Post-vasectomy semen analysis: Follow-up of patients at three Cape Town Metropole facilities.

DR. MICHAEL LESLIE LE ROUX
Student number: LRXMIC022

SUBMITTED TO THE UNIVERSITY OF CAPE TOWN
In partial fulfilment of the requirements for the degree

Master's Degree (MMed) in Family Medicine

Faculty of Health Sciences
UNIVERSITY OF CAPE TOWN

SUPERVISOR: A/PROF KLAUS VON PRESSENTIN
Division of Family Medicine, Department of Family, Community and Emergency Care, Faculty of Health Sciences, University of Cape Town

DECLARATION

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

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

Signature: Signed by candidate

Date: 10/08/2023

Plagiarism Declaration

"This thesis/dissertation has been submitted to the Turnitin module (or equivalent similarity and originality checking software) and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor."

Name: Michael Leslie Le Roux

Student number: LRXMIC022

Signature: Signed by candidate

Date: 11/08/2023

ACKNOWLEDGEMENTS

The research journey that I embarked on, has been challenging, but very enjoyable. I wish to thank my loving wife, Jenna-lee, for all the support that she provided. My supervisor, Professor Klaus von Pressentin, played a huge part in the process by guiding me and providing valuable input. I want to thank Dr Alaofin Omatayo (public health researcher), who assisted us with the dataset management and analysis.

At each of the facilities that we included in the research, some individuals assisted with the collection of data phase. I wish to thank each of them for their valuable contribution.

- Wesfleur Hospital: Dr Renaldo Christoffels, Dr Abimbola Ugoagwu, Sr Shafieka Fortuin
- Heideveld CDC: Dr. Elma De Vries, Dr Jennie Morgan, Ms Divine English
- Mitchell's Plain CHC: Dr Roland Kroukamp, Sr Amanda Hansen, Sr Arendse

I would like to thank Professor John Lazarus in the Department of Urology at Groote Schuur Hospital for providing valuable information on the protocols for vasectomies.

I would also like to thank the clerks at the three facilities who assisted in the collection of the folders. Thank you to the staff at the Reproductive Medicine Unit at Groote Schuur Hospital who took the time to assist me in retrieving the results of the post-vasectomy semen analysis.

I would like to extend my gratitude to Professor Tasleem Ras, who introduced me to the research topic.

FORMAT

We used the author submission guidelines from the South African Family Practice journal to assist in the write-up of the research.[20] The paper is not yet published, but we aim to submit it for publication. The original research article is in the publication-ready format.

CONTRIBUTIONS

Under the guidance of Professor Klaus von Pressentin, my supervisor, I was the primary author in the write-up of this dissertation. I was also supported by Dr Alaofin Omatayo who assisted with the statistics and cleaning of the data. During the collection of data process, I was supported by my supervisor and Dr.Omatayo. I thus opted for using the term "we" when describing the data collection process, as they provided valuable input.

Table of Contents

APPENDICES

Addendum A- Data collection tool

Addendum B- UCT HREC approval letter and Approval Letters from Provincial Health Research Committee to access the three facilities in our study.

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

AUA	**American Urological Association**
CEO	**Chief Executive Officer**
CDC	**Community Day Centre**
CHC	**Community Health Centre**
COVID-19	**Coronavirus Disease 2019**
CUA	**Canadian Urological Association**
DHS	**District Health Services**
EAU	**European Association of Urology**
FAMSA	**Family South Africa**
GSH	**Groote Schuur Hospital**
HCDC	**Heideveld CDC**
HREC	**Human Research Ethics Committee**
KM	**Kilometres**
LARC	**Long-acting Reversible Contraception**
MMed	**Masters of Medicine**
MPCHC	**Mitchell's Plain CHC**
NHLS	**National Health Laboratory Services**
NPO's	**Non-Profit Organisations**
NSH	**New Somerset Hospital**
PHCR	**Provincial Health Research Committee**
PVSA	**Post-vasectomy Semen Analysis**
RMU	**Reproductive Medicine Unit**
UCT	**University of Cape Town**
UN	**United Nations**
WCGH	**Western Cape Government Health**
WFH	**Wesfleur Hospital**
WHO	**World Health Organization**

ABSTRACT

Background: Vasectomies are generally considered an underutilised method of contraception worldwide. Our study was aimed at determining patient adherence to the post-vasectomy follow-up plans and whether the procedures were done successfully by the different categories of surgeons at three facilities in the Cape Town Metropole.

Methods: We conducted a retrospective chart review of patient folders at three study sites. The sites included were Wesfleur Hospital, Heideveld CDC and Mitchell's Plain CHC. The sociodemographic data and procedure information was extracted from theatre records and patient folders. We retrieved the results of the post-vasectomy semen analysis (PVSA) from the Reproductive Medicine Unit at Groote Schuur Hospital.

Results: Our study population included 270 patients who had vasectomies from September 2016 to July 2021. Only 122 (45.2%) PVSA results from those patients that adhered to the follow-up protocol were retrievable, of which 115 (94.2%) showed that the procedure was successfully done. This is below the global estimated success rate of 99%.

Conclusion: Missing data from the patient records influenced the results significantly. It was thus not possible to achieve our study objectives fully. A data collection instrument was developed and standardised stationery, already in use at some of the sites, was implemented to provide more complete datasets for future audits.

Contribution: The study identified flaws in record-keeping practices at the three study sites. The implementation of the stationery and the data collection instrument may assist future research and quality improvement projects, by tracking procedural success and patient adherence to post-vasectomy semen analyses.

