SUITABILITY OF RAPID PSA TEST FOR PROSTATE CANCER SCREENING IN TANZANIA

By

Daniel Robina Ligoha

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CERTIFICATION

The undersigned certifies that he has read and hereby recommend for examination by Muhimbili University of Health and Allied Sciences a dissertation entitled ***Suitability of rapid PSA test for prostate cancer screening in Tanzania,*** in fulfillment of the requirements for the degree of Master of Science in Biochemistry of the Muhimbili University of Health and Allied Sciences.

_____

Dr. Teddy Mselle

(SUPERVISOR)

Date _____

_____

Dr. Francis Dida

(SUPERVISOR)

Date_____

DECLARATION AND COPYRIGHT

I, Daniel Robina Ligoha, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

Signature……. Date…….

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This work is a result of numerous contributions; it is therefore my obligation to say thanks with fairness to all who deserves.

Special thanks to the almighty God for giving me health and strength to do this work.

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I take this opportunity as well to acclaim all my teachers within and outside the Biochemistry department. They selflessly imparted me with knowledge and skills; to them all I have nothing that can equal offer than asking them to accept my humble thanks.

Lastly, I would like to thank my family for their endless support throughout this venture morally, spiritually, materially, their love and provide me with enough time and courage.

DEDICATION

This dissertation is dedicated to my beloved mother, Janeth Mpoli.

ABSTRACT

Background

Prostate cancer is the second leading cause of death in men above 50 years old. Because of late diagnosis, many people turn to hospital when the disease is at an advanced stage, and no longer manageable. Despite the wide uses of prostate specific antigen (PSA) as screening tool in the world, very few Tanzanians have access to this service. The quantitative PSA assay currently used in Tanzania is not widely available because it requires: expensive equipment, skilled personnel and the test itself is costly. However, in other countries, a qualitative assay which is relatively cheap, does not require sophisticated instrument and can be used even in remote areas is available and in use. Therefore in order to detect early prostate cancer, a suitable screening tool is required to be developed and implemented, since the disease is potentially curable when diagnosed early.

Aim of the study

The aim of this study was to establish the accuracy of qualitative (rapid) PSA test by comparing with quantitative PSA ELISA assay and to determine whether obesity affects the level of PSA among Tanzanian men above 45 years of age.

Methodology

A total of 185 men above 45 years of age were recruited, blood sample were analyzed at the MUHAS-Microbiology laboratory, by both qualitative PSA method, and quantitative PSA ELISA assay. Participants filled in questionnaires from which the BMI data, smoking status and alcohol consumption behaviors were obtained. Data were analyzed using SPSS version 17.

Results

Using PSA ELISA as a gold standard, the rapid PSA test showed sensitivity of 95.2%, specificity of 82.4%, PPV and PNV of 55.5% and 82.4% respectively. The BMI correlate with PSA level (r= 0.908) likewise obesity was strongly associated with elevated PSA level, with a relative risk of 1.24. On the other hand, other risk factors (smoking status and alcohol consumption) showed negative association with PSA level. Their relative risks were 0.38 and 0.39 respectively.

Conclusion

Rapid PSA test could be used for mass screening of prostate cancer so as to increase access of the test to most of Tanzanian men. Obesity, smoking and alcohol consumption are risk factors that could interfere with PSA screening.

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ABBREVIATION

ASC	America Society of Cancer
BMI	Body Mass Index
CHRP	Centre for Human Rights Promotion
DNA	Deoxyribonucleic Acid
DRE	Digital Rectal Examination
ELISA	Enzyme Linked Immunosorbent Assay
HDL	High Density Lipoprotein
HRP	Horseradish Peroxide
MNH	Muhimbili National Hospital
MPL	Multi purpose Laboratory
MUHAS	Muhimbili University of Health and Allied Science
O.D	Optical Density
ORCI	Ocean Road Cancer Institute
PCA3	Prostate Cancer Antigen 3
PSA	Prostate Specific-Antigen
PVN	Predictive Value of Negative Test
PPV	Positive Predictive Value of Test
TMB	3,3',5,5,' tetramethyl-benzidine
TRL	Tanzania Railway Limited

WHO	World Health Organization

CHAPTER ONE

1.0. Introduction and Background

1.1. Prostate cancer

Prostate cancer is a malignant that arises in the prostate gland. As with many cancers, if it is advanced or left untreated in early stages, it may eventually spread through either the blood or lymphatic fluid to distant organs. Fortunately, prostate cancer is a slow growing cancer compared to others [1]. Studies have shown that with advancing age, many old men would eventually develop at least some microscopic evidence of prostate cancer, however, this growth is very slow that, in vast majority of men with prostate cancer, they will "die with it, rather than die from it [2].

Although we are in the 21st century, prostate cancer continues to be the most commonly diagnosed malignancy in men, and is the number two cause of death due to cancer among men [3]. Recent data revealed that there were up to 180,000 new cases of prostate cancer diagnosed, and approximately 30,400 deaths due to prostate cancer globally in the year 2003.Thus, early detection of clinically significant cancer remains important.

PSA estimation, digital rectal examination and transrectal ultrasonography have been used to screen for prostate cancer, out of the three screening tools the sensitivity and positive predictive value of PSA is the highest, hence determination of PSA values plays an important role in screening and management of prostate cancer [4].

There is no retrievable data on the extent of prostate cancer in Tanzania, as no study has been done to look at the prevalence of prostate cancer. However a total of 47 men were referred to Ocean road cancer institute (ORCI) for the treatment of prostate cancer in the year 2010 [5]. In Tanzania routine screening for prostate cancer is not done, primarily because of the cost, lack of awareness and lack of suitable and user friendly screening tool.

There are a number of hospitals particularly in Dar es Salaam where PSA testing can be done. In these hospitals the cost to test ranges from 30,000 to 45,000 Tanzanian shillings, which is

too costly to most men. In the regions where a large population of Tanzanians lives, such facilities are none existent. Therefore this study will look for suitability of the qualitative (rapid) PSA test which is a one step rapid test that can be easily used to screen men even in remote areas and at the same time establish the baseline of PSA level in our country.

1.2. Prostate specific antigen (PSA)

Prostate-Specific Antigen is a 33KD serine protease of the Kallikrein family that is produced primarily by prostatic luminal epithelial cells [6]. The function of this enzyme, which is secreted in high concentrations into the prostatic ductal system, is to serve as a liquifactant of the seminal coagulum. While PSA is primarily produced by prostatic epithelial cells, PSA has also been detected in trace amounts in the periurethral glands, endometrium, normal breast tissue, breast tumors, breast milk, female serum, adrenal neoplasms and renal cell carcinomas [7].

