. The interviews were conducted in English by the researcher and audio recorded, each interview lasted for an average of 20 to 30 minutes. The researcher continued with the interviews until enough data was collected and there were no new themes that emerged. A total of 22 women were interviewed.

3.7 Data processing and analysis

Data analysis was done manually using thematic analysis. Braun and Clarke (2006) explain thematic analysis as a method of identifying, analysing and reporting themes within data (15). Before the analysis, the researcher transcribed the audio recorded interviews verbatim into a MS Word transcript document.

The researcher then repeatedly read through the transcripts to try and gain an understanding and sense of the interview as a whole. The researcher identified codes from the first five scripts. The initial codes were revised until the researcher was satisfied that the codes were appropriate. The codes were then applied to the rest of the scripts. After coding, the researcher identified emerging themes, which in

turn were developed into theme clusters and ultimately into theme categories. These themes are presented in chapter four.

3.8 Position of the researcher

The researcher coordinates a Maternal and Women's Health Program in Tshwane District. The program provides sexual reproductive health services which include contraceptive services. The key responsibilities of the researcher include ensuring that facilities have policies and that health care workers are trained on them and adhere to them. It is part of the researcher's responsibilities to ensure that contraceptive services rendered in the district are of good quality. It is also to assist the facilities to identify gaps and come up with plans to improve the implementation of contraceptive services. This study is going to assist with the identification of gaps in the implementation of contraceptive services.

The researcher was careful not to be bias during the analysis. The researcher remained aware of her professional background, previous experience and knowledge including personal assumptions.

3.9 Measures to ensure trustworthiness

The value of this proposed study was based on an assessment of trustworthiness, using the criteria of credibility, transferability, dependability and confirmability (34).

3.9.1 Credibility

Krefting refers to the ability of a qualitative study to present accurate descriptions or interpretations of human experiences in such a way that people who share that experience would immediately recognise the descriptions (34). A pilot study was carried out to increase the credibility of the study as well as to gain clarity on issues

that may be faced during interviews. The participants of the study were selected using purposive sampling, which also increased the credibility of the study as data was collected from participants who have experienced the etonogestrel implant as a method of contraception.

3.9.2 Applicability

Applicability refers to the degree to which the findings can be applied to other settings, contexts or other groups (34). The strategy used to attain applicability is transferability. In this study, the researcher ensured applicability by using purposive sampling with participants that have experienced the use of the etonogestrel implant. The researcher has provided a dense description of the research design and methodology. Interviews were analysed to make sure they were coded and interpreted in a consistent manner, and a dense description of findings was done.

3.9.3 Consistency

The criterion for consistency is concerned with the extent to which the replication of the study in a similar context and with similar participants will yield consistent findings (34). Dependability is the strategy that is used to establish consistency. In this study dependability was established through complete description of the research design and methods to ensure that it can be duplicated. Code-recode procedures were followed when data was analysed.

3.9.4 Neutrality

Neutrality refers to the degree to which findings are truly respondents' responses and are free from bias in the research process and the findings (34). The strategy used to ensure neutrality is confirmability. In this study confirmability was ensured through auditing the data with emphasis on the important steps which ought to be taken during data analysis.

3.10. Ethical considerations

This study sought ethical approval from the Human Research Ethics Committee of the University of Witwatersrand (Appendix 8).

Permission to conduct the study was also granted by the Tshwane District Research Council (Appendix 6) and by Gauteng's Department of Health (NHRD REFERENCE NUMBER GP 201905002). Informed consent for the interview (Appendix 2) and audio recording (Appendix 3) was given by the participants. It was only after the potential participant had signed to give consent that the researcher continued with the interview. For confidentiality, the names of the participants were not used. In addition, the files with the transcripts, the recorded tapes and consent forms will be kept under lock and key for a period of six years.

3.11 Conclusion

This chapter covered a description of the research process, methodology and the data collection methods that were applied. This was a qualitative research study, including qualitative cross-sectional interviews, to collect data from women using the etonogestrel contraceptive implant. The study sample was drawn from a population of women who had accessed primary health care services in Tshwane District for removal of the Implanon, and voluntarily consented to participate in the study. Permission to conduct the study was granted by the management of all involved institutions before the recruitment and selection of the participants. The pilot interview was conducted with two participants. Data was collected from 22 participants through semi-structured individual in-depth interviews conducted by the researcher. Analysis of the data was done manually using thematic analysis. The validity of the data was assured by adhering to the four criteria of assessing validity in qualitative research, namely: credibility,

transferability, dependability and confirmability. Ethical approval was obtained from the Human Research Ethics Committee of the University of Witwatersrand. The next chapter contains the findings of the study.

Chapter 4: Findings

4.1 Introduction

In this chapter, the findings of the data collected using in depth interviews with women using the etonogestrel contraceptive will be presented. In the first section, the demographic profile of the participants will be presented. This will be followed by a section on the themes that emerged during the data analysis process and these will be presented using direct quotations. The aim of the study was to explore women's experiences of using the etonogestrel contraceptive implant.

4.2 Section A: Socio- demographic characteristics

A total of 22 women using the etonogestrel contraceptive implant participated in the study. The age of the participants ranged between 18 and 44 years. Fourteen had completed high school education, four had tertiary education, three were in grade 12 at the time of the study, and one participant had dropped out of school in Grade 10. Only one participant was of the Islamic faith, the rest of the participants were of the Christian faith. Fifteen participants were single, six were married and only one was engaged to be married. Ten of the participants had some source of income through either employment or self-employment, seven were unemployed while the rest of the participants were still studying.