INTRODUCTION

Vasectomies are generally considered an underutilised method of contraception in the world.[1] There are many other methods of contraception available, but they are largely aimed at the female population according to survey-based estimates done by the United Nations (UN).[2] While doing the literature review, it was evident that the most up-to-date research on post-vasectomy follow-up has been conducted internationally. In our African context, there has not been published research on this topic recently. The most recent study in South Africa on vasectomies was published in 2009 and reviewed data that was collected at Karl Bremer Hospital for vasectomies done between January 2004 and December 2005.[1] That study found that vasectomies can be done safely by junior doctors (in this instance, urology registrars) in a secondary-level hospital and that the procedure should be promoted as an effective form of contraception for men in South Africa.

The American Urological Association (AUA) guidelines,[3] The Canadian Urological Association (CUA) guideline[4] and the European Association of Urology (EAU)[5] generally align on the management of patients who wish to have vasectomies as their form of contraception.

The WHO (World Health Organization) states that access to high-quality and affordable sexual and reproductive health services is fundamental for all.[6] Men and women consider the effectiveness of a contraceptive method the most important factor in choosing one.[7] Different contraceptive methods exist and are classified as non-reversible, long-acting reversible contraception (LARC), hormonal and barrier methods. These include male (vasectomy) and female (bilateral tubal ligation) sterilization, the use of intra-uterine devices, implants, injectables, oral contraceptive pills, male and female condoms, vaginal barrier methods (diaphragm, cervical cap, etc.), emergency contraception and other modern methods such as the vaginal ring.[8] Worldwide, contraception is used by most women in the reproductive age range (15-49 years).[9]

According to survey-based estimates by the United Nations, the preferred form of contraception is the injectable.[2] The survey revealed that most forms of contraception use have declined from the year 2003 to 2016. The use of the injectable method has declined from 28.4% (2003) to 23.9% (2016). Female sterilisation also declined from 14.3% (2003) to 7.7% (2016). The use of the male condom is the second-most used contraceptive method (8.8%), followed by the oral contraceptive pill (8.4%).[2]

Vasectomy is the contraception of choice for 6-8% of married couples worldwide, involving 42-60 million men.[10] Despite the safety, effectiveness, and permanence of vasectomy, the use of this method has plateaued globally and has continued to fade especially in low-and middle-income countries, including African countries, which have a close to 0% prevalence. [11] The prevalence of vasectomies as a contraceptive method in South Africa was estimated to be 0.6% in 2016 and is only more commonly used than the female condom (0.1%).[2]

In the 2019 update of the South African Contraception guidelines by the National Department of Health, which builds on the guidelines published in 2012, vasectomy was defined as a permanent form of contraception offered to men who do not want to have children.[12] The guideline briefly describes the eligibility criteria and the effectiveness of the procedure. It also suggests the post-procedure follow-up semen analysis be done after 3 months and mentions the possible complications that could arise. The South African guidelines are largely based on updates that are recommended by the WHO and are in keeping with the guidelines of the American Urology Association [3] and the European Association of Urology.[5]

The Western Cape Government describes the different, free family planning methods that are available on their website.[13] This provides the public with easily accessible information and enables them to make informed decisions about their contraceptive method. In our local setting in the Cape Town metropolitan area, vasectomies are currently offered as a voluntary and free service. The service is currently offered at the primary healthcare level and is performed by family physicians and family medicine registrars. Communication with the Department of Urology at Groote Schuur Hospital (GSH) revealed that they previously assisted with the procedure at the primary healthcare level but have ceased direct involvement due to the availability of skilled family physicians to continue the service (*Prof J Lazarus, personal communication, 25 November 2021)*.

The primary health care sector has been the setting where vasectomies are currently being performed and there are three facilities in the Cape Metro district health services that provide this service, which include Wesfleur Hospital (WFH), Mitchell's Plain Community Health Centre (MPCHC) and Heideveld Community Day Centre (HCDC).

Patients receive extensive counselling about the procedure and the effects of it, before consenting. Patients are counselled about the pre-and post-procedure prerequisites. They are

given a date to present at the facility for the procedure and are counselled again, before signing consent to proceed with the vasectomies. The counselling includes information on the procedure, the risk of complications, the success rate, and the possible failure that could exist if the post-vasectomy follow-up plan is not adhered to.

A post-vasectomy semen analysis (PVSA) is done to confirm the success of the procedure. The American Urological Association provided guidelines for the interpretation of the PVSA. [3] In some international studies, it was found that patients do not adhere to the follow-up visits to have their semen analysis done. Diederichs et. al explored the possible reasons for the non-adherence to PVSA in the form of qualitative research and found a range of answers that were given by patients.[14] Some of the reasons include patients feeling that they are too busy to follow up, patients feeling confident that the procedure was correctly done and patients describing that the process of the procedure was too inconvenient.[14]

2.1 Review of the American Urological Association (AUA) vasectomy guideline and its relation to the South African context.

The purpose of this very detailed, guideline is to provide clinicians with needed guidance in performing vasectomies.[3] This guideline is used globally, and it provides updates on pre-existing guidelines and includes pre-and post-procedure counselling. The AUA conducted a large systematic review in compiling the guideline. The data included various studies and included reasons for couples choosing vasectomy as a contraception method. These reasons ranged from preference to safety in female partners who could not use other forms of contraception due to medical reasons. Some characteristics that were found to be associated with choosing this method were the older age of the male partner, longer marriage, white race, previous failure of the male method, etc.[3]

The three techniques used to perform the procedure, include conventional vasectomy (scalpel used to make midline incision 1.5cm - 3cm long), the no-scalpel technique, and the minimally invasive technique. The latter two techniques are similar and differ in the instruments that are required to perform them.