However quantifiable levels used in clinical practice essentially make PSA organ-specific leading to its use as an important marker of prostatic disease [8]. As a functional product of normal prostatic epithelial tissue, PSA levels will not only reflect changes due to cancer, but also changes due to inflammation, trauma, or benign proliferation. Because PSA is usually found in low concentration in serum, measured elevations of PSA in serum have allowed it become an important marker for prostate cancer [9]. While controversy exists regarding the mode of transport into serum, elevations of PSA during disease processes are believed to be a product of disruption of the normal cellular architecture within the normal prostate gland [7, 9]. The loss of barrier afforded by basal layer and basement membranes within the normal gland are described as a likely site for the egress of PSA into the circulation during prostatic disease [10].

One study established a reference range of 0-4.0 ng/ml to define normal PSA levels [9]. This level was obtained using the Tandem-R assay (hybritech) in 860 healthy men. Their analysis revealed that values in all men under age 40, and 97% of men over 40 were less than or equal to 4.0ng/ml. results from large screening studies have further supported these values in determining normal levels. While further studies have attempted to refine the sensitivity and

specificity of these levels, to date, these values remain the standard from which elevations are compared [6, 8, 10].

Information regarding the clinical presentation is paramount to the interpretation of an elevated serum PSA. As noted earlier, other prostatic disease processes may affect PSA. Elevations due to instrumentation, such as from biopsy or urethral procedures require up to 4 weeks before accurate levels may be obtained; as the half life of PSA is up to 2.2-3.2 days [11, 12]. Other types of manipulation such as those from DRE have been found not to be associated with significant elevation of PSA, and thus rarely produce false positive results [11]. While PSA elevations are suggested to occur following catheterization or cystoscopy, studies evaluating this failed to confirm a strong association [13].

1.3 Research problem statement

Prostate cancer is the most common form of cancer amongst men who are above 50 years of age. It is the number two cause of deaths among men diagnosed with cancer second only to lung cancer. According to the American Society of Cancer (ACS), in the United States, it is projected that one man out of six will develop prostate cancer during his lifetime [14]. Of all men diagnosed with cancer each year, more than one fourth has prostate cancer. As with all cancers, the earlier prostate cancer is detected, the more easily and effectively it can be treated. In sub-Saharans countries including Tanzania many patients report to the hospital late, at the time when the disease is already advanced. It is therefore imperative for men over 50 years of age to undergo testing for prostate cancer at least once every year. In Tanzania, screening for prostate cancer is available in very few health facilities, majority of which are located in urban centers. However, the vast majority of the elderly men are concentrated in the remote areas, where health care services are limited and cancer screening procedures, including PSA for cancer of prostate screening are nonexistent.

The goal of this study therefore is to investigate the suitability of the rapid PSA test as a screening tool for prostate cancer in Tanzania. Results from this study would help to inform the ministry of health and social welfare and policy makers, and advocate for countrywide provision of rapid PSA test kits for prostate cancer screening. This will result in early detection of prostate cancer and thus save lives of men who would have otherwise die of prostate cancer.

1.4. Research questions

- Is rapid PSA test a suitable screening tool for prostate cancer in Tanzania?
- What is the baseline PSA level among Tanzanian men?
- To what extent does obesity influence the level of PSA in the blood?

1.5. Study objectives

1.5.1. Broad objective

To establish the suitability of PSA rapid test for prostate cancer screening and the relationship between obesity and PSA level among Tanzania men above 45 years of age.

1.5.2. Specific objectives

- To determine PSA level in men above 45 years using quantitative PSA ELISA
- To determine the sensitivity and specificity of PSA rapid tests against quantitative PSA ELISA (which is considered as gold standard), among Tanzanian men
- To examine association between obesity and level of PSA in the blood

1.6. Justification

Late diagnosis of prostate cancer results into death and costly management. Screening for prostate cancer is beneficial because if the disease is detected at an early stage, the treatment would be cheaper, and more effective. Rapid PSA test is a simple screening tool for prostate cancer used in western countries, which is not available in Tanzania. However, there are no studies on validity of this tool and the baseline PSA level in Tanzania.

In this study we investigated the accuracy of PSA rapid test, which can be used as screening tool, whereby a large population of elderly men all over the country will be reached and screened as the test is cost effective and user friendly.

Many studies have reported a negative relationship between obesity and PSA level, which results into later diagnosis of more advanced stage prostate cancer. Eventually, results into high prostate cancer mortality. Therefore we wanted to validate those reported findings in our context of Tanzanian men.

CHAPTER TWO

2.0. LITERATURE REVIEW

2.1. Prostate-specific antigen

A number of studies regarding the use of prostate specific antigen (PSA) as a screening tool for prostate cancer have been published. One study was designed to evaluate the validity of PSA in identifying men who subsequently were or were not clinically diagnosed with prostate cancer it was found that the use of PSA had a significant informative role due to its ability to detect nearly 80% of all aggressive cancers diagnosed within 5 years and about 50% of aggressive cancers appearing as much as 9 or 10 years later. This study revealed its high specificity such that only 96 of 1098 men who remained free of a prostate cancer diagnosis through 10 years had a false-positive test results [15].

In another study [16], conducted in Sweden as a part of Malmo Preventive Project the relationship between concentrations of prostate specific antigen at age 60 and subsequent diagnosis of clinically relevant prostate cancer in an unscreened population was determined to evaluate whether screening for prostate cancer and chemoprevention could be stratified by risk. The total of 1167 men aged 60 were recruited and followed up to the age of 85 years. It was observed that the concentration of PSA at the age 60 predicted the risk that a man will die from prostate cancer by the age of 85 and the association between PSA and death from prostate cancer was stronger than the association between PSA and cancer detectable at biopsy, suggesting that PSA concentration is more useful in detecting tumors of greater malignant potential.

In a review study of PSA and prostate cancer screening several studies were revised and authors came up with the conclusion that, PSA remains the commonest screening test of prostate cancer [17]. However, various tests including prostate cancer antigen 3 (PCA3) urine markers, have been developed to enhance the accuracy of PSA test.

In Tanzania, a study which was designed to correlate Gleason's score and pretreatment PSA level reported the usefulness of PSA in planning the choice of therapy in patients with prostate

cancer in order to improve the prognosis, and revealed that the correlation between Gleason's score and pretreatment PSA levels was statistically significant ($p<0.05$) [18].