4.3 Presentation of themes

Table 2: Themes and sub-themes obtained from the experiences of women who use(d) the etonogestrel contraceptive implant and their reasons for removal.

| Themes | Sub-themes |
|--------------------------|---|
| 1. Reasons for insertion | 11. Motivation by family member or friend 1.2. Convenience of using the contraceptive implant 1.3. Other contraceptives being out of stock in health care facilities 1.4. Coercion |

| | |
|--|--|
| 2. Counselling and follow-up care | 2.1. Counselling before the insertion of the contraceptive implant 2.2. Follow up check-ups after the insertion of the contraceptive implant |
| 3. What the participants liked about using contraceptive implant | 3.1. Effectiveness of the contraceptive implant 3.2. Absence of side effects 3.3. Less visits to the facilities for contraceptive services |
| 4. Reasons for removal of the contraceptive implant. | 4.1. Heavy menses / Irregular bleeding 4.2. Dizziness 4.3. Headache 4.4. Weight gain 4.5. Weight loss |
| 5.Improvement on retention of women for contraceptive implant | 5.1. Proper counselling services before the insertion of the contraceptive implant 5.2. Improve management of side effects |

4.4. Women’s experiences in using the etonegestrel contraceptive implant.

Qualitative data was collected from 22 women, who accessed a health care facility to remove the Implanon, through an in-depth interview. These women were asked to describe their experiences of using the etonogestrel contraceptive implant. In addition, reasons for requesting early removal of the etonogestrel contraceptive implant and possible solutions to promote the use of the implant were explored. From these in-depth interviews, five main themes, namely: “Reasons for insertion”, “Counselling and follow-up care”, “What the participants liked about using contraceptive implant”, “Reasons for removal of the contraceptive implant,” and “Improvement on retention of women for contraceptive implant” were developed with subthemes as shown in Table 4.3 above.

4.5 Women's reasons for choosing the etonogestrel contraceptive implant

When the experiences of women who use the contraceptive implant as method of contraception were explored, different reasons were mentioned. The participants mentioned motivation by a family member or friend, convenience, other contraceptive methods being out of stock in health facilities and being coerced into inserting the contraceptive implant as the main reasons for inserting the contraceptive implant.

4.5.1 Motivation by family member or friend

Most of the participants mentioned that they learnt about the contraceptive implant from friends and family. Some of the participants indicated that they were motivated to insert the contraceptive implant by a friend or family member. This means that they went to a health care facility having already decided on the implant as a contraceptive method, as indicated in this quotation:

"I heard it from my friend, she has the implant and does not give her problems she still has it even now and then I came to insert it". (Stanza 02)

The same sentiment was shared by another participant. She said:

"Uhm, I heard from my friend. Yes, then I decided to insert it". (Laudium 03)

4.5.2 Convenience of using contraceptive implant

The participants highlighted that because the contraceptive implant is effective for three years, it was convenient to use, unlike the injectable that only last for three months or the oral contraceptive which needs to be collected monthly. The visits to the facility are also limited. This was illustrated in the following statements:

“...It was convenient for me because I felt that three years, it’s going to stay for three years I don’t have to go for injection now and then”. (Eersterust 02)

4.5.3 Other contraceptives being out of stock in health care facilities

There were some participants who felt that they did not really have a choice. These participants stated that they had come to the facility for continuation of the oral/injection contraceptive method, but was out of stock at the time. The implant was the only available contraception and they had no choice but to opt for it. This is indicated in this quotation:

“I was at the clinic for the injection and they said they are finished, the only thing available is the implant and loop and they said I had to choose, and I chose the implant.” (Ubuntu 02)

4.5.4 Coercion

Four participants indicated that they did not choose the implant contraception. They stated that they were coerced to insert the implant. These are the participants who were denied discharge from the hospital unless they agreed to have the implant inserted. Others had the implant inserted because of defaulting on their injectable method. This is illustrated in the following statements:

“To put this in. So, I was jumping my dates, for the injection, yes, so here at the clinic, they decided to put me the implant.” (Bophelong 03)

“No, I didn’t have choice, they told me if I didn’t insert then we won’t discharge you, then I didn’t have a choice”. (Bophelong 04)

4.6 Women's experience of counselling and follow-up care

Participants were asked about counselling received before the insertion of the contraceptive implant and the advice given post insertion. Most participants expressed that they received some information about the Implanon, however there were participants who did not receive any counselling and one participant could not remember the details of the processes during implant insertion as it was inserted five years ago. Furthermore, not all of the participants were given follow up dates for check-ups post contraceptive implant insertion.

4.6.1 Counselling

Participants highlighted that they received counselling before the insertion of the contraceptive implant although most of the participants felt that the information that was given to them before the insertion of the contraceptive implant was not sufficient enough to help them make an informed decision. There were some participants who did not receive counselling at all and one participant could not remember as she had inserted the implant five years ago. This is indicated in this quotation:

*They just explained to me not any counselling per se, they just explained to me how it works that it will be for three years then give me a booklet with information.”
(Eersterust 01)*

4.6.2 Follow up care

Most participants stated that there was no scheduled follow up dates post contraceptive implant insertion apart from a few participants who were scheduled for follow up appointments, two of the participants were told to come back if they are experiencing any problems. This is indicated in these quotations:

“Mhm no they just told me that like I should just come to the clinic if maybe I’m having any problems regarding the implant”. (Laudium 01

“If I have a problem, I can come to the clinic but me I don’t have a problem, that it why I didn’t come to the clinic”. (Laudium 05)

Follow up care enables the health care worker to determine if the user is experiencing any problems from using the implant contraceptive. It also helps with addressing any concerns the user may have and also provides an opportunity for further counselling.

4.7 Women’s positive experiences of using contraceptive implant

Some of the participants verbalised being happy and satisfied with the contraceptive implant for various reasons. The participants were happy about the fact that it provides protection from unwanted pregnancy. In addition to effectiveness, the absence of side effects contributed to satisfaction with the contraceptive implant. Two participants were happy with the method but had to remove it because it had expired and they requested reinsertion afterwards. Furthermore, one participant who wanted to conceive did not experience any problems with the contraceptive implant.

