MANAGEMENT AND HEALTH RELATED QUALITY OF LIFE AMONG PATIENTS WITH PROSTATE CANCER AT KENYATTA NATIONAL HOSPITAL: A DESCRIPTIVE CROSS-SECTIONAL STUDY

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A Research Dissertation submitted in partial fulfilment of the Requirements for the Award of the Master of Pharmacy in Clinical Pharmacy of the University of Nairobi

NOVEMBER 2021

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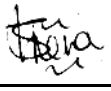
2. Signature:  Date: 17th November 2021

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DEDICATION

I wish to dedicate this work to my father, Joshua Kamau Mwangi, for his unwavering support, guidance and constant encouragement through this course.

ACKNOWLEDGEMENTS

Thank you to the Almighty God for His grace.

I would like to acknowledge my supervisors, Dr. Peter N. Karimi and Dr. Irene W. Weru for their guidance, correction and assistance during the course of this research. I would especially like to thank Dr. Karimi, as our course coordinator for always keeping us on our toes.

To the nurses, staff and patients of the Urology clinic (Clinic 24) and the Cancer treatment centre (CTC) as well as the oncology pharmacy staff, thank you for your accommodation, support and cooperation during the process of data collection.

To my classmates, the Clinical Pharmacy Class of 2021, thank you for your camaraderie especially during the pandemic. Good luck in all your endeavours.

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ABBREVIATIONS AND ACRONYMS

^{223}Ra	Radium-223
ADT	Androgen Deprivation Therapy
ARTA	Androgen Receptor Targeted Agent
BMI	Body Mass Index
BT	Brachytherapy
CF	Cognitive functioning
CRPC	Castrate Resistant Prostate Cancer
CTC	Cancer Treatment Centre
DRE	Digital Rectal Examination
EBRT	External Beam Radiation Therapy
EORTC	European Organisation for the Research and Treatment of Cancer
ESMO	European Society of Medical Oncology
FI	Financial difficulties
HBOC	Hereditary Breast and Ovarian Cancer Syndrome
HRQoL	Health-Related Quality of Life
KNH	Kenyatta National Hospital
LHRH	Luteinising Hormone Releasing Hormone
LUTS	Lower Urinary Tract Symptoms
mHNPC	Metastatic Hormone Naïve Prostate Cancer
mpMRI	Multiparametric Magnetic Resonance Imaging
NCCN	National Comprehensive Cancer Network
PC	Prostate Cancer
PF	Physical functioning
PLND	Pelvic Lymph Node Dissection
PSA	Prostate Specific Antigen
RF	Role functioning
RP	Radical Prostatectomy
RT	Radiation Therapy
SAC	Sexual activity
SF	Social functioning
TRUS	Transrectal ultrasonography
UON	University of Nairobi
WHO	World Health Organisation

OPERATIONAL DEFINITIONS

Advanced Disease – "disease that has spread to distant sites such as the lymph nodes and organs of the body such as bone or lungs"

Androgen Deprivation Therapy- "surgical castration using orchiectomy or medical castration using LHRH agonists or antagonists to achieve serum testosterone levels < 50 ng/dl"

Castration Resistant Prostate Cancer – "disease which exhibits progression while on ADT, despite serum testosterone being at castration levels."

Clinically Localised Disease – "disease that is confined within the prostate"

Clinically Significant Disease – "prostate cancer which if left untreated will affect the patient's health"

Cognitive functioning- "the ability to maintain concentration while performing activities and/or memory loss."

Combined Androgen Blockade- "combination of ADT with non-steroidal antiandrogens, androgen-receptor targeted agents or a CYP17 inhibitor"

Emotional functioning- "feelings of anxiety, tension, worry, depression and irritability and lack thereof."

Financial difficulties- "the financial toxicity caused by or associated with the disease and its management."

Health-Related Quality of Life – "extent to which one's usual or expected physical, emotional, and social well-being is affected by a medical condition or its's treatment"

Locally Advanced Disease – "cancer that has broken through the prostatic capsule and has invaded nearby tissues"

Physical functioning – "ability of a person to perform strenuous activities with ease, walk short and/or long distances and perform activities of self-care without any help."