2.2. Relationship between obesity and prostate cancer

Studies have shown that obesity, characterized by excess fatty tissues has been shown to increase the risk for development of several common cancers [19]. According to the study done by Heber et al. in 1992, there are a number of biological processes common to these conditions that could lead to a causal interrelationship. Many hormones involved in obesity also play a role in the initiation and promotion of cancer both at a cellular, paracrine, and systemic levels [20]. In developed countries, the most common form of cancers (including; lung cancer, breast cancer, prostate cancer, pancreatic cancer, ovarian cancer, uterine cancer, kidney cancer and gallbladder cancer) is epithelial cell cancers. Further, interactions between epithelial and stromal components within the tissue (as well as hormones reaching the organ via the circulation) may play a role in stimulating tumor development and growth [20]

According to Nimrod et al. there are at least four different mechanisms by which increased hormone secretion may promote cancer development. First, obesity leads to increased production of growth-promoting steroid hormones that can bind to nuclear receptors in hormone-dependent tumor cells. For example, estrogens [21] are produced in excess amounts through aromatization of adrenal androgens by adipose stromal tissues in peripheral fat tissues. Second, free hormone levels can be affected by hormone-hormone interactions as in the case where upper body obesity is associated with reduced sex hormone binding globulin (SHBG) levels leading to increased free levels of circulating estrogens and testosterone [22]. Third, steroid hormone action can trigger increased oxidant-stress-promoting cell proliferation and DNA damage [23]. Androgens have been demonstrated to increase oxidant stress in prostate cancer cells, and oxidant defense mechanisms have been shown to be impaired early in the cancer process. Finally, obesity can increase the production of paracrine factors and hormones which stimulate the production of steroid hormones in cancer tissue through interactions between stromal and epithelial compartments in tissues. Many of these paracrine factors are cytokines produced by both fat cells and white blood cells. Obesity is associated

with increased circulating levels of cytokines, and these levels are reduced with weight loss [24]. The fat cell, which is the source of many of these so-called adipocytokines, may play a significant role in the ability of fat tissue to preserve immune resistance to infections. It has long been recognized that malnutrition is associated with multiple impairments of immune function including impaired T-helper cell function. Hence, the ability of fat to store calories provides a separate important function to protect immune defenses [25].

Cancer and heart disease are today replacing infectious diseases as the primary cause of death, as obesity becomes more common in developing countries. It is possible that the increased cytokine secretion observed in obesity is simultaneously having a beneficial effect on infectious disease resistance while at the same time increasing the risk of cancer. These observations may be related to the present findings that cholesterol-rich membrane micro domains regulate a survival function in human prostate cancer cells

However, recent studies have shown that PSA level are lower in obese men [25], suggesting a cause for later detection of prostate cancer in obese men.

CHAPTER THREE

3.0. Methodology

3.1. Description of study population and area

This study screened men above 45 years from different places of Dar es Salaam city who were not diagnosed to have prostate cancer, and consented to be part of study including residents of Namanga-Msasani, Kijitonyama and TRL's workers.

3.2. Study design

This was a cross sectional study, whereby men above 45 years were recruited and screened for prostate cancer using PSA level, obesity status using BMI and filled questionnaires to determine their demographic and lifestyle characteristics.

3.3. Sample size

Sample size was calculated using presumed prevalence of prostate cancer since the actual prevalence of prostate cancer in Tanzania is not known. According to the American cancer society, it is projected that one man out of six will develop prostate cancer during his life time. This gives expected prevalence of 1/6 (17%) which was used to determine the sample size.

- Study sample size formula;

$$N = \frac{t^2 \times P(1-P)}{d^2}$$

Whereby N= required sample

t= confidence level at 95% (1.96)

P= Prevalence of the disease (17%)

d= margin of error at 5% (0.05)

Then, total of 217 participants were required, but only 185 men were recruited in this study.

3.4. Recruitment and exclusion criteria

3.4.1. Inclusion criteria

This study recruited volunteer with the following criteria

- Apparently healthy men aged above 45 years
- Have consented to participate in the study
- Abstained from sex for two days

3.4.2. Exclusion criteria

This study did not include volunteer who were;

- Men who did not consent to participate in the study
- Men below 45years
- Men with other health complications including: prostatitis, dysuria, and benign prostatic hyperplasia (BPH)
- Had sex in the past two days
- Men who had DRE within 4 weeks.

3.5. Sample collection procedures

3.5.1. Blood sample collection

Through venepuncture, 5mls of blood were collected in coagulated tubes (red top) which were labeled with participant's name and study number for effective identification. Serum was separated from blood cells as soon as possible by centrifugation at 3000 *r.p.m* for five minutes. The serum obtained was stored in freezer at -20^0C.

Hemolyzed samples were excluded from analysis. On the day of the assay frozen sample were slowly thawed and brought to room temperature.

3.5.2. Obesity determination

Obesity was determined using BMI whereby individual's height and weight were measured. Participants were weighed after removing their shoes and emptying their pockets, standing height was measured using stadiometer with a vertical backboard and a movable headboard.

Then BMI was determined by the following formula

BMI = weight/ (height * height)

(Weight in kilograms and height in meters)

Table 1: The International Classification of adult underweight, overweight and obesity according to BMI

Classification	**BMI(kg/m²)**	
	Principal cut-off points	**Additional cut-off points**
Underweight	**<18.50**	**<18.50**
Severe thinness	<16.00	<16.00
Moderate thinness	16.00 - 16.99	16.00 - 16.99
Mild thinness	17.00 - 18.49	17.00 - 18.49
Normal range	**18.50 - 24.99**	**18.50 - 22.99**
		23.00 - 24.99
Overweight	**≥25.00**	**≥25.00**
Pre-obese	25.00 - 29.99	25.00 - 27.49
		27.50 - 29.99
Obese	**≥30.00**	**≥30.00**
Obese class I	30.00 - 34.99	30.00 - 32.49
		32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49
		37.50 - 39.99
Obese class III	≥40.00	≥40.00

Source: Adapted from WHO, 1995, WHO, 2000 and WHO 2004.

However, in this study BMI was categorized only into two groups; obese for those with BMI greater or equal to 30 and non obese for those with BMI less than 30.

3.5.3. Socio-demographic characteristics

Demographic data and lifestyle characteristics were determined using a structured questionnaire. Participants were asked about their smoking behavior, alcohol consumption, family history of prostate cancer and previous exposure to DRE.

3.6. Detection of PSA level in serum

3.6.1. Detection of PSA level using rapid PSA test kit

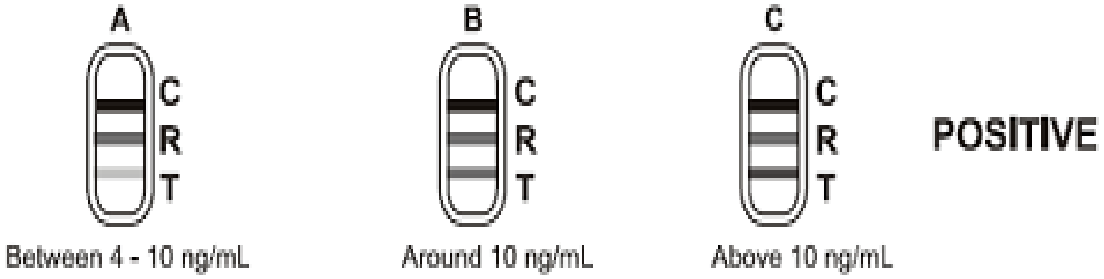
DIAQUICK PSA test, a semi-quantitative assay was used to identify a PSA level above 4ng/mL in human blood. This test however does not determine the exact concentration of PSA.