According to feedback from the Department of Urology at GSH, the no-scalpel technique is generally used in South Africa. This is in keeping with the European Association of Urology guidelines. In the three facilities that were part of our research, this technique was preferred. The no-scalpel technique causes less discomfort for patients during the procedure and fewer post-operative complications.[3]

The AUA guideline states that the procedure is a permanent form of contraception and should be described as such in the counselling session. It should also be made clear that the procedure does not ensure immediate sterility and requires additional methods of contraception until a follow-up semen analysis confirms azoospermia or non-motile sperm has been achieved. The guideline suggests follow-up at eight to sixteen weeks post-vasectomy for semen analysis to be done. If sperm is still present, then repeat semen analysis at six months post-procedure. The failure or success and further management will thus depend on this result.

2.2 Current South African guidelines on vasectomies

The European Association of Urology (EUA) guidelines [5] are currently being relied on in South Africa and locally in the Cape Town metropolitan area. The guideline is in keeping with the American Guidelines as described above but is focussed on the clinical recommendations.

The no-scalpel technique is preferred due to fewer early complications such as hematoma infection and less post-operative pain. The pre-operative counselling is also emphasized and includes information on post-procedure follow-up semen analysis. The preferred period following the procedure is three months, in which at least 20 ejaculations should have occurred.

The success of the procedure is measured by the absence of sperm in the ejaculate, referred to as azoospermia, or the presence of less than 100 000, non-motile spermatozoa per millilitre after three months. In the events where the above criteria are not met, it is recommended that semen analysis be repeated at intervals of 6 weeks. Failure of the vasectomy is the presence of motile spermatozoa after six months and it is thus advised that the vasectomy should be redone.

There is currently little known about the post-vasectomy semen analysis adherence pattern in our local setting. From the literature review and based on our anecdotal clinical experience, it was evident that patient adherence to the post-procedure follow-up plan was generally poor. The data or lack thereof, in our setting, was not previously recorded. The research study can thus be considered as a baseline in our local context. We sought to determine adherence to the follow-up plan, including PVSA, and use this baseline data to assess current practice locally.

Our research aimed to determine the number of vasectomies that were done in three facilities in the Cape Town Metropolitan region over the past five years and whether the patients had

the recommended follow-up semen analysis at 3 months (and 6 months, when indicated in cases where semen was still present in semen analysis at 3 months post-procedure).
We were also interested in finding out whether the guidelines, locally, are in keeping with the AUA and EUA guidelines.

2.3 Study objectives

1. To determine the number of patients that had vasectomies done at the three facilities over the period 2016 to 2021.
2. To record demographic data of the patients who underwent vasectomies.
3. To determine the percentage of patients who had a post-vasectomy semen analysis done according to the guidelines to evaluate the outcome (success/failure) of the procedure.
4. To determine the association between the success of the procedure and the cadre of surgeons performing the procedure.

RESEARCH METHODS AND DESIGN

Study design

We conducted a retrospective descriptive audit which analysed the data captured via patient record reviews at three primary healthcare sites offering a vasectomy service in the western half of the Cape Town Metropole, Western Cape.

Setting

The three primary healthcare facilities included were Wesfleur District Hospital, Mitchell's Plain CHC and Heideveld CHC.

Figure 1: Map of Cape Town Metropolitan Municipality. [19]

These facilities have a day theatre for small surgical procedures where the vasectomies are performed by different cadres of skilled doctors, including medical officers, registrars, and family physicians. The public is informed about the availability of this service by advertising in the facilities as well as on Western Cape Government Health websites.[13] The service is voluntary and is advertised as a permanent method of contraception.

Wesfleur Hospital

Wesfleur Hospital is a district hospital that is situated in Atlantis. Atlantis falls under the City of Cape Town Municipality but is also part of the Southern and Western sub-structure in the Metro Health services. In the last census that was done in 2011, the

population was estimated to be 67 491.[15] Wesfleur Hospital serves this population, and their services include but are not limited to, chronic illness care, maternity care, child health services, emergency health care and minor surgical procedures.

The facility has two family physicians, family medicine registrars, medical officers and medical interns. Wesfleur Hospital has a full complement of nursing staff to cover the various workspaces. Outreach programmes from the University of Cape Town (UCT) family medicine department and specialist services, including paediatrics, gynaecology, internal medicine and orthopaedics from the regional hospital provide the facility with the support needed.

The referral hospitals are New Somerset Hospital (regional hospital), Groote Schuur Hospital (tertiary hospital) and Red Cross War Memorial Children's Hospital. The referral hospitals are all situated in the centre of Cape Town, approximately 65 kilometres from Atlantis.

The population is largely Afrikaans-speaking, as described in the most recent census. [15] The male-to-female ratio was close to 1:1. The population consist of 68.5% of adults that fall in the working age group (15-64 years old). On average there were approximately four people per household. Only 3.1% of the population that is older than twenty completed higher education. The average income ranged from R9 600 to R153 800 per annum and 12.6% had no income.

The district hospital is situated centrally and is accessible by the community through public transport and is within walking distance of the remainder of the population. The Municipal public bus/other transport services are available for travel to the referral hospitals.

Mitchells Plain Community Health Centre (CHC)

Mitchell's Plain also falls under the City of Cape Town Metropolitan as well as the Southern and Western sub-structure in the Metro Health services. According to the census done in 2011, the population was 310 485 with an average of approximately four people per household.[16] The male-to-female ratio was almost 1:1. It was found that 35% of the population aged older than twenty completed matric or higher and 76% of the labour force (15-64 years old) was employed.

The community is served by Mitchell's Plain CHC, which is situated centrally and is accessible by the population through public transport. The CHC is staffed with a

family physician, medical officers, medical interns, allied health staff and nursing staff that fulfil daily duties to serve the population.