The statement below demonstrates that:

“I liked the fact that it was helping to prevent pregnancy”. (Stanza 03)

“It’s treating me well like my body is still the same, I am having my periods, it’s really treating me well”. (Stanza 04)

On the other hand, other participants were thrilled with the fact that they do not have to visit health care facilities often to access contraceptive services. This is illustrated in this statement:

“At first what I was liking about it is because I don’t have to go to the clinic now and then”. (Bophelong 05)

One participant who was on antiretroviral treatment had been using the contraceptive implant for two years and four months and was happy with it. She however had to remove the implant because she was pregnant.

4.8 Women’s reasons for removing the contraceptive implant

In this study, the analysed data revealed numerous reasons why the participants decided to remove the contraceptive implant. Despite the benefits of the contraceptive implant which include effectiveness and convenience, participants decided to remove the implant before the expiry date. Most of the reasons for early removal were related to the side effects they experienced with the implant contraception. The participants reported irregular bleeding and heavy menses, dizziness, headache, weight gain and weight loss as the main reasons for removing the contraceptive implant before the expiry date. The statements below demonstrate that:

“It’s because of this, the bleeding I couldn’t handle it anymore.” (Eersterust 01)

In addition, some participants experienced other side effects as well. Three participants reported concerns over the dizziness they were experiencing as a result of the implant. This was indicated in this statement:

“I’m here for removal, my mom said I must come and remove it because it doesn’t suit my body, I’m always dizzy things like that.” (Stanza 03)

There were other participants who reported that the decision to remove the contraceptive implant was due to constant headaches as indicated in this statement:

“Yes, the only problem was that I always had headaches and I consulted a doctor and he said it’s the implant”. (Laudium 03)

One of the participants was concerned with weight gain as she has gained almost 10 kilograms since the insertion of the implant. In contrast, another participant was worried about weight loss, this is indicated in these statements:

“No, the only thing that I was worried about, it was my weight, yha cause I was 75 and now I’m around 85 somewhere there”. (Laudium 01)

“Yes, then I was losing weight, I was happy but now people were talking saying I’m sick” (Ubuntu 02)

Four participants removed the implant because it had expired and one participant was planning to conceive.

4.9 Ways to retain in care women on Implanon contraceptive

The participants were asked to suggest ways to ensure retention of the implant contraceptive. Firstly, the majority expressed concerns about the counselling given by health care workers before the insertion of the contraceptive implant.

Proper pre-counselling services was strongly suggested as a means to reduce early removal of the contraceptive implant. The participants felt that if women received

proper counselling before the insertion of the implant, that would enable them to make informed decisions about using it.. Furthermore, adequate knowledge about the contraceptive implant would prepare them for the possible side effects and about ways to treat or curb them. This is what one participant said:

“...a small gathering just to explain that implant works like this and if you have side effects, like if your periods don’t stop, we have another method for you to stop like they should explain more”. (Bophelong 04)

In addition, some of the participants felt that their side effects were not managed to their satisfaction. They suggested that proper management of the Implanon side effects could improve the retention rates. For example, one of the participants presented her side effects to the facility a number of times, but her complaint was not resolved. This is indicated in this quotation:

“She just told me that, she just gave me the pills to start the... with the pill to see what is going on actually, so I went there it never stopped”. (Stanza 01)

One participant also consulted the facility with prolonged bleeding and according to her, she was not given proper information and she felt that she was not managed properly. This is evident in this quotation:

“I went to the clinic they never told me that I must finish the whole eeh packet of the tablets, then after I should wait for, it takes like a month isn’t, I thought maybe if I want to stop them like today, I need to take those tablets today and then they’re gonna stop today”.(Bophelong 05)

4.10 Conclusion

This chapter presented and discussed the findings of the study. The themes discussed were: reasons for insertion, counselling and follow up care, positive experiences, reasons for removal of the contraceptive implant and retention improvement suggestions. The themes illustrated the experiences of women who had used the Implanon and their reasons for removing the contraceptive implant. The next chapter provides a discussion of the findings in relation to the literature and the conclusions.

Chapter 5: Discussion

5.1 Introduction

This study describes the experiences of women using the etonogestrel contraceptive implant and the reasons for removal in Tshwane District, Gauteng. The key themes established in this study are: reasons for insertion, counselling and follow up care, what the participants liked about using contraceptive implant, reasons for removal of the contraceptive implant and improvement on retention of women for contraceptive implant. This chapter provides a summary discussion on these highlighted themes.

5.2 Summary of the key findings

Firstly, this study shows that majority of women learnt about the contraceptive implant from friends and family. This means that they came to facility with the intention of having the implant contraception inserted. This reflects the awareness the community has about contraceptive methods available in the public facilities. Surprisingly, only a few participants mentioned health care facilities as their source of information, except for those who had the implant inserted due to stock outs of alternative contraceptive methods in the facilities. The picture is different from the study conducted in KwaZulu Natal using a mixed method design, in which more than 50% of participants heard about the implant from the primary health care workers (15). The South African National Guidelines state that clients should have access to “accurate, unbiased information about all available methods in order to make an informed choice” (5). In this study, only one participant was a first-time contraceptive user, and it would be expected that all the other participants were familiar with all the other contraceptive methods available. This information ought to be discussed during the initial visit so that an informed and medically eligible choice can be made by the client (5).

5.2.1 Reasons for inserting the contraceptive implant

This study has established that some women decided to insert the contraceptive implant because of its convenience, considering that it is effective for three years. Similar with another study (6). Contrary to that, some women felt that they did not have a choice as only the contraceptive implant was available when they accessed facilities for continuation of the contraceptive method they were using. Gauteng is one of the provinces that were identified by the Stop Stockouts Project (SSP) for experiencing contraceptive stockouts early in 2018. Stock outs lead to an increased risk of unwanted pregnancy, economic stress and compromised psychological wellbeing which in turn undermines reproductive and contraceptive health rights (35).