Role functioning – "ability to perform activities of daily life as well as any leisure activities without any limitation."

Social functioning- "interference of the disease and its management with family life and/or social relationships and activities."

Prostate Cancer – "a malignant tumour of the prostate gland"

ABSTRACT

Background: Advances made in the screening, diagnosis and management of prostate cancer have improved the survival rates of patients. However, the majority of these treatments including surgery, radiation therapy and pharmacotherapy, have an impact on the subsequent health-related quality of life of these patients. Since it is an important prognostic factor of survival, failure to evaluate the health-related quality of life and its predictors in these patients typically results in long-term deficits in their overall well-being, that is, their physical, social, emotional and mental health.

Objectives: The objective of this study was to evaluate the management and health-related quality of life among patients with prostate cancer at Kenyatta National Hospital.

Methodology: This was a descriptive cross-sectional study. The sample size of 62 patients who met the eligibility criteria was selected through simple random sampling on the respective clinic days of the cancer treatment centre and urology clinic. Data was collected through a pre-tested structured questionnaire and Health-related Quality of Life (HRQoL) tools (EORTC-QLQ-C30 and EORTC-QLQ-PR25) after which it was analysed using STATA version 13 software. Descriptive analysis was used to summarise the continuous and categorical variables. Spearman's rho (r_s) correlation was used to determine the predictors of HRQoL based on the strength and significance of association because, on analysis, the data was not normally distributed. The level of significance was set a 0.05.

Results: Participants within this study had a mean age of 70.5 (± 7.35) years. The majority (52, 83.9%) of the patients had a PSA above 20 ng/ml. 21 (33.9%) were graded as Gleason group 5 and 41 (66.1%) Stage IV disease at diagnosis. Fifty (80.9%) participants were on hormonal therapy, with the majority of them being on combined androgen blockade. The overall HRQoL was 65.1. Fatigue, one of the major complaints among these patients, was negatively associated with physical functioning (p = 0.0005), role functioning (p = 0.0026), social functioning (p= 0.0001), financial difficulties (p= 0.0077) and quality of life (p= 0.0050).

Conclusion: Fatigue was the most common predictor of poor HRQoL in several scales of measurement.

Recommendation: Strategies should be employed to ensure the early detection and treatment of PC. The management of PC should be streamlined to align with established national and international treatment guidelines. For those on management, frequent assessment of HRQoL should be carried out and interventions instituted immediately.

CHAPTER ONE: INTRODUCTION

1.1 Background

The global incidence of cancer per year is expected to increase to 29.5 million cases by the year 2040, making it a major cause of death and disease worldwide (1,2). The increasing incidence has been attributed to factors such as tobacco smoking, a longer lifespan, better medical services, improved wealth, changing dietary patterns, urbanisation and environmental pollution and it carries with it considerable healthcare costs (2,3). Prostate cancer (PC) is the fourth most frequently diagnosed cancer worldwide after breast, lung and colorectal cancers (4). Among Kenyan men, it is the most frequently diagnosed cancer while ranking third among the cancers diagnosed in both men and women (5).

Despite its comparatively lower incidence and mortality in Africa, this disease exhibits a preponderance for the black race (6,7). It progresses slowly with an indolent course, affecting mainly elderly men (8). The burden of new PC cases in Kenya is highest in those aged between 65 and 74 years (9). There exists a strong association between PC, family history, *BRCA1/2* mutations, Hereditary Breast and Ovarian Cancer (HBOC) Syndrome and Lynch syndrome (10,11). First degree relatives carry twice the risk of developing the disease and the risk increases with the early onset of disease (8,10). Modifiable risk factors include diets high in fat, high body mass index (BMI), and exposure to environmental toxins such as cadmium (10,12).