Assay procedure

1. All materials and specimens were brought to room temperature
2. The test card was removed from the sealed pouch.
3. Using a transfer pipette, 3 drops of sample were added into the sample well of the test card
4. Result was interpreted by two independent observers at 5 and 10minutes

Interpretation of results

1. Positive: If in addition to the control band the color of the test band is equal or stronger than that of the reference band, it indicates a PSA level ≥4.0ng/mL.



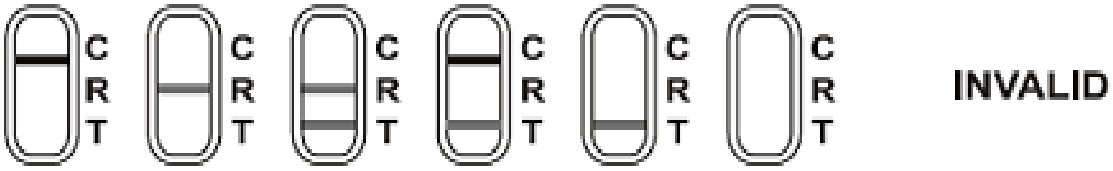
Source; DIAQUICK PSA Cassette operating manual

2. Negative: If in addition to the control band only a colored reference band appears or the color intensity of the test band is less than that of the reference band, it indicates a PSA <4ng/mL.



Source; DIAQUICK PSA Cassette operating manual

3. Invalid: The test result is invalid if a colored band does not form in the control region. The sample must be retested, using a new test device.



Source; DIAQUICK PSA Cassette operating manual

3.6.2. Quantification of serum PSA by ELISA

DIALAB PSA ELISA kit was used for the quantitative determination of human prostate-specific antigen (PSA) concentration in the blood

Principles of the assay

This assay is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the sandwich principle. The micro wells are coated with an antibody, directed towards an epitope of an antigen molecule. An aliquot of patient serum is incubated in the coated well with enzyme conjugated second antibody (E-Ab), directed towards a different region of the antigen molecule. After incubation the unbound E-Ab is washed off. The amount of bound E-Ab is proportional to concentration of antigen in the sample. After adding the substrate solution, the intensity of colour developed is proportional to the antigen concentration in the sample. The measured Optical densities of the calibrators are used to construct a calibration curve against which the unknown samples are calculated.

The procedure

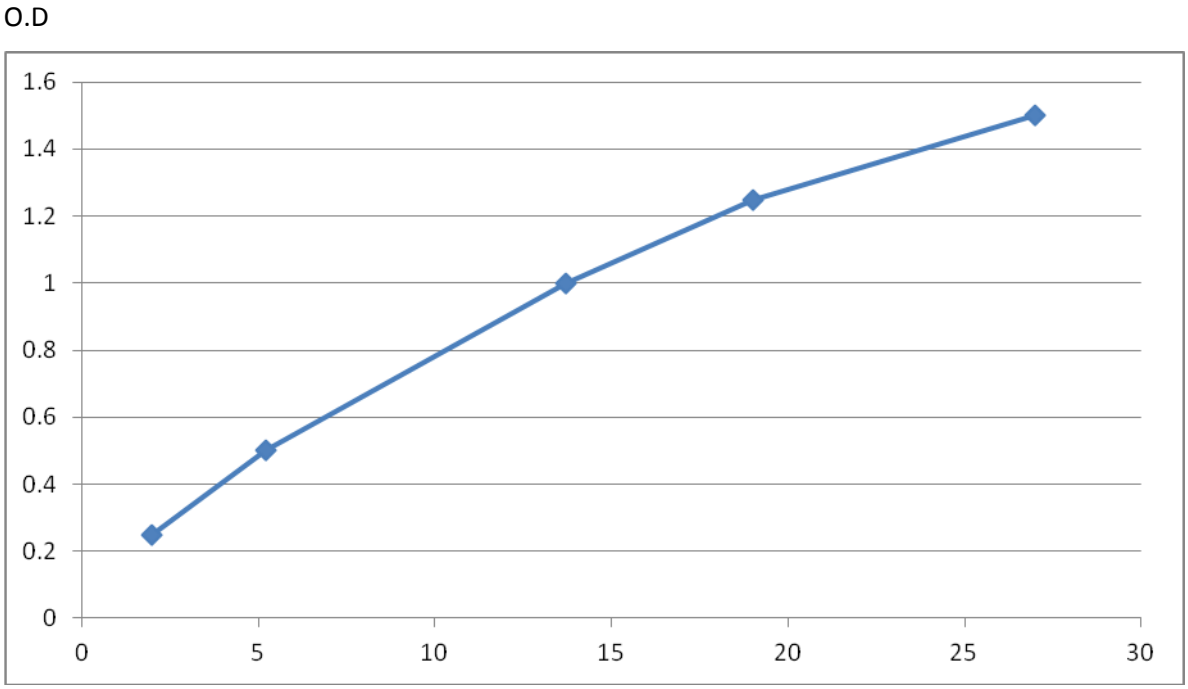
1. Prior to use all reagents, calibrators, controls and samples were brought to room temperature (18-25^{0}C)
2. The plate map was designed and the required microplate formatted to document the position of wells with respect to the samples, calibrators and controls to ensure later identification.
3. In duplicate 25µL of calibrators, controls or samples was pipetted into respective wells. Samples with PSA values above 25ng/mL were diluted with the diluents.
4. Plates were then incubated at room temperature for 5minutes.
5. Thereafter, 100µL of enzyme conjugate was added into each well and mixed for about 10 seconds, and incubated at room temperature for one hour.
6. The plate was washed using ELISA washer with distilled water 6x.
7. Thereafter, 100µL of the substrate was added into each well, and then incubated for 20 minutes at room temperature
8. About 100µL/well of sulphuric acid (stop) solution was added
9. Using an ELISA reader, the plate was read at 450nm, after which a standard curve was plotted and the amount of PSA in test samples were determined from the graph.

Interpretation of the results

1. Mean absorbance was calculated for each duplicate and the blank value was subtracted from the mean absorbance values.

2. The calibration curve was drawn by plotting absorbance values for standards against appropriate PSA concentration
3. Finally, the PSA concentrations were read off for the control and the samples.

Figure 1: The PSA standard curve



3.7. Control

In this study, we included two types of control, five negative controls of women blood samples (since women do not express PSA) and four positive controls from diagnosed men.

3.8. **Management of cases**

All participants who were found to be positive by the ELISA assay were referred to the Ocean Road cancer Institute (ORCI) for further investigations and management

3.9. Data entry and analysis

Data were entered using MS Excel 2007, cleaned and analyzed using SPSS 17 version Statistical software.