Other women felt that they were coerced by health care workers into implant insertion. As discussed in the findings, these are the participants who were denied discharge from the hospital unless they agreed to have the implant inserted. Others had the implant inserted because of defaulting their injectable method. The coercion found in this study is concerning as health care workers are supposed to give clients adequate information about the different contraceptive methods. Based on the information given, the client should be able to make an informed decision (5).

5.2.2 Counselling services at health care facilities

Furthermore, the study revealed a gap in counselling services rendered at health facilities before the insertion of the implant as well as a lack of proper follow up thereafter. The findings from this study showed that the majority of the participants did

indeed receive some information about the implant before its insertion. However, the information received was not sufficient enough to assist them to make informed choices. The study conducted by Mgobhozi (2017) in KZN had similar findings, participants were not adequately counselled and given information about the implant (15).

The study by Flore *et al* (2016) also supports this as it highlights the importance of counselling women about contraceptive methods available, whether one is already aware of the implant from other sources or not (6). These findings are in line with other African studies (3, 14, 29, 36). Therefore, continuation rates can be improved if women are adequately counselled and educated about the contraceptive implant, this would enable women to make informed decisions about using the contraceptive implant (26).

5.2.3 Follow up care

The study also revealed a gap in proper follow up care after the insertion of the implant. Majority of the participants stated that they were not given dates for when they were to return for follow up care. The National Contraceptive Clinical guidelines have no guidance on post contraceptive implant insertion follow up. Rowlands (2014) stated that although follow up is not indicated, women should be encouraged to visit a health facility should they experience any problems (5, 37).

In the Tshwane District, women are given a six weeks later follow up date for review, they are also encouraged to come back if they experience any problems. This has a positive impact on continuation rates as follow up care enables the health care worker to identify any problems experienced by the contraceptive user. Follow up care

facilitates dealing with any concerns that the user might have and provides an opportunity for further counselling (25).

5.2.4 Management of side effects

It is worth noting that the study participants had the contraceptive implant removed before the expiry date mainly due to side effects experienced. In most cases, the women reported that these side effects were neither explained to them nor were they properly managed at the facilities. A cross sectional quantitative study conducted by Burusie (2013) stated that proper management of side effects in the facilities could improve continuity rates and satisfaction with the contraceptive implant (10).

Women should be counselled by trained health care workers about the possible side effects caused by inserting the contraceptive implant, they should also be encouraged to visit the facility if they experience any problems or side effects (4, 13, 25).

5.3 Conclusion

The findings of this study revealed that most women choose contraceptive implant because it is convenient and effective. Regardless of the several benefits outlined above, they decided to remove the contraceptive implant before the expiry date due to intolerable side effects. These findings further suggest a gap in counselling services rendered at health facilities before the insertion of the implant, coupled with proper follow up post insertion. It is crucial that health care providers provide counselling and management of side effects services. Additionally, clear guidance on follow up post insertion should be outlined in the National Contraceptive Clinical guidelines. These guidelines should include counselling and side effects

management guidelines specific to subdermal implants. The 2012 National Contraceptive guidelines give guidance on general counselling and management of side effects related to progesterone only contraceptives. There is however no guidance that is specific to subdermal implants or intra uterine devices. The next chapter provides conclusions, recommendations and contribution of the study.

Chapter 6: Conclusions and recommendations

6.1 Conclusions

The findings of this study revealed that most women opt for the contraceptive implant because it is convenient and effective. These findings are consistent with other studies. Convenience and source of information influence the decision to opt for the contraceptive implant. Women are motivated to use the implant mainly due to its convenience. Regardless of several benefits outlined above, the participants in this study decided to remove the contraceptive implant before the expiry date due to intolerable side effects. These findings suggest a gap in counselling services rendered, management of side effects and proper follow up and are consistent with other findings from literature. It is therefore critical that health care providers are well trained in counselling and in managing the side effects of the contraceptive implant. Additionally, clear guidance on the follow up process post insertion of the implant should be outlined in the National Contraceptive Clinical guidelines.

6.2 Study limitations

In this study, only women who have removed the contraceptive implant participated. Therefore, the data collected was mostly from women who have removed the implant before its expiry date and not those who have kept the contraceptive implant.

Recall bias may have occurred depending on the period between insertion and removal of the contraceptive implant.

6.3 Recommendations and policy implications

In terms of rendering contraceptive implant services, gaps in the counselling services, follow up care and management of the side effects were revealed in this study. The findings and recommendations from this study may assist policy makers in reviewing

National Contraception and Fertility Planning Policies as well as Service Delivery Guidelines for the provision of improved contraception services. Below are the highlights on what can be done to improve the quality of contraceptive services rendered and to improve the retention of women who use contraception implants.

6.3.1 Department of Health

The Department of health should strengthen access to contraception services by ensuring availability of mixed methods in the facilities and limit stock outs. This will enable women to choose their method of choice autonomously.

A training program on contraceptive methods should ensure that health care providers are trained adequately and mentored thereafter to ensure competency post training.

According to the 2012 National Contraception, Fertility Planning Policy and Service Delivery Guidelines, follow up visits should be scheduled if clinically necessary. The National Contraceptive Clinical Guidelines do not include information on follow up post contraceptive implant insertion. Furthermore, the National Contraceptive Clinical Guidelines contain no specific guidance on managing side effects specific to subdermal implant. They also do not contain guidance on specific counselling methods related to the implant. In this study, the majority of the participants stated that they were not given scheduled appointments to come back for follow up care, this has a negative impact on the continuation rates of the contraceptive implant. In addition, this study identified a gap in knowledge health care professionals have on pre-counselling and managing the side effects caused by contraceptive implants. Therefore, the following should be incorporated in National Contraception Clinical Guidelines:

- Clear guidelines on a post insertion follow up process pertaining to the contraception implant.