The management of PC may utilise either conservative, surgical, radiological or pharmacological measures, alone or in combination, depending on the disease stage, risk stratification and life expectancy of the patient (12). The management of PC in Africa is complicated by the presentation of patients with more aggressive disease, lower rates of screening, the high cost or absence of chemotherapy and hormonal therapy as well as the limited number of facilities and radio-oncology personnel (13–15).

Studies and surveillance data show that the survival rates of the disease have continued to improve over the years, partly due to increased and improved screening, early detection and advances in management (16–18). In the United States, the survival rate after 5 years for localised disease is nearly 100% and that of all stages of PC after 10 years is 98% (16). However, the impact of these treatments on a patients' quality of life is significant, affecting both general (physical and social performance) and

disease-specific (bowel, sexual and urinary functions) health-related quality of life (19,20). Fatigue, insomnia and sexual functions are typically the most affected, and those undergoing chemotherapy have the worst quality of life (19).

Health-related quality of life (HRQoL) is termed as a broad concept that spans multiple dimensions which include "disease symptoms, treatment side effects, functional status in physical, mental and social domains and general perceptions of well-being and life satisfaction"(21). Cella defines HRQoL more specifically as the "extent to which one's usual or expected physical, emotional, and social well-being is affected by a medical condition or its treatment" (22). It has been found that persons within the general population have a higher HRQoL than those diagnosed and being managed for PC and it even differs depending on the type of treatment modality used (23). It has become increasingly important to assess the HRQoL of patients as it is not enough to just cure the disease, ameliorate its symptoms or induce remission, but also to ensure the total well-being of a person during and after treatment, beyond the survival of that person.

1.2 Problem Statement

In Kenya, cancer is among the top three causes of mortality (24). The increasing morbidity and mortality in the country prompted the Government of Kenya to launch the National Cancer Control Strategy. The objective of this strategy is to "reducing cancer incidence, morbidity, mortality, cancer down-staging and survival rate in Kenya through access to population-based primary prevention, early detection, quality diagnostics, treatment and palliative care services" (24). The National Cancer Treatment Protocols 2019 outlines several treatment modalities for PC, the majority of which carry several physical adverse effects such as bowel and sexual dysfunction and the associated financial toxicity that affect a person's quality of life (19,25).

In Kenyatta National Hospital (KNH), most of the research done concerning PC had centred around its screening, diagnosis, incidence, certain aspects of management and their outcomes. No study had been done on the overall management of these patients, their HRQoL and its predictors. Failure to investigate the HRQoL, which is considered a significant prognostic factor of survival, potentially exposes patients to long-term deficits in physical, emotional and cognitive health (26,27).

1.3 Research Purpose

The study's purpose was to determine the various treatment options for prostate cancer at KNH and the HRQoL of these patients. It also aimed to look at the predictive capacity of sociodemographic and clinical factors on HRQoL. The study findings were expected to improve the overall management of PC by taking into account all the physical, emotional and mental aspects of health.

1.4 Objectives

1.4.1 Main objective

To evaluate the management and HRQoL among patients with prostate cancer at KNH.

1.4.2 Specific objectives

1. To describe the management of PC at KNH.
2. To assess the HRQoL of patients with PC at KNH.
3. To determine the predictors of HRQoL in patients with PC at KNH.

1.5 Research Questions

1. How is PC managed at KNH?
2. What is the HRQoL of patients with PC at KNH?
3. What are the predictors of HRQoL in patients with PC at KNH?

1.6 Study justification and expected use of the results

The study was expected to provide key insights into the management of prostate cancer among patients with PC at Kenyatta National Hospital and their HRQoL. The findings were expected to be of particular benefit to the patients and healthcare providers as they would enable them to come up with better-informed decisions concerning their individual choice of treatment and design of treatment regimens, therefore improving overall disease management. Demonstration of the utility of the tools that measure HRQoL and the scores will lead to their incorporation into day-to-day practice. Furthermore, the identification of these predictors early in the management of the disease will lead to the initiation of interventions and control strategies that will alleviate the unfavourable effects of the disease and its management strategies. The

study will also form a basis for further research for the staff and students working and learning within KNH.