The services that are provided, range from small surgical procedures, provision of chronic illness follow-up care, and trauma care to antenatal and maternity care. The small surgical procedure includes the vasectomy service that is offered to the male population. The service was unfortunately suspended due to the destruction of the theatre by a fire that broke out in September 2019. The renovation of the theatre was completed, and these small surgical procedures are offered again since the end of 2022.

The CHC refers patients to Mitchell's Plain District Hospital, which is less than 5km from the CHC. The district Hospital is staffed with a variety of specialist disciplines including general surgery, obstetrics and gynaecology, psychiatry, internal medicine, paediatrics, anaesthesiology and emergency medicine.

Heideveld Community Day Centre (CDC)

Heideveld is a suburb that falls under the Athlone district which is in The City of Cape Town metropolitan as well as the Southern and Western sub-structure in the Metro Health services. The population was estimated to be 21 288 in the 2011 census with approximately five people per household.[17] This population has a male-to-female ratio that is slightly skewed towards having more females. The census found that 31% of those aged 20 years and older completed matric or higher and that 70% of the labour force (15-64 years old) was employed.

Heideveld CDC is approximately 10km from the centre of Cape Town and the referring hospitals, which are New Somerset Hospital (NSH) and Groote Schuur Hospital (GSH). The CDC is staffed with a family physician, medical officers, medical interns, allied health staff and nursing staff that serve the community. The services include chronic illness care, maternity care, trauma care, and the provision of small surgical procedures which include vasectomies.

These three facilities have been responsible for providing this service to their respective communities. Family medicine registrars and family physicians do outreach to these facilities to perform the procedures. All three facilities were affected by the Covid-19 pandemic and had to suspend surgical services early in March 2020. [18] The service recommenced around March 2021 when lockdown restrictions were eased.

Study population and sampling strategy

The population for the study included all the men who underwent vasectomies at these facilities from the year 2016 to 2021. This time frame was used because some of the facilities started doing vasectomies in the year 2016. We opted to use the year 2021 as our cut-off time to collect as much data as possible. No sampling was done. We included all the available records in that timeframe.

Data collection

The data was collected by visiting the three facilities. These visits were pre-arranged with the facility managers and the family physicians.

The data sources of patient information varied at the three facilities given the different modes and practices of record keeping encountered.

- Wesfleur Hospital made use of theatre record books in which they recorded the details of the procedures that were done. There were some electronic copies of the records, but these were incomplete. The semen analyses were not done at GSH. Patients were given the option of having it done privately at their cost. These results were not recorded in the patient folders.
- Heideveld CDC also made use of record books to record the information on the procedures. The details of the procedures were stored in the patient folders. We encountered standardized stationery which detailed the pre-procedure counselling, signed consent forms, surgical notes, and a follow-up plan. However, no copies of the results of the semen analysis were available in these patient records.
- Mitchell's Plain CHC also made use of record books to capture the data on the procedures, but these records were destroyed in a fire that burned down the theatre in September 2019. No backup system at the facility was in place to obtain information about the procedures. With the help of the Reproductive Medicine Unit at GSH we were able to retrieve electronic copies of the results of patients that had vasectomies done. From these electronic records, we were able to obtain the patients' details to do a folder review.

The information-gathering process consisted of a review of patient records as well as, in the case of Mitchell's Plain CHC, theatre notes kept by the theatre staff.

We developed and piloted a data collection tool with a set of demographic and procedural variables (see Addendum A). The demographic data that we gathered at the three facilities were retrieved from electronic databases and patient folders. These demographic variables

included age, marital status, employment status, and the number of children of these patients. Procedural data variables were informed by the guidelines as described in the literature review.[3] The information from the patient folders was captured in a Microsoft Excel spreadsheet and later transferred to SPSS (Statistical Package for the Social Sciences).

Data analysis

The analysis of this quantitative data was performed with the assistance of an independent statistician. We used SPSS (Statistical Package for the Social Sciences) to analyse the data. We were able to use the software to calculate the percentages of the different variables and to determine the association between the success of the procedure and the performing surgeon. The data is presented in the form of tables and charts.

Ethical considerations

Ethics approval was obtained by the University of Cape Town's Human Research Ethics Committee (Ref 196/2022). We also received approval from the Western Cape Provincial Health Research Committee as well as the Chief Executive Officers of the three facilities to conduct the research (see Addendum B).

RESULTS

The total population for our study was 270 patients who had vasectomies done at the three facilities from September 2016 until July 2021. The frequency and percentages of the number of procedures done at the different facilities are noted in Table 1. Wesfleur Hospital and Mitchell's Plain CHC started doing the procedures in the year 2016 and recorded 99 (36.7%) and 89 (33.0%) vasectomies, respectively. Heideveld CDC recorded 82 (30.4%) vasectomies that were done since the year 2018.

Facilities	**Frequency (N=270)**	**Percentage (%)**
HCDC	82	30.4
MPCHC	89	33.0
WFH	99	36.7

Table 1. Number of vasectomies done at the three facilities

Sociodemographic data of patients

Table 2 is representative of the sociodemographic data. Most patients that underwent the vasectomies were between the ages of 30 years and 50 years (78.5%). The age of the patients was unknown in 10.7% of the records. Around half of the patients (53%) were married and in a large portion of patients, the marital status was unknown (45.2%).

Thirty-six per cent of the population had three to four children. There was a substantial number of folders in which the number of children was not recorded (36.7%).

The folder review also found that of all the patients whose employment status was recorded were employed (62.2%).