3.9.1. **Determination of rapid DIAQUICK PSA performance**

Sensitivity, specificity, predictive value of positive and negative test was obtained using the following table and formulas respectively.

Table 2: Sensitivity and Specificity of a Screening test

Screen test (DIAQUICK PSA test)	**ELISA(Gold standard)**		**Total**
	Positive	**Negative**	
Test positive	(TP)	(FP)	(T+)
Test negative	(FN)	(TN)	(T-)
Total	(D+)	(D-)	(N)

- Sensitivity =TP/D+ × 100%
- Specificity = TN/D- × 100%
- The predictive value of a positive test (PVP) = TP/T+ × 100%
- The predictive value of a negative test (PVN) = TN/T- × 100%

3.9.2. Prevalence of men with abnormal PSA levels

Proportion of men with abnormal PSA level was used to establish prevalence of men with abnormal PSA levels

3.9.3. Determination of relationship between obesity and PSA level

Relationship between obesity and PSA level was established by determining the correlation coefficient

3.9.4. Determination of association between smoking, alcohol and PSA level

Association between smoking, alcohol consumption and PSA level were assessed through relative risk analysis by 2×2 table shown here below.

Table 3: A 2x2 table for analysis of relative risk

RISK	**PSA LEVEL**	
	High (above 4ng/ mL)	**Low (below 4ng/ mL)**
Smokers	a	b
Non smokers	c	d

Relative risk (RR) = a/(a+b) ÷ c/(c+d)

With 95% confidence interval InRR = InRR ± 1.96SE(InRR)

3.10. Ethical clearance and permission

Ethical clearance was obtained from the Muhimbili University of Health and Allied Sciences (MUHAS) Ethical Review Board (ERB). Samples were collected after informed consent was received from the study participants after the aim of the research, their usefulness in the community as well as the role of participants during the study was explained. Further, participants were assured of confidentiality of the information collected. In order to maintain confidentiality study numbers were given and laboratory findings were handled carefully to restrict unauthorized access and were given only to the responsible person.

3.11. Limitation of the study

Although many men responded for this screening study and were ready for enrollment, because of budgetary restrictions, we recruited only a few since we only managed to buy only three test kits of PSA ELISA capable of analysis of only 144 samples including standards and controls samples.

CHAPTER FOUR

4.0. Results

4.1. Demographic characteristics and rapid PSA screening results.

We screened 185 men aged 45 to 85 years (mean 54), using DIAQUICK PSA kit. The frequency of participants per age group is tabulated here under.

Figure 2: Age distribution of study participants

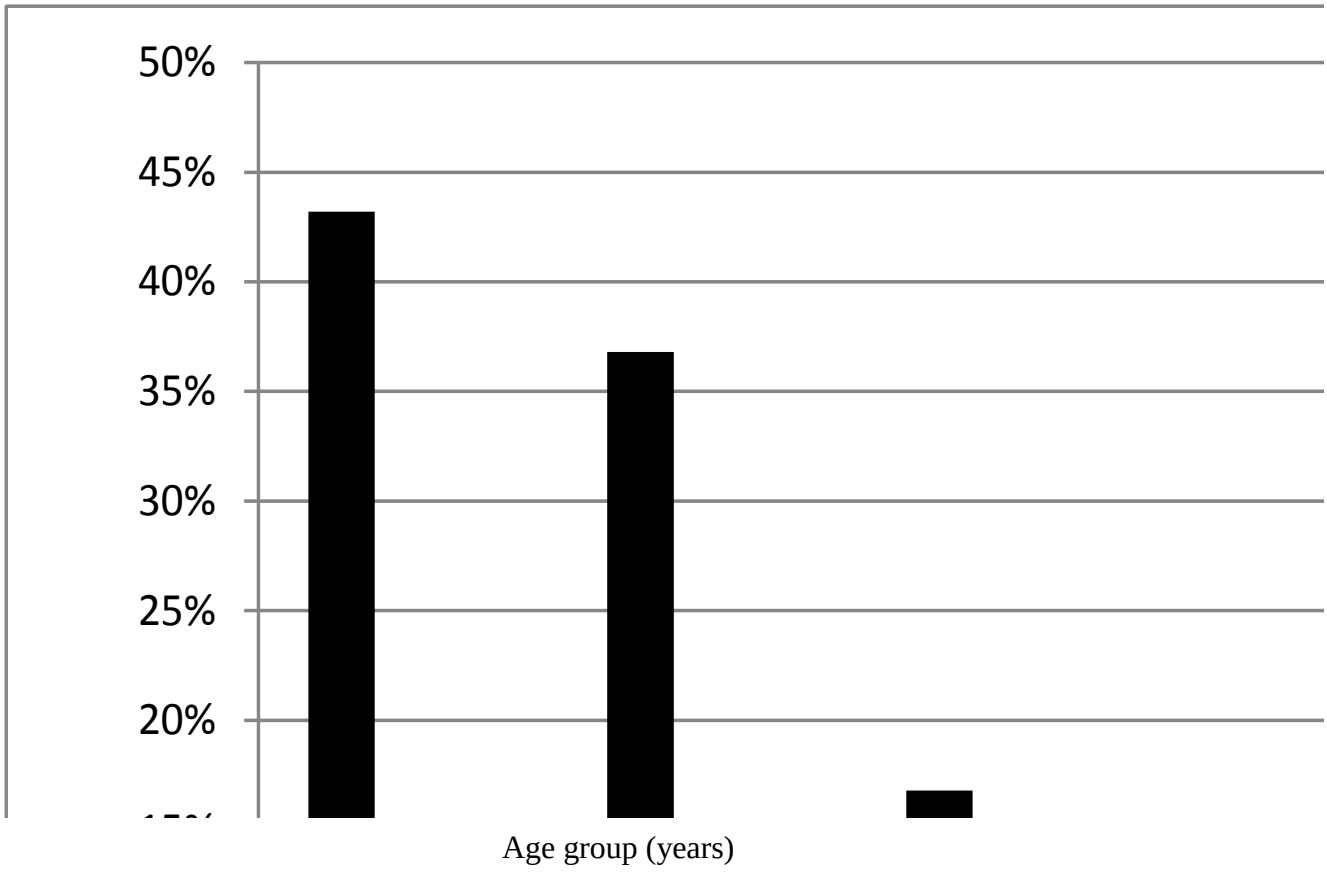


Table 4: Socio-demographic characteristics and rapid PSA screening results (n=185).