The study will be used to inform policy development within the institution and contribute directly to the National Cancer Control Strategy that will be reviewed in 2022 and will be disseminated to KNH, the University of Nairobi and all other stakeholders involved and those who will benefit directly or indirectly from it.

1.7 Delimitations

The study was conducted at the KNH Cancer Treatment Centre (CTC) and the urology clinic with the inclusion of patients who met the eligibility criteria and were chosen via simple random sampling.

1.8 Limitations

Cross-sectional study designs are prone to selection bias and are limited in their generalizability unless they are well designed. The use of simple random sampling in the selection of study participants was used to try to overcome this. It is also difficult to assess causality and determine the temporality of some variables in a cross-sectional study.

Questionnaires are prone to non-response bias where a participant refuses to respond and response bias where a respondent fails to give accurate information but instead give information that pleases the investigator. They also tend to be inflexible, offering little room for interpretation or explanation. The use of subjective measures may have an impact on the reliability of the study findings. To overcome these limitations, a pilot study of the well-structured questionnaires was conducted to identify any potential problems and rectify them.

1.9 Conceptual Framework

Independent variables **Dependent variable**

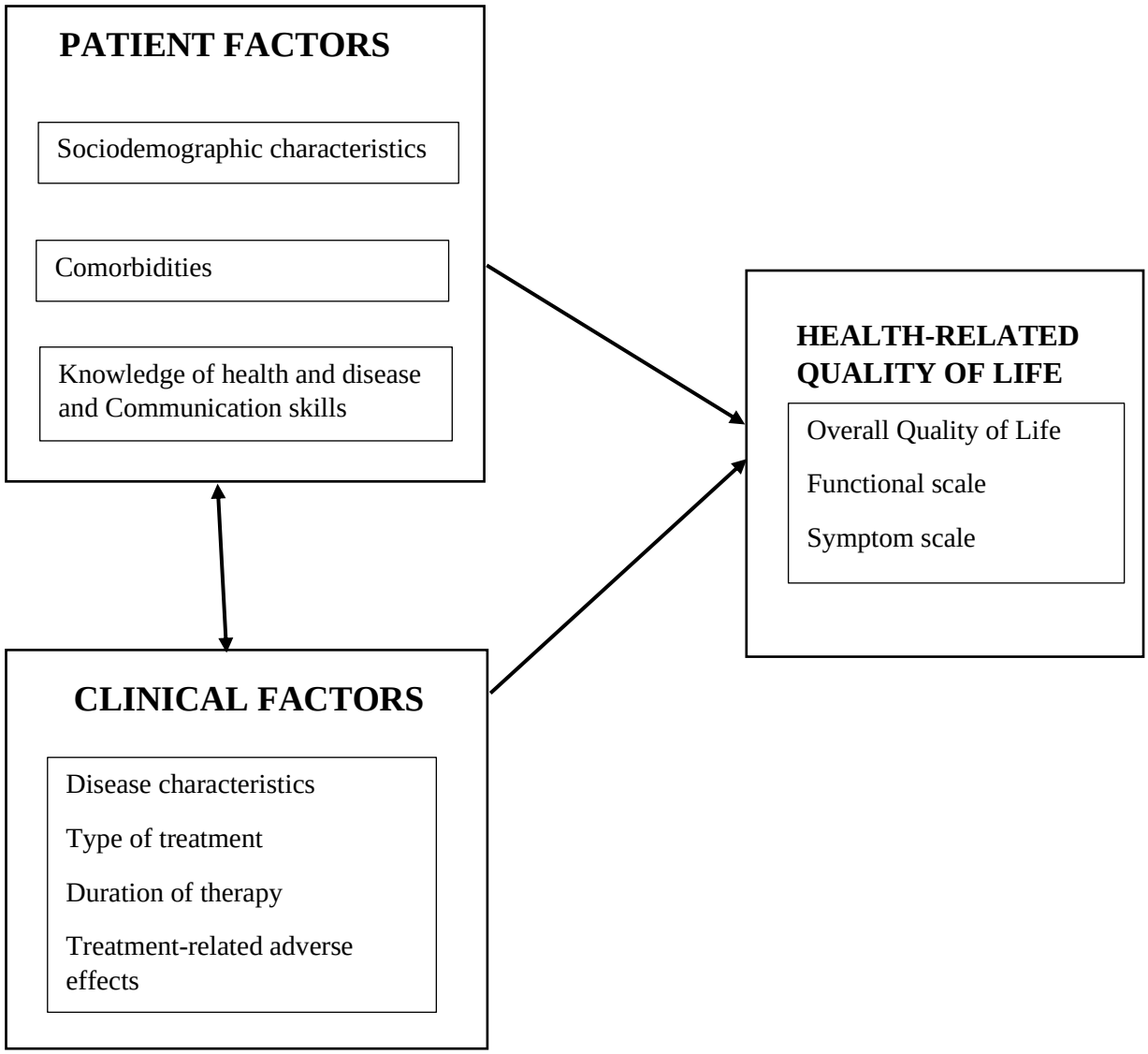


Figure 1. 1 Conceptual framework ***Source: Author, 2021***

The HRQoL is the main outcome variable and it is defined as "the extent to which one's usual or expected physical, emotional, and social well-being is affected by a medical condition or its's treatment". For purposes of this study, the outcome was measured on three scales: global health status, functional and symptoms scales based on the European Organisation for Research and Treatment of Cancer (EORTC) tools QLQ-C30 and QLQ-PR25, which are self-administered questionnaires (28).

The independent variables that determine a patient with prostate cancer's HRQoL may be classified into either patient factors or clinical factors. Clinical factors include the disease characteristics, (Gleason score/Grade Group, clinical stage and PSA level), type and duration of treatment (observation, active surveillance, surgical interventions, radiation therapy, chemotherapy and targeted and hormonal therapy) and treatment-related adverse effects. Poor disease characteristics and neoadjuvant androgen deprivation therapy is associated with poorer HRQoL (29).