Variables	Categories	Frequency N=270	Percentage
Age (years)	0-29	12	4.4
	30-39	129	47.8
	40-49	83	30.7
	50-59	16	5.9
	60-99	1	0.4
	Unknown	29	10.7
Employment Status	Employed	168	62.2
	Unemployed	0	0
	Unknown	102	37.8
Marital Status	Married	143	53.0
	Divorced	3	1.1
	Widow	1	0.4
	Unknown	122	45.2
	Single	1	0.4
Number of Children	< = 2	45	16.7
	3 - 4	98	36.3
	> 4	28	10.4
	Unknown	99	36.7

Table 2. Sociodemographic data

The number of patients who adhered to follow-up, and success/failure of the procedure as determined by the Post Vasectomy Semen Analysis

Table 3 represents the results of the post-vasectomy semen analysis that was performed. The results were obtained from the Reproductive Medicine Unit (RMU) at Groote Schuur Hospital where the analysis was done. The results for two of the facilities were collected, namely Mitchells Plain CHC and Heideveld CDC. The results for Wesfleur Hospital (WFH) were not available as it was not standard protocol to refer patients for their semen analysis at the RMU. A total of 99 vasectomies were recorded at WFH and upon the folder review, none of the results was available.

The Heideveld CDC theatre records showed 82 vasectomies that were done. Our folder review revealed that only 49 (59.7%) of the results were unknown. This was found to be due to factors such as patient folders that were not retrieved or patients that did not go for their

post-vasectomy semen analysis. The PVSA results revealed that 27 out of 33 known results were successful (81.8%). Six of the known results were unsuccessful (18.2%).

Mitchells Plain CHC theatre records were not available due to damage to them. The results of all the PVSAs that were done at the facility were retrieved from the RMU at GSH. A total of 89 PVSA results were found on an electronic database at the RMU. These showed that 88 of the procedures done, were successful (98.9%). Only one procedure was unsuccessful (1.1%).

A total of 122 patients (45.1%) are thus known to have adhered to the post-procedure follow-up plan. Of these 122 patients whose PVSA results were known, 115 procedures were successful (94.2%).

Facility	**Results of PVSA**						**Total number**
	Successful (n)	*%*	*Unsuccessful (n)*	*%*	*Unknown (n)*	*%*	
HCDC	27	81.8	6	18.2	49	59.8	82
MPCHC	88	98.9	1	1.1	0	0	89
WFH	0	0	0	0	99	100	99
Total	115	94.2	7	5.8	148	54.8	270

Table 3. Post-vasectomy semen analysis results

The need for a repeat vasectomy globally is less than 1% [4], which currently leaves the results below the target. These results could be due to surgical technique, surgeon experience, and unconfirmed vas deferens occlusion. The current international and local guidelines do not require histological evidence of vas deferens occlusion [3], but it was recently included in our local protocols to send specimens (left and right vas deferens) for histological confirmation. This will ensure that the procedure was successfully done and whether failure (risk of falling pregnant, which is 1 in 2000) was simply due to the procedure not being 100% reliable [3].

The association between performing surgeon and the success of vasectomy.

The vasectomies were performed by urologists (36.3%), family physicians (45.6%), family medicine registrars (8.9%) and medical officers (1.9%). In 20 (7.4%) of the recorded total procedures (270), the surgeon category was not known. This was due to missing data from the patient records as well as missing patient folders.

Table 4 demonstrates that our data is skewed, and that the unknown category of data is the major contributing factor. The table shows the counts and the success percentages obtained by the different surgeon categories. According to the results, urologists had a success percentage of 97.2% (72 out of 74 known results). Family physicians had a success of 85.7% (24 out of 28 known results), but this was largely due to 77.2% (95 out of 123) of the PVSA in this category being unknown.

The missing data from the patient records review thus makes it very difficult for us to accurately determine the association between the success of the procedure and the performing surgeon.

	POST-VASECTOMY SEMEN ANALYSIS OUTCOME							
SURGEON CATEGORY	Successful (n)	%	Unsuccessful (n)	%	Unknown (n)	%	Total (n)	%
Family Physician	24	85.7	4	14.3	95	64.2	123	45.6
Urologist	72	97.2	2	2.8	24	16.2	98	36.3
Family Medicine Registrar	2	100	0	0	22	14.9	24	8.9
Medical Officer	0	0	0	0	5	3.4	5	1.9
Unknown cadre category	17	94.4	1	5.6	2	1.4	20	7.4
TOTAL	115	94.2	7	5.8	148	54.8	270	

Table 4. Surgeon cadre association with post-vasectomy semen analysis outcome

DISCUSSION

Key findings

The study revealed that there has been uptake of this contraceptive method at all three facilities. We found that the success of the procedure was high, but the accuracy of the findings was limited considerably due to missing data. Our findings also determined that a considerable proportion of patients did not follow up for PVSA. Health service strengthening activities have been implemented subsequently to address these issues identified in the baseline audit.

Discussion of the key findings

It is refreshing to know that there is utilisation of this contraceptive method in our local setting. The findings are in keeping with existing knowledge that it is an underutilised method.[1] This may be due to poorly informed communities about the method and its effectiveness, although our study did not collect data to confirm this hypothesis. All three facilities have health promoters that are responsible for the distribution of information about the procedure. They offer counselling for males who show an interest in undergoing vasectomies.

The global success of vasectomies is currently estimated to be 99%.[4] Our findings report that the success at these facilities is below this target (94.2%); however, this value needs to be carefully evaluated considering the considerable percentage of missing data.

There have been some international studies that showed that the follow-up after having a vasectomy is generally low and non-adherence was found to be greater than 30%.[14] The reasons for the low follow-up percentage have been explored on an international level and include patients feeling that they are too busy to follow up, patients feeling confident that the procedure was correctly done and patients describing that the process of the procedure was too inconvenient.[14] The reasons for non-adherence have not yet been explored on a local level. Our findings revealed that 45.2% of patients adhered to the recommended follow-up appointment for the PVSA. This puts the non-adherence percentage at 54.8%, which is in keeping with internationally described follow-up rates.