Characteristics	Measure
Age in years, mean ± SD	53.98±8.505
Race	
African	185 (100%)
Body Mass Index	
Mean ± SD (kg/ m^2)	26.48 ± 4.51
Obese	46 (24.9%)
Non obese	139 (75.1%)
Rapid PSA test results	
Negative	149 (80.5%)
Positive	36 (19.5%)
Demographic & lifestyle	
Family history of Prostate cancer	
Yes	11 (5.9%)
No	174 (94.1%)
Smoking	
Yes	28 (15.1%)
No	157 (84.9%)
Alcohol consumption	
Yes	92 (49.7%)
No	93 (50.3%)
DRE history	
Yes	0 (O%)
No	100 (100%)

DRE: Digital rectal examination; PSA: Prostate-specific antigen; SD: Standard deviation

Table 4 shows the socio-demographic characteristics, and rapid PSA screening results, the average BMI of the men was 26.48 whereby 24.9% were obese. Only 36% were positive for rapid PSA test, and none of the men had previously screened for prostate cancer. Men who smoke and drink alcohol were 28 and 92 respectively, and 5.9% of men reported to have history of prostate cancer in their family. None of the participants previous had screened for prostate cancer by DRE, PSA or TRUS. All participants were African by race.

4.2. Performance of rapid PSA test versus ELISA PSA (gold standard) assay

Table 5: Comparison between the rapid DIAQUICK PSA test and ELISA assay

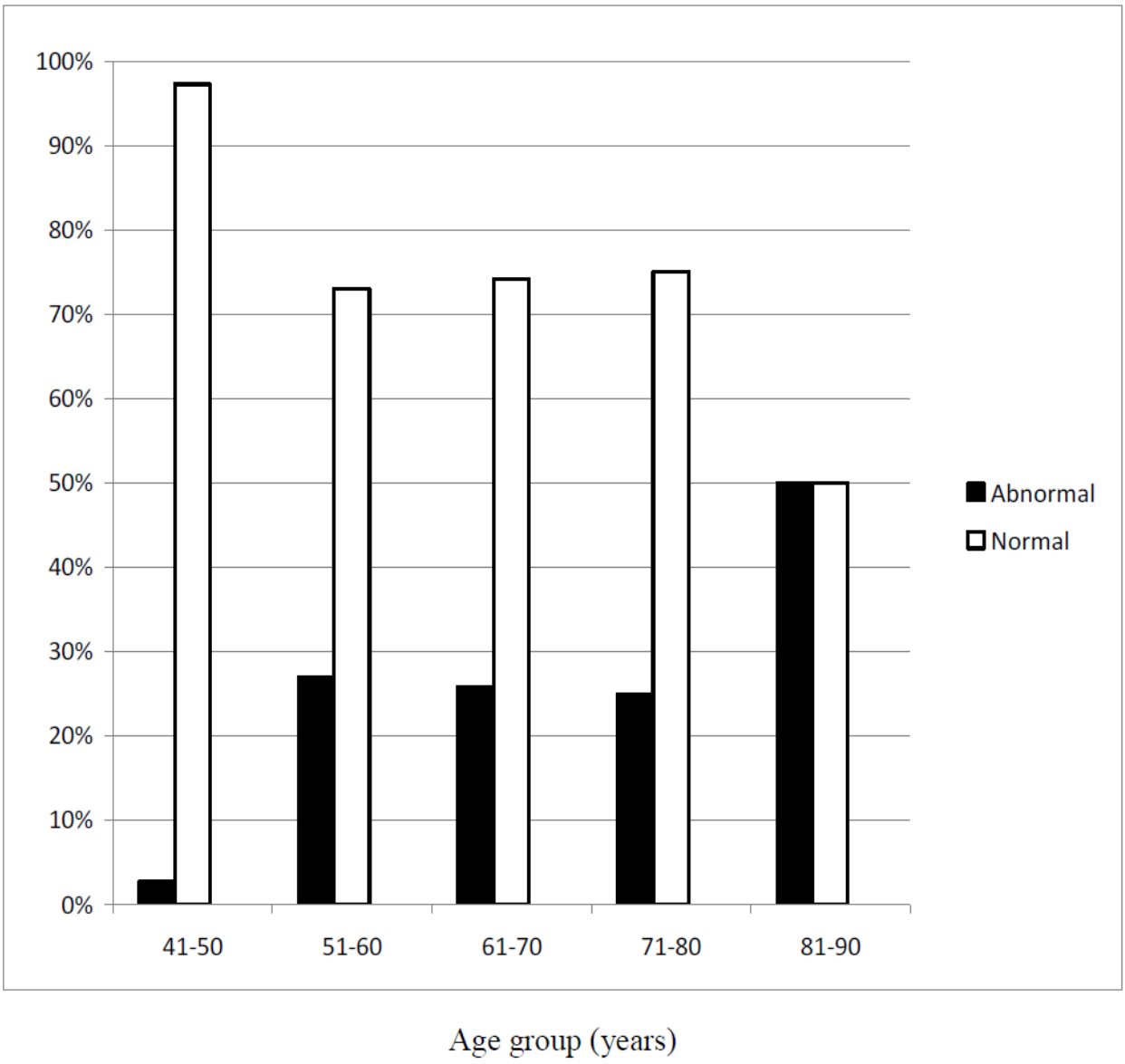
Screen test	**ELISA (Gold standard)**		**Total**
	Positive	**Negative**	
Test positive	20	16	36
Test negative	1	75	76
Total	21	91	112

Quantitative PSA by ELISA is considered to be the gold standard for PSA estimation. A comparison of the rapid PSA test with ELISA assay revealed that the rapid test had sensitivity of 95.23% and specificity of 82.42%. On the other hand their predictive value of positive and negative tests was 55.55% and 82.42% respectively. The prevalence of men in this study, with higher level of PSA above 4ng/ mL was 11.4%.

4.3. Age and the level of PSA

The frequency of abnormal PSA values with age in men above 45 years of age. It was found that men 81-90 years of age had the highest percentage (50%) of abnormal PSA, followed by the 71-80, 61-70, 51-60 and the 45-50 age groups with 25%, 25.8%, 27.% and 2.8% respectively.

Figure 3: The proportion of men with abnormal PSA level increases with Age



4.4. Results of the controls

We estimated PSA levels from blood samples of 5 women who served as control, and all were negative by ELISA, indication a PSA level below 0.2 ng/mL, which was below the detection limit of the quantitative ELISA PSA assay used in this study. On the other hand the positive control was positive to the rapid PSA test

4.5. Association between Obesity and level of PSA in blood

We determined whether obesity affects the level of PSA in the blood. We found that there was no correlation between the BMI and the level of PSA in the blood (r = 0.908). Surprisingly, when participants were grouped into either obese or non obese using BMI, the relative risk of obese men above age of 45 years having elevated PSA was 1.24 with 95% CI of RR (1.06, 1.45)

4.6. Lifestyle risk factors

In this study, smoking behavior and alcohol consumption where investigated to see if they are involved in manipulating the level of PSA. Risk analysis showed that smoking and alcohol consumption reduce risk of having elevated PSA. The following are their relative risk (RR) and 95% CI of RR 0.38 (0.145, 0.99) and 0.39 (0.32, 0.47) respectively.