- Clear guidelines on the management of side effects which will enable facilities to develop treatment protocols.
- Standardised topics that need to be discussed during counselling before the insertion of the contraceptive implant.

6.3.2 Health Care Providers

In this study only few participants mentioned health care facilities as their source of information, except for those women who inserted the implant due to stock outs in the facilities. This highlights a gap in counselling on available contraceptive methods, which would otherwise allow women to make informed decisions about the contraceptive method they choose to use. Therefore, health care providers should give information about available contraceptive methods to all women who visit public health facilities.

This study revealed that women removed the contraceptive implant prematurely because of side effects which were neither explained to them nor properly managed at the facilities. This study also highlighted a gap in the follow up care post contraceptive implant, as majority of the women were not given a follow up date neither were they told when to return to the facility. Therefore, health care providers should:

- Give proper counselling before the insertion, with emphasis on possible side effects and what to do should they prevail.
- Manage side effects properly to improve the contraceptive implant continuity rate.
- Follow up on those using have had the implant inserted as this could assist with the retention of the contraceptive implant users.

6.4 Contribution of the study

Few studies have been conducted in South Africa to assess the implementation of the new contraceptive method, specifically pertaining to end-use experiences and the reasons for early removal. Such a study has never been conducted in the Tshwane district either.

The study confirmed the results of existing studies which also identified convenience and effectiveness as incentives to using the Implanon. However, this study also revealed how the unavailability of contraceptive methods in the facilities (stock outs) affects the woman's right to choose the method she prefers. Some participants had no choice but to opt for the method that was available at the time.

This study revealed a practice where women were coerced by health care professionals to insert the implant and this was not found in other similar studies.

The study also revealed that health care workers need to provide proper counselling before the insertion of the implant. They also need to manage the side effects properly in order to improve the retention rates of the contraceptive implant. The need for follow up care post insertion of the contraceptive implant was revealed in this study, this finding was also confirmed in some studies conducted on Implanon.

6.5 Conclusion

The aim of the study was to explore experiences of women using the etonogestrel contraceptive implant and to determine the reasons for early removal of the implant. This chapter discussed the conclusions of the study, recommendations, policy implications and the contribution of the study. This study revealed that women removed the contraceptive implant prematurely due to side effects experienced. These

side effects were also either not explained to them or properly managed at the facilities. This study will contribute to the knowledge base and assist in improving the implementation of contraceptive and fertility services in primary health care facilities, using research-based findings.

References

1. Dreyer G. Contraception. A South African Perspective. 5th Edition. South Africa. Cape Town: Van Schaik Publishers; 2017.
2. Given LM. The Sage Encyclopedia of Qualitative Research Methods. 2009.
3. Patel M. Contraception: Everyone's responsibility. South African Medical Journal. 2014;104(9):644.
4. Irinyenikan T. Perception of Women about Implanon as a Contraceptive Method in Akure Western Nigeria. British Journal of Medicine and Medical Research. 2016;12:1-6.
5. Health SANDo. National Contraception and Fertility Planning Policy and Service Delivery Guidelines. Pretoria, South Africa: Government Printer; 2012.
6. Flore M, Chen X, Bonney A, Mullan J, Hadley B. Patient's perspectives about why they have their contraceptive Implanon NXT device removed early. Australian Family Physician. 2016;45(10):740-4.
7. Birhane K HS, Fantahun M. Early discontinuation of Implanon and its associated factors among women who ever used Implanon in Ofla District, Tigray, Northern Ethiopia. International Journal of Pharma Sciences and Research. 2015;6(3):544-51.
8. Belcastro P. New Birth control Implant: Is it safe. HEALTH NOTES. 2007;26(1):1 and 3.
9. Ismail H, Mansour, D, Singh, M. Migration of Implanon. Journal of Family Planning and Reproductive Health Care. 2006;32:157-9.
10. Burusie A. Reasons for Premature Removal of Implanon among Users in Arsi Zone, Oromia Region, Ethiopia, 2013. Reproductive System and Sexual Disorders, Current Research. 2013;4(1):1-6.
11. Ezegwui HU, Ikeako, L.C, Ishiekwene, C.I, Oguanua, T.C. The discontinuation rate and reasons for discontinuation of Implanon at the family planning clinic of University of Nigeria Teaching Hospital (UNTH) Enugu, Nigeria. Niger J Med. 2011;20(4):448-50.
12. Rai K, Gupta, S, Cotter, S. Experience with Implanon northeast London family planning clinic. European Journal of Contraception and Reproductive Health Care. 2004;9(1):39-46.
13. Madungu NH, Abdul MA, Bawa U, Kolawole B. Uptake of hormonal implants contraceptives in Zaria, Northern Nigeria. Open Journal of Obstetrics and Gynaecology. 2015;5(268-273).