The poor follow-up rate may be a result of the patients not being well informed of the follow-up protocols. Our facilities are also known to be very busy and full daily. In many instances, this leads to long waiting times for patients which may impact adherence. Health promotors

at some of the facilities aim to stay in contact with patients following the procedure via telephone or messaging service, and thus ensure that they follow up for the appointments to have their PVSA done. The process involves the staff (nurses and health promotors) making appointments for patients at GSH RMU for their follow-up tests to determine success. Reports from counsellors at the facilities reveal that the implementation of the appointment system has been very helpful in assuring patient adherence.

The nature of the relationship between the cadre of surgeons that performed the vasectomies and the outcome of the procedure could not be described accurately. It is, however, evident from our findings that the urologists had a large percentage of success, and this could have been due to the implementation and maintenance of the PVSA pathway that was set in place by them and their local teams (theatre staff). We found from anecdotal testimony from staff that the role of the theatre nurse in the referral of patients to GSH RMU ensured that they followed up for their PVSA (*Sr Arendse, personal communication, 2021*). Family physicians are currently the only cadre performing vasectomies at the facilities. The results revealed they had a success rate of 85.7% and that it was largely impacted by unknown PVSA results. It is likely that these results underestimate the success rate as anecdotal reports from staff at the facilities revealed very few failed procedures (*Sr Arendse and Ms English, personal communication, 2021*).

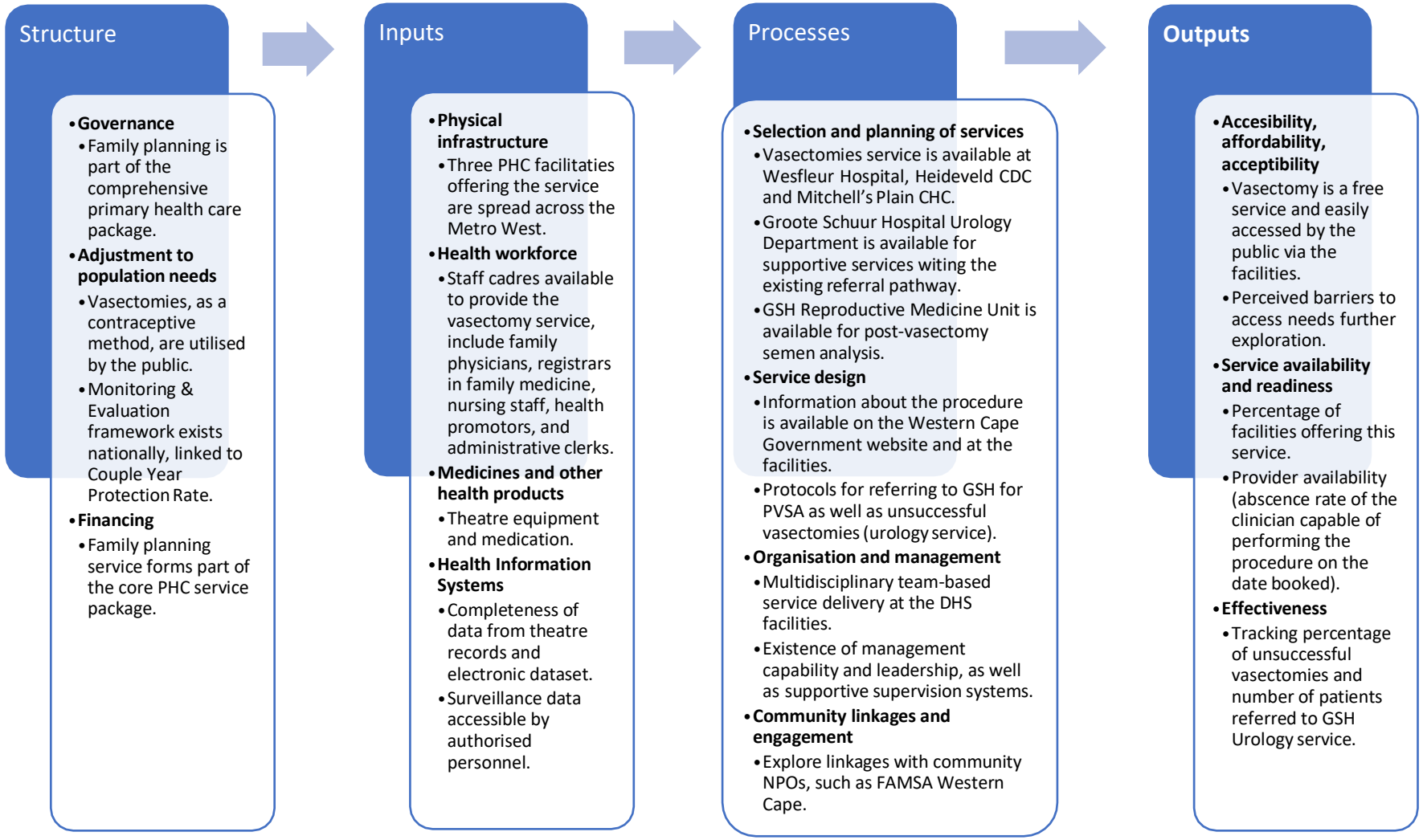
Implications for ongoing vasectomy service strengthening activities

The WHO's primary healthcare monitoring conceptual framework describes how clinical governance, policy frameworks, healthcare workforce, and health information systems all contribute to quality service delivery and continuity of care.[21] A suggested framework which is based on the WHO's primary health care monitoring conceptual framework is illustrated in Figure 2, which could assist in the improvement of the vasectomy service from a health systems perspective.