CHAPTER FIVE

5.0. Discussion

Most of prostate cancer cases present late when the disease is no longer manageable with the available therapeutic modalities. To avoid costly treatment with poor prognosis associated with advanced disease following late diagnosis, an early detection using a simple, less costly and accurate screening tool is required for prostate cancer.

Prostate-specific antigen is a widely accepted serum marker for detection of prostate cancer; this has come due to its high specificity and PVP when compared with other available screening modalities like DRE, and TRUS [4]. Apart from screening, PSA is also used in monitoring progress of prostate cancer treatment. There are two forms through which PSA can be measured. The qualitative and quantitative method, of these quantitative is the most common assay that has been used for several years here in Tanzania. Measurement of PSA values by a quantitative method requires special equipment and costs approximately 30,000-45,000 Tanzanian shillings per assay. On the other hand, the qualitative PSA test (which is a rapid test cassette) can be priced at 3,000-5000 per test which is much lower. For mass screening of abnormal PSA values, a simpler, more effective method would be preferable. The rapid PSA cassette does not need special equipment, because this is qualitative detection method that utilizes the principle of immunochromatography.

In this study we evaluated the accuracy of the rapid PSA cassette using the quantitative PSA assay as a gold standard. There was 95.23% sensitivity, 82.42% specificity, 55.55% predictive value of positive test and 82.42% predictive value of negative test. These findings ascertain that rapid PSA test's usefulness in mass screening, because of its ability to detect nearly all men with abnormal level of PSA, and give negative results in the vast majority of the negative cases. Unfortunately, one sample with PSA concentration of 8ng/mL showed false negative and 16 samples with PSA concentration <4ng/mL showed false positive. We failed to compare this finding with

other studies due to difference in settings as many studies compared rapid PSA test with other tests like DRE or TRUS. But in our study we compared between the two PSA assays (qualitative and quantitative).

Obesity was determined using BMI, and results revealed that there was no correlation between BMI and PSA level (*p-value*, 0.908), which is contrary to other studies done in the US [26]. Perhaps the reason for this discrepancy could be due to the relative low prevalence of obesity in Tanzania [27]. However when BMI data were classified to either obese or non obese, relative risk analysis showed that obesity men are in high risk to have abnormal PSA, RR 1.24 (1.06, 1.45). This finding is different from others due to the fact that prevalence of obesity among Tanzanian men is high (24.9%).

The prevalence of abnormal PSA level was highest in the age group of 81-90 and lower in 41-50 with the rate of 50% and 2.78% respectively. This observation is comparable to many studies which showed that PSA level increases with age [8]. Smokers have low risk of having abnormal PSA level. Our study reveals that the risk for smokers to have elevated PSA level is very low (less than 38%) compared to non smokers. This observation is similar to what was found in a recently published paper which looked at an association between smoking and PSA and found a inverse association between smoking and total PSA [28].

Likewise, we observed a similar association in men who take alcohol, where we found a relative risk of 0.39 with 95% confidence interval of (0.32, 0.47) among alcohol drinkers, indicating that consumption of alcohol influences the level of PSA. Similar results were reported in the study of the effect of alcohol and tobacco on PSA level [29].

Finally, it was noted that the vast majority of participants were not aware about prostate cancer, and that all men (100%) had not been previously screened for the disease.

CHAPTER SIX

6.0. Conclusion and Recommendations

6.1. Conclusion

Because of lack of awareness, and absence of a convenient and economic affordable tool, screening for prostate cancer is not routinely performed among older men in Tanzania. If qualitative rapid PSA is introduced this service could be made available.

This study shows that rapid PSA test is an accurate and suitable tool which could be used to provide screening services to most of Tanzanian men in needy as we found it to be effective in detecting most of men with abnormal PSA level. This could results into minimization of cost and labor required for mass screening using quantitative PSA and increases the availability of the service. Further, among Tanzanian men, obesity is associated with high PSA level while, smoking and alcohol consumption is associated with low levels of PSA thus increasing the risk of missed, and late diagnosis of prostate cancer.

6.2. Recommendations

We recommend rapid PSA test to be used as screening tool for prostate cancer because the test is very cheap, user friendly and readily available. Positive qualitative PSA results must be first verified with quantitative assay before a patient is referred for further management.

Because of lack of awareness of prostate cancer among men, there is an urgent need to extend advocacy regarding prostate cancer highlighting the importance of early diagnosis as pioneered by the 50plus group.

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8. APPENDICES.

8.1. Appendix I

INFORMED CONSENT FORM AND PROCEDURE

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Suitability of rapid PSA test for prostate cancer screening in Tanzania.

Researcher

Name: Daniel Ligoha (Msc. Candidate)
Email: ligodan2007@yahoo.com
Tel: +255714523280
Dept.: Biochemistry

Introduction

You are being invited to volunteer as a subject in a study being conducted at Muhimbili University of Health and Allied Sciences (MUHAS), and Ocean Road Cancer Institute (ORCI). This consent form provides you with the information you will need when considering whether or not to participate in this study. If you decide to participate, you will be asked to sign this consent form which states that you have read the *Summary of the Study*, that any questions you have about the study have been answered, and that you agree to participate. You will be given a copy of this form to keep for your records.

Study Purpose

Through this study, we will develop a suitable screening tool that will enhance the process of extending screening services for prostate cancer to the majority and better understand the risk associated with obesity with respect to prostate cancer.

Only men above 45 years will be eligible to participate in this study.

Study Procedures

If you decide to participate in this study, about 4-5mls of blood sample will collected for PSA quantification and also you will be asked to take height and weight measurements so as to determine your body mass index. This will be done once except for those who may found positive to this test. They will be referred for further diagnosis using needle biopsy at Ocean road cancer institute.

To ensure confidentiality of all of your information, you will be assigned a ***Study ID*** number that will become your *Study ID* number throughout this study.

Study Risks

Your participation in this study involves no physical risk.

Study Benefits

Benefits to you may include a chance to ascertain your health status regarding the risk of developing prostate cancer and for those who will be found positive will receive early treatment which is very effective we offered in early stage of the disease.

Cost to the Subject

There are no costs for participating in this study.

Compensation

No any compensation will be offered by participating in this study

Confidentiality

If you consent to participate in this evaluation, your personal information will be kept confidential.

Funding

This study is funded by the ministry of health and social welfare

Voluntary participation and withdrawal from the study

The decision whether to be in this study is entirely up to you. Participation is voluntary. You can refuse to participate, or withdraw from the evaluation at any time, and such a decision will not affect your relationship with the ministry of health and social welfare and MUHAS either now or in the future. Nor will a refusal or withdrawal of participation result in the loss of any other benefits to which you are otherwise entitled. Signing this form does not waive any of your legal rights.