14. Pillay D, Chersich, MF, Morroni, C, Pleaner, M, Naidoo, N, Mullick, S, Rees, H. User perspective on Implanon NXT in South Africa: A survey of 12 public- sector facilities. *South African Medical Journal*. 2017;107(10):815-21.
15. Mgobhozi LN. Exploring women's experiences and perceptions on the use of Implanon as a contraceptive method in a selected primary health care facility in kwaZulu - Natal [Thesis]. Durban: kwaZulu-Natal; 2017.
16. Burusie A. Reasons for Premature Removal of Implanon among Users in Arsi Zone ,Oromia Region, Ethiopia, 2013. *Reproductive System and Sexual Disorders: Current Research*. 2013;4(1):1-6.
17. Ezegwui HU, Ikeako LC, Ishiekwene CI, Oguanua TC. The discontinuation rate and reasons for discontinuation of implanon at the family planning clinic of University of Nigeria Teaching Hospital (UNTH) Enugu, Nigeria. *Nigerian journal of medicine : journal of the National Association of Resident Doctors of Nigeria*. 2011;20(4):448-50.
18. Health Do. National Contraception Clinical Guidelines: A companion to the National Contraceptive and Fertility Planning Policy and Service Delivery Guidelines. In: Africa DoHRoS, editor. Pretoria 2012.
19. Dahan-Farkas NE, Irhuma M. Long-acting reversible hormonal contraception. *South African Medical Journal*. 2016;58(5):64-8.
20. Jacobstein R. Liftoff: The Blossoming of Contraceptive Implant Use in Africa. *Glob Health Sci Pract*. 2018;6(1):17-39.
21. Moodley A, Mohamed, O. Prevalence and predictors of Implanon uptake in Ugu (Ugu North Sub District) 2016/17. *South African Family Practice*. 2019;61(2):48-52.
22. Rabopape LE, Muthelo, L, Malema, N.R, Mothiba, TM. Views of Adolescent Girls on the use of Implanon in a Public Primary Health Care Clinic in Limpopo Province, South Africa. *The Open Public Health Journal*. 2019;12:276-83.
23. Mastor A, Khaing, S, Omar, S. User's perspectives on Implanon in Malaysia, a multicultural Asian country. *Dove Press Journal: Open Access Journal of Contraception*. 2011.
24. Hoggart L, Newton, VL. Young women's experiences of side-effects from contraceptive implants: a challenge to bodily control. *Reproductive Health Matters*. 2013;21(41):196-204.
25. Asaye MM, Nigussie, T.S, Ambaw, W.M. "Early Implanon Discontinuation and Associated Factors among Implanon User Women in Debre Tabor Town, Public Health

Facilities, Northwest Ethiopia,2016",. *International Journal of Reproductive Medicine*. 2018;2018.

26. Mrwebi KP, Ter Goon,D, Owolabi, E.O, Seekoe,E, Ajayi,A.I. Reasons for discontinuation of Implanon among users in Buffalo City Metropolitan Municipality,South Africa:A cross sectional study. *African journal of reproductive health*. 2018;22(1):113-9.

27. Pyra M, Heffron, R., Mugo, N. R., Nanda, K., Thomas, K. K., Celum, C., Kourtis, A. P., Were, E., Rees, H., Bukusi, E., Baeten, J. M., . Effectiveness of hormonal contraception in HIV-infected women using antiretroviral therapy. *AIDS (London, England)*. 2015;29(17):2353–9.

28. Health SANDo. *Guideline for the Prevention of Mother to Child Transmission of Communicable Infections*. Pretoria: National Department of Health; 2019.

29. Adeagbo O, Mullick,S, Pillay,D, Chersich,M, Morroni,C, Naidoo,N, Pleaner,M, Rees,H. Uptake and early removals of Implanon NXT in South Africa: Perceptions and attitudes of healthcare workers. *South African Medical Journal*. 2017;107(10):822-6.

30. Conner M. Prospective prediction of health - related behaviours with the theory of planned behaviour. *Theory of Panned Behaviour (TPB,1991)*. 2010.

31. Kato S. *A Study of Research Method*. Japan: University of Business Administration, Bunkyo Gakuin, 2002.

32. Polit DF, Beck,C.T. *Essentials of Nursing Research: Appraising Evidence for Nursing Practice*. 8th Edition ed. Philadelphia: Lippincott Williams & Wilkins; 2004.

33. de Vos A, Strydom,H, Fouche ' CSL. *Research at grassroots for social sciences and human service professions*. Second ed. Pretoria: Van Schaik Publishers; 2002. p. 210-1.

34. Krefting L. Rigor in Qualitative Research: The Assessment of Trustworthiness. *American Journal of Occupational Therapy*. 1991;45(3):214-22.

35. Pikoli Z. Stop stockouts reveals massive contraceptive shortages. *Daily Maverick*. 2020 12 February 2020.

36. Utaile MM DM, Nida ET, Boneya AT. A qualitative study on reasons for early removal of Implanon among users in Arba Minch town, Gamo Goffa zone, South Ethiopia: a phenomenological approach. *BMC Women's Health*. 2020;20(1).

37. Rowlands S, Searle,S. Contraceptive implants: current perspectives. *Open Access Journal of Contraception* 2014;5.

Appendix 1: Information Sheet and Informed Consent

1. Introduction

Hello, my name is Noluthando Bunu. I am registered as a Master's student at University of Witwatersrand Johannesburg. I am conducting a study to understand the experiences of using etonogestrel contraceptive implant among women in Tshwane District.

This consent form will give you information to help you decide whether you would like to participate in an interview as part of the study.

1. Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, and risks, and your right to withdraw from the study at any time.
2. You should fully understand what is involved before you decide to take part in this study.
3. If you have any questions, do not hesitate to ask me.
4. You should not agree to take part unless you are satisfied about all the procedures involved.
5. If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study. You will be given a copy to keep.

2. Purpose of the study

To understand the experiences of using etonogestrel contraceptive implant among women in

Tshwane District.

3. Why I would like to interview you

You are requested to participate in the study because of your experience of using contraceptive implant. The information regarding your experience will assist with planning on how to improve contraceptive and fertility services in the district.

4. Length of the study and number of participants

The study will be conducted in Tshwane District focusing in Provincial Primary Health Care

Facilities in sub district three and six. The study will take place from February to March 2019.

5. Procedures

I will interview you and take notes using a semi-structured interview guide. The interview will take approximately 45 minutes. Your responses will be audio-recorded.