A revised clinical care pathway to inform the delivery of an evidence-informed vasectomy service emerged during the audit and was developed in partnership with the local teams (Box 1). Capturing information on an electronic platform can result in easier access and ultimately comprehensive, patient-centred care. It would ensure follow-up in cases where patients disengage from the services. Standardised stationery for the vasectomy process exists and

was already being used at MPCHC and HCDC. This has since been introduced at WFH to ensure a uniform approach to vasectomies.

Figure 2: Vasectomy service framework



Box 1: Vasectomy clinical care pathway for Metro West PHC facilities

- Patients access information from the Western Cape Government website and from health promotors at the facilities.
- They receive counselling on the procedure and are booked to have the vasectomy done.
- Relevant information about the patient is captured in their folders.
- Informed consent is obtained by the cadre of surgeon who will be performing the vasectomy.
- The vasectomies are then performed according to guidelines and the post-procedure plan is discussed with the patient.
- Health Promotors/ theatre staff book appointments at Groote Schuur Hospital Reproductive Medicine Unit for post-vasectomy semen analysis and stay in contact with patients to ensure adherence to the follow-up plan.
- Results are retrieved by authorised personnel and captured on record.
- Patients are informed of the results and whether the vasectomy was successful or whether it was unsuccessful.
- In the event of an unsuccessful vasectomy, patients are referred to Groote Schuur Hospital Urology Department for further management.

Study strengths and limitations

Our study represents a baseline audit to shed light on a service which was poorly understood outside the local facility and to inform future research. The audit process enabled us to identify some gaps in the care pathway process, from the recruitment of patients for vasectomies to documenting the pre-and-post-procedure process. Active engagement with the local role-players facilitated the implementation of enhanced systems and record-keeping, which include electronic data collection tools that we developed, as well as standardised stationery to ensure an efficient process.

Our study is a retrospective cross-sectional observational design and thus in itself is a limitation due to its inferiority compared to prospective studies. This cross-sectional design may only highlight possible associations between variables and does not allow us to describe causation. Two of the major limiting factors in our research were the destruction of the theatre records at MPCHC due to fire, as well as incomplete record-keeping encountered in the available records. Due to the missing data, it was not possible for us to accurately

describe the possible association between the success of the vasectomies and the cadre of surgeon.

Recommendations

Record-keeping should be standardised at all three facilities as part of a clinical care pathway. This has already been set in place and should be monitored and evaluated on an ongoing basis to ensure efficiency. Health promoters should continue to play a big role in the recruitment and counselling of patients for vasectomies and could be allocated as the central person for the arrangement of appointments for PVSA. The ideal nucleus in this instance would be the health promoter as it would be fitting to complete a process which was initiated by them during the counselling before the procedure. Stronger linkages with community networks and NPO's such as FAMSA (Family South Africa) should be built to assist with counselling for families about the option as a family planning method.

The family physicians based at these facilities are currently the primary surgical cadre performing the procedure. Results of the PVSA should be easily accessible by them for review and post-procedure counselling of the patients.

There is an opportunity for further research, which could include an audit of the record-keeping, determining the success of the procedure using histology and PVSA, an association between the surgeon and the outcome of the vasectomy, adherence to follow-up protocol and qualitative research to find out factors that play a role in non-adherence to follow up, as well as exploring perceived barriers to accessing the service.

CONCLUSION

Our study shows that vasectomy as a form of contraception is being utilised in our communities. This makes it important for information about the procedure to be made available to the public. It is evident from our study that missing records influenced the outcome of our results. The data collection instrument that we implemented in partnership with the local teams will ensure the availability of adequate records to allow for complete datasets in future studies. The need for better record-keeping practices can lead to more efficient monitoring of the success of the procedures. Patient adherence to the follow-up PVSA was found to be low, but this could also be explored further through surveys and qualitative interviews and improved with revised clinical care protocols. Family physicians and family medicine registrars are currently the surgeons that perform vasectomies in primary healthcare settings. The success rate of the procedures done by these cadres of surgeons could not be established accurately in our study, but the findings and monitoring processes that are in place can enable future researchers to explore this further.

DECLARATIONS REQUIRED BY TARGET JOURNAL

COMPETING INTEREST

The author and supervisor declare that they have no financial or professional gain from conducting this research.

AUTHOR CONTRIBUTION

The original research article was written for the minor dissertation in the Family Medicine Postgraduate program. The author was guided and supported by his supervisor in the data collection and write-up process.

FUNDING

The study was funded by a UCT MMed budget of R 5 000.

DATA AVAILABILITY

The data and findings of this study will be distributed to the three facilities and will be available to all stakeholders upon request.

REFERENCES

1. Trollip GS, Fisher M, Naidoo A, Theron PD, Heyns CF. Vasectomy under local anaesthesia performed free of charge as a family planning service: complications and results. South African Medical Journal. 2009;99(4).
2. United Nations Department of Economics and Social Affairs, Population Division (2021). World Contraceptive Use 2021.
3. Sharlip ID, Belker AM, Honig S, Labrecque M, Marmar JL, Ross LS, Sandlow JI, Sokal DC. Vasectomy: AUA guideline. The Journal of urology. 2012 Dec 1;188(6):2482-91.
4. Zini A, Grantmyre J, Chan P. CUA guideline: Vasectomy. Canadian Urological Association Journal. 2016 Jul;10(7-8):E274.
5. Dohle GR, Diemer T, Kopa Z, Krausz C, Giwercman A, Jungwirth A. European Association of Urology guidelines on vasectomy. Actas Urológicas Españolas (English Edition). 2012 May 1;36(5):276-81.
6. World Health Organization. Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health. Center for Communication Programs (CCP), Knowledge for Health Project. Family Planning: A Global Handbook for Providers. 2018. Available from: https://www.who.int/publications/i/item/9780999203705.
7. Awadalla M, Contraceptive Effectiveness; Shoupe D, editor. The Handbook of Contraception: Evidence Based Practice Recommendations and Rationales. Third edition; Humana Press; 2020
8. United Nations, Department of Economic and Social Affairs, Population Division (2021). *World Contraceptive Use 2021 and Estimates and Projections of Family Planning Indicators 2021. Methodology report*. UN DESA/POP/2021/DC/NO. 1.
9. Sah S, Jaiswal A, Paul P. CURRENT STATUS OF CONTRACEPTIVES USE.
10. Patel AP, Smith RP. Vasectomy reversal: a clinical update. Asian journal of andrology.2016 May;18(3):365.
11. Shelton JD, Jacobstein R. Vasectomy: a long, slow haul to successful takeoff. Global Health: Science and Practice. 2016 Dec 23;4(4):514-7.
12. National Contraception Clinical Guidelines (2019), Chapter 6.5, Page 52.
13. Western Cape Government, Family Planning (Contraception), 2022 Feb 16. Available from: https://www.westerncape.gov.za/site-page/family-planning.