Contacts

If you have any questions, please ask, and we will do our best to answer them**.**

If you have additional questions in the future, please contact

Dr. Teddy F. Mselle, +255655585814

Dr. Francis Dida +255657094059

Daniel Ligoha +255714523280

Statement of Consent

I have reviewed the study design outlined above and have had any questions I have about the study answered to my satisfaction. I understand that my participation is voluntary and that I can withdraw from the study at any time without prejudice. Signing this form does not waive any of my legal rights.

By signing below, you are indicating that this form has been explained to you, that understand it, and any questions you have about the evaluation have been answered. You are indicating that you understand the ways the study data may be used and how your privacy will be protected. By signing this form, you are agreeing to participate in the study *at this time only*.

I ACKNOWLEDGE THAT I HAVE READ THE ABOVE EXPLANATION OF THIS EVALUATION THAT ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I AGREE TO PARTICIPATE IN THIS STUDY.

_____ Signature of study volunteer

_____ Printed name of study volunteer

Date _____

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE SUBJECT THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS STUDY.

_____ Signature of researcher/designate

Date _____

8.2. Appendix II

FOMU YA KUOMBA IDHINI NA UTARATIBU WA KUSHIRIKI KATIKA UTAFITI

Jina la utafiti: Uwezo wa vitendanishi haraka vya PSA katika utambuzi wa kansa ya tezi dume hapa Tanzania

Jina Mtafiti: Daniel Ligoha (MSc. Mgombea)

Barua pepe: ligodan2007@yahoo.com

Simu:+ 255714523280

Idara: Biokemia

UTANGULIZI: Ndugu unakaribishwa kujitolea kushiriki katika utafiti utakaofanywa hapa katika chuo kikuu cha afya cha Muhimbili na taasisi ya saratani ya Ocean Road. Fomu hii ya ridhaa inakupa maelekezo ambayo utapaswa kuyazingatia kabla hujaamua kushiriki ama kutokushiriki katika uchunguzi huu. Utaulizwa kwa saini fomu hii ya ridhaa ambayo inasema ya kuwa umesoma Muhtasari wa somo na kuuelewa na kwamba maswali yoyote kuhusiana na tafiti hii umejibiwa vyema na kuridhika na hivyo unakubali kushiriki. Utapewa nakala ya fomu hii kwa ajili ya kuweka rekodi zako.

LENGO LA UTAFITI: Kuthibitisha matumizi ya vitendanishi katika uchunguzi wa kansa ya tezi dume

UTARATIBU WA UTAFITI: Kama utaamua kushiriki katika utafiti huu, utaombwa kutoa sampuli ya damu kati ya mililita nne au tano kwa ajili ya kuangalia wingi wa PSA na pia utaombwa kuchukua vipimo vya urefu na uzito ili kutambua hali yako ya unene. Hii itafanyika mara moja ila kwa wale ambao wanaweza kupatikana chanya kwa mtihani huu. Wataelekezwa kwenda Ocean Road kwa uchunguzi zaidi. Kuhakikisha siri yote ya taarifa yako, utapewa namba ya utambulisho itakayotumika wakati wote wa utafiti

ATHARI ZA KUSHIRIKI: Utafiti huu hauna athari yeyote kwa mshiriki

FAIDA ZA KUSHIRIKI: Faida ya kushiriki katika utafiti huu ni nafasi ya kuweza kutambua hali yako kiafya hasa kuona kama unamwelekeo wa kuugua kansa ya tezi dume na hivyo kupata matibabu mapema.

GHARAMA ZA USHIRIKI: Hakuna gharama yoyote kwa ajili ya kushiriki katika tafiti hii.

FIDIA: Hakuna fidia yoyote itakayolipwa kwa kushiriki katika utafiti huu

SIRI: Kama ambavyo fomu ya ridhaa ya kushiriki katika tathmini hii ilivyoeleza, habari yako binafsi itakuwa siri.

MDHAMINI WA TAFITI HII: Utafiti huu unafadhiliwa na wizara ya afya na ustawi wa jamii

UHIARI WA KUSHIRIKI NA KUJIONDOA KWENYE UTAFITI: Uamuzi wakukataa au kujiunga katika utafiti huu ni juu yako mwenyewe na muda wowote utakapoona huhitaji kuendelea na utafiti huu unaweza kujiondoa bila faini yeyote. Na uamuzi huo hauwezi kuasiri uhusiano wako na wizara ya afya na ustawi wa jamii na chuo kikuu cha Muhimbili. Au kupoteza haki zako za msingi

MAWASILIANO: Kama una maswali yoyote, tafadhali uliza, na sisi kufanya kazi nzuri ya kujibu maswali yako. Kama una maswali ya ziada katika siku zijazo, tafadhali wasiliana na

Dr Teddy Mselle + 255655585814

Dr. Francis Dida +255657094059

Daniel Ligoha +255714523280

TAARIFA YA KIBALI

Mimi binafsi nimeisoma maelezo ya utafiti huu kama ilivyoainishwa hapo juu na kuelewa na maswali yangu yote kuhusiana na utafiti yamejibiwa na nimeridhika. Nimeelewa kuwa ushiriki wangu ni wa hiyari na kwamba ninaweza kujiondoa muda wowote bila chuki. Kutia saini fomu hii haina maana kuondoa haki zangu za kisheria kwa namna yeyote ile Kwa kutia saini hapa chini, tunaamini kwamba kwamba maelezo yaliyomo ndani ya fomu hii yameelezwa kwako na wewe umyafahamu, maswali yako kuhusu utafiti huu wamekujibu kikamilifu na hivyo basi, umeelewa namna taarifa zako zitakavyofanyiwa kazi na usiri wake. Kwa kutia saini fomu hii, inamanisha umekubali kushiriki katika utafiti wakati huu tu.

Mimi nakubali kuwa Nimesoma maelezo ya hapo juu ya utafiti huu kwamba maswali yangu yote yamejibiwa na nimeridhika, hivyo nakubali kushiriki katika utafiti huu.

_____ Sahihi ya mwenye kujitolea

_____ Tarehe

Mimi nathibitisha kwamba nimemweleza kikamilifu mtajwa hapo juu asili, kusudi, utaratibu, hatari iwezekanayo na faida za utafiti huu _____.

_____ Sahihi ya mtafiti / mteule Date _____

8.3. Appendix III:
CASE REPORT FORM & LABORATORY INVESTIGATION.

Title; Suitability of rapid PSA test for prostate cancer screening in Tanzania

Participant details

Name:…….

Study No……

Age……..Height……..Weight……

BMI……..Obese/Non obese

Race:…….

Occupation……

Family history of prostate cancer…….

Smoking/ Alcohol consumption……

Laboratory findings

PSA level results

Qualitative PSA test……Positive/Negative

PSA ELISA test…….ng/**m**l