The interview will take about one hour or so to complete. All the information gathered during the interviews including personal information will be kept confidential, and no identifying information will be requested.

6. Will any of the study procedures result in any inconvenience?

During the interview, I will ask you questions about yourself and the service rendered during the time you inserted and removed the contraceptive implant at the facility. You do not have to answer any of the questions if you do not feel comfortable doing so.

7. Benefits

You will not benefit directly from the study but other women at large may benefit. Your answer will help the sexual reproductive health programme to understand the issues around its implementation. The answers provided may help to improve implementation of the programme in Primary Health Care facilities.

8. Rights as a participant in the study

Your decision to participate in this study is completely free and you can decline to be part of the study at any time, without stating any reason. Your decision participate in this study will not affect the services you receive at the clinic.

9. Financial arrangements

There is no cost to you for being in the study.

10. Reimbursement for study participation

You will not receive any remuneration for participating in the study.

11. Confidentiality

All information obtained during the course of this study will be kept strictly confidential.

Data that may be reported in scientific journals will not include any information that identifies neither your facility nor yourself as a participant in this study.

If you want any information regarding your rights as a research participant, or complaints regarding this research study, you may contact the Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent

committee established to help protect the rights of research participants at (011) 717 1234 Should you have any questions concerning this study, please contact me:

Researcher: Noluthando Bunu Tel: 0782760725 Email:
noluthandobunu@gmail.com

Supervisor: Dr Juliet Nyasulu Tel:0117172657 Email:
Juliet.Nyasulu@wits.ac.za

Appendix 2: Consent Form for Participation

Title of project: Experiences of women using etonogestrel contraceptive implant and reasons for removal in Tshwane District, Gauteng

Name of researcher: Noluthando Bunu

I,, agree to participate in this research project. The research has been explained to me and I understand what my participation will involve. Please circle the relevant options below.

I agree that my participation will remain anonymous YES NO

I agree that the researcher may use anonymous quotes
in her research report YES NO

I agree that the interview may be audio recorded YES NO

I agree that the information I provide may be used
anonymously by other researchers following this project YES NO

..... (Signature)

..... (Name of participant)

..... (Date)

Appendix 3: Consent Form – Audio Recording Interview

Study title: Experiences of women using etonogestrel contraceptive implant and reasons for removal in Tshwane district, Gauteng province.

I, the undersigned agree to participate in this study research study “Experiences of women using etonogestrel contraceptive implant and reasons for removal in Tshwane district, Gauteng province” and provide consent for the audio recording of the interview.

Name: _____

Signature: _____

Witness Signature: _____

Date: _____

Appendix 4: Interview Guide

Introduction

Thank you for your participation in our research study. We are going to talk about your experiences of using etonogestrel contraceptive implant. The study will assist in improving care rendered in contraceptive and fertility services in Tshwane District.

SECTION A

1. Age in years

2. Marital status

| Married | Single | Widowed | Divorced |
|---------|--------|---------|----------|
| | | | |

3. Religion

| Christian | Muslim | Catholic | Other (Specify) |
|-----------|--------|----------|-----------------|
| | | | |

4. Level of education

| Primary school | High school | Tertiary | None |
|----------------|-------------|----------|------|
| | | | |

5. Occupational status

| | | | |
|----------|------------------------------|------------|---------|
| Employed | Self-employed/ Part time job | Unemployed | Student |
| | | | |

SECTION B

FERTILITY AND CONTRACEPTION USE

1. Have you ever been pregnant before? Probing questions

- How many times?
- How many children are alive?

2. Have you ever used any contraception method before?

□ What are those other methods used if any?

| Contraceptive Implant | Injectable | Oral Contraceptive Pills | Intra Uterine Device | Condom | Other | None |
|-----------------------|------------|--------------------------|----------------------|--------|-------|------|
| | | | | | | |

3. Tell me about your understanding of the contraceptive implant?
Probing questions

- How did you know about the contraceptive implant?

| Word of mouth | Facility or Clients Provider | School | Television | Internet | Other |
|---------------|------------------------------|--------|------------|----------|-------|
| | | | | | |

- Why did you choose to use the contraceptive implant?

4. Explain to me what you were counselled on before the insertion of the contraceptive implant?

Probes:

- Efficacy of contraceptive implant
- Duration effect
- Benefits
- Side effects

5. When was the contraceptive implant inserted?

6. Where was the contraceptive implant inserted?

Probing questions

- By whom was the contraceptive implant inserted?
 - Were there any follow up visits after the insertion of implant?
7. For how long have you used the contraceptive implant?

8. What is your experience of using contraceptive implant?

Probing questions

- What did you like about using the implant?
- What were concerns about using implant?

9. What advise were you given after the implant insertion?

- Care of the insertion site
- How quickly does contraceptive implant work
- Follow up visits to the clinic
- What to do if experiencing side effects
- Protection against sexually transmitted infections
- When and where to return for removal

10. Why did you decide to remove the implant?

Probing questions

- Partner aware of the contraceptive implant?
- Approved the use of the contraceptive method?

11. Were you offered any other contraceptive method after the removal of the contraceptive implant?

12. If yes what options were you offered and what is your decision?

13. What do you think are the challenges in provision on contraceptive implant services?

14. What do you think can be done to address these challenges mentioned above?

Do you have any questions you would like to ask me?

[END OF INTERVIEW]

Thank you very much for your time and participation!

Interview stop time: _____

INTERVIEWER NOTES AND COMMENTS:

Appendix 5: Letter of request to conduct the study

6 Hendrik Potgieter Road

Thaba Tshwane

Pretoria

0183

2 May 2019

Tshwane District Health Services

Fedsure Building

Corner Lillian Ngoyi and Pretorius Street

Pretoria

0001

Dear Sir/ Madam

Re: Request for permission to conduct research in Tshwane Primary Health Care facilities

I am Ms. Noluthando Bunu currently registered as a Master of Public Health student at the University of Witwatersrand. As part of the course requirements, I will be conducting a research study. My research title is: Experiences of women using etonogestrel contraceptive implant and reasons for removal in Tshwane District, South

Africa. The aim of the study is to understand women's experiences of using etonogestrel contraceptive implant during 2016 to December 2018 in Tshwane District, South Africa.