14. Diederichs J, McMahon P, Tomas J, Muller AJ. Reasons for not completing post-vasectomy semen analysis. Canadian Family Physician. 2019 Sep 1;65(9):e391-6.
15. Department of Statistics South Africa, statistics by place, City of Cape Town, Atlantis, 2011. Available from:http://www.statssa.gov.za/? page_id=4286&id=294.
16. Department of Statistics South Africa, statistics by place, City of Cape Town, Mitchell's Plain, 2011. Available from: http://www.statssa.gov.za/? page_id=4286&id=329.
17. City of Cape Town-2011 Census suburb Heideveld, July 2013. Available from: https://resource.capetown.gov.za/documentcentre/Documents/Maps%20and %20statistics/2011_Census_CT_Suburb_Heideveld_Profile.pdf.
18. Western Cape Government, City of Cape Town, COVID-19 employee safety FAQ's: Help stop the spread, 2020. Available from: https://coronavirus.westerncape.gov.za/files/atoms/files/10011232HC%20COCT %20Covid-19%20Employee%20Safety%20Guide%20REV7.pdf.
19. National Government, Municipalities of South Africa, Cape Town Metropolitan municipality maps, 2012-2023. Available from: https://municipalities.co.za/map/6/city-of-cape-town-metropolitan-municipality.
20. AOSIS publishing, South African Family Practice, submission guidelines, 2023. Available from: https://safpj.co.za/index.php/safpj/pages/view/submission-guidelines#part_1.
21. World Health Organization. Primary health care measurement framework and indicators: monitoring health systems through a primary health care lens. Web annex: technical specifications. Available from: https://www.who.int/publications/i/item/9789240044210.

ADDENDUM A

Data Collection Tool

Facility			THEATRE STATISTICS			DATE: JUNE 2016 TO 2021										
Date	Name	Surname	Folder numb	Age	Suburb/resid	Marital statu	Number of Childre	Emplyoment statu	Procedure done	Surgeon	Surgeon designation	Post- vasectomy semen ar	Results	3 months	6 months	

ADDENDUM B

UCT HREC approval letter and Approval Letters from Provincial Health Research Committee to access the three facilities in our study.

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

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

28 March 2022

HREC REF: 196/2022

A/Prof K von Pressentin
Division of Family Medicine
Falmouth Building -FHS
Email: klaus.vonpressentin@uct.ac.za
Student: mleslie24@gmail.com

Dear A/Prof von Pressentin

PROJECT TITLE: POST-PROCEDURE SEMEN ANALYSIS FOLLOW-UP OF PATIENTS WHO UNDERWENT VASECTOMIES AT THREE CAPE METROPOLE FACILITIES OVER A 5-YEAR PERIOD (2016 TO 2021)-
(MASTERS CANDIDATE-DR MICHAEL LE ROUX)

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

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

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, our letter dated 02 February 2022 provides guidance found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Approval is granted for one year until the 30 March 2023.

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

The HREC acknowledge that the student: Dr Michael Le Roux will also be involved in this study.

Please quote the HREC REF 196/2022 in all your correspondence.

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

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

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

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

REFERENCE: WC_202204_012
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Prof Klaus Von Pressentin, Dr Michael Leslie Le Roux

Re: Post-procedure semen analysis follow-up of patients who underwent vasectomies at three Cape Town Metropole facilities over a 5-year period (2016 to 2021)

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

Wesfleur Hospital	**Earl Meyer**	**083 491 7328**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted and the constraints caused by the Covid-19 epidemic above are respected and adhered to.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**Annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) and an updated ethics clearance letter to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

PROF. V ZWEIGENTHAL
DIRECTORATE: HEALTH INTELLIGENCE
DATE: 16 May 2022
CC

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

REFERENCE: WC_202204_012
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Prof Klaus Von Pressentin, Dr Michael Leslie Le Roux

Re: Post-procedure semen analysis follow-up of patients who underwent vasectomies at three Cape Town Metropole facilities over a 5-year period (2016 to 2021)

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

Mitchells Plain CHC	**Sr Amanda Hansen**	**021 391 5820**
Heideveld CDC	**Sr Gercia Human**	**021 638 1690**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted and the constraints caused by the Covid-19 epidemic above are respected and adhered to.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**Annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) and an updated ethics clearance letter to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.
5. You are required to notify the substructure office when you commence with your study at the above-mentioned facility(ies) and inform them when you have completed the study at the facility. **Klipfontein - Mitchells Plain Substructure:** Nomtha Bell-Mandla - 021 370 5000 Nomtha.Bell-Mandla@westerncape.gov.za.

Yours sincerely

PROF. V ZWEIGENTHAL
DIRECTORATE: HEALTH INTELLIGENCE
DATE: 27 June 2022
CC