I hereby request permission to collect data in your Primary Health Care Facilities. Data will be collected using in-depth interviews from women accessing Reproductive Health Services for removal of the contraceptive implant who meet the inclusion criteria. The study is voluntary and the participants will not receive any remuneration.

Please find attached my provisional approval letter from Wits Human Research Ethics Committee.

Please let me know if you require any further information.

Yours sincerely

(Mrs.) Noluthando Bunu

Cell no: 0782760725

Email: 1449059@students.wits.ac.za

Supervisor: Dr Juliet Nyasulu

[Tel:0117172657](tel:0117172657)

Email: Juliet.Nyasulu@wits.ac.za

Appendix 6: Permission letter from Tshwane District Health Services



GAL
HEALTH
REPUBLIC

GAUTENG PROVINCE

REPUBLIC OF SOUTH AFRICA

Enquiries: Mpho Moshime-Shabagu Tel: +27 12 451 9036

E-mail: Mpho.Moshime@gauteng.gov.za

TSHWANE RESEARCH COMMITTEE: CLEARANCE CERTIFICATE

DATE ISSUED: 09/07/2019

PROJECT NUMBER: 40/2019

NHRD REFERENCE NUMBER: GP 201905 002

TOPIC: Experiences of women using etonogestrel contraceptive implant and reasons for removal in Tshwane District, Gauteng.

Name of the Researcher: Mrs Noluthando
Bunu

Name of the Supervisor: Dr Juliet Nyasulu
Dr Wiedaad Slemming

Facilities: Eersterust CHC
Stanza Bopape CHC
Laudium CHC
Bophelong Clinic
Holani Clinic
Ubuntu Clinic
Skinner Street Clinic

Name of the Department: University of Witwatersrand

NB: THIS OFFICE REQUEST A FULL REPORT ON THE OUTCOME OF THE RESEARCH DONE AND

NOTE THAT RESUBMISSION OF THE PROTOCOL BY RESEARCHER(S) IS REQUIRED IF THERE IS DEPARTURE FROM THE PROTOCOL PROCEDURES AS APPROVED BY THE COMMITTEE.

DECISION OF THE COMMITTEE:

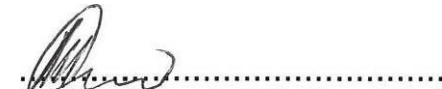


Mr. e er Silwimba
M. e er Silwimba

APPROVED

Date.... IC I n I lfi.....

Deputy Chairperson: Tshwane Research Committee



Mr. Mothomone Pitsi
r. Mothomone Pitsi

Date: 2019/07/06

Chief Director: Tshwane District Health

Appendix 7: Permission letter from Primary Health Care: Tshwane

Annexure 1



DECLARATION OF INTENT FROM THE PHC MANAGER FOR TSHWANE PROVINCIAL CLINICS

I give preliminary permission to Mrs Noluthando Bunu to do his or her research on "Experiences of women using etonogestrel contraceptive implant and reasons for removal in Tshwane District, Gauteng" in

BOPHELONG (REGION C) CLINIC EERSTERUST CHC HOLANI CLINIC LAUDIUM CHC

SKINNER STREET CLINIC STANZA BOPAPE CHC UBUNTU CLINIC

I know that the final approval will be from the Tshwane Regional Research

Ethics

Committee and that this is only to indicate that the clinic/hospital is willing to assist.

Other comments or conditions prescribed by the PHC Manager to the Researcher are

The researcher to have an entry meeting with potential facilities before starting with the data collection.

DR. SL PHOSHOPHOSHO

ACTING PRIMARY HEALTH CARE: TSHWANE

Date: 10/01/19

Appendix 8: Wits Human Research Ethics Committee Clearance Certificate

| | |
|--|--|
| 1. UNIVERSITY Of TH E WITWATERSRAND, 1011ANNESBURG | HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) |
|--|--|

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Ms N Bunu

School of Public Health

Division of Community Paediatrics

Medical School

University

E-mail: noluthandobunu@gmail.com

cc: Supervisor: Dr J Nyasulu <Juliet.Nyasula@wits.ac.za> and <HREC-

Medical.ResearchOffice@wits.ac.za>

FROM: Iain Burns

Human Research Ethics Committee (Medical)

Tel: 01 1 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 2019/07/01

REF: R 14/49

PROTOCOL NO: M190270 (This is your ethics application study reference number

Please quote this reference number in all correspondence relating to this study)

PROJECT TITLE: Experiences of women using etonogestrel contraceptive implant and reasons for removal in Tshwane District, Gauteng

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

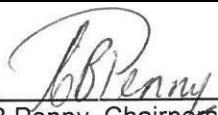


MSWorks2000/lain0007/Clearscan.wps

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Ms N Bunu

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CLEARANCE
CERTIFICATE NO. M190270



Dr CB Penny, Chairperson, HREC (Medical)

2019/07/01

NAME: Ms N Bunu

(Principal Investigator)

DEPARTMENT: School of Public Health

Division of Community Paediatrics

Medical School

University

PROJECT TITLE: Experiences of women using

etonogestrel contraceptive implant and

reasons for removal in

Tshwane District, Gauteng

DATE CONSIDERED: 2019/02/22

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Dr J Nyasulu

APPROVED BY:

DATE OF APPROVAL:

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. I agree to submit a yearly progress report. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in February and will therefore reports and re-certification will be due early in the month of February each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL

ENQUIRES