Patient factors include the sociodemographic characteristics (age, marital status, level of income and financial capability, level of education, employment status, and BMI), the type and number of comorbidities the patient has and the level of knowledge they have concerning their health status as well as their communication skills. The factors may either be poor or good predictors of HRQoL. A high level of education, early disease stage and knowledge on health status have been found to have a positive effect on HRQoL (29). Comorbidities such as cardiovascular disease adversely affect HRQoL in patients with PC, and most patients usually die of these causes (8,30).

The connection and interplay between these variables are depicted in the conceptual framework (**Figure 1.1**).

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter describes the epidemiology of PC as well as reviews current literature on the HRQoL of patients with PC on various management options.

2.2 Epidemiology of Prostate Cancer

PC is a primary malignant tumour of the prostate gland. Adenocarcinomas comprise the largest proportion of PC making up 95%, with the remaining 5% being interstitial cell or small cell carcinomas (31). The majority of PCs (60-70%) arise from the gland's peripheral zone (31,32). The most common sites of prostate metastasis are bone, where the involvement of weight-bearing bones leads to pathological fractures, lymph nodes and the lungs (8,33).

This disease may be asymptomatic in the early stages due to its slowly progressing nature (34,35). Lower urinary tract symptoms (LUTS) are the main presenting complaint in symptomatic patients with other symptoms being fatigue, weight loss, dyspnoea and pain in the lower back and pelvis (36,37). The non-specific nature of the symptoms presents a diagnostic challenge with Benign prostatic hyperplasia or prostatitis (35).

Screening for PC is accomplished using the Prostate Specific Antigen (PSA). Serum levels of PSA are affected by any disease condition of the prostate, prostate manipulation, race, age, BMI and the use of medications such as 5-α-reductase inhibitors (38,39). PSA testing is also associated with many potential false results, both negatives and positives (40). The widespread use of PSA has contributed to the excess and often unnecessary diagnosis and treatment of clinically insignificant (that which if left untreated will not affect the patient) PC and the underdiagnosis of clinically significant PC, therefore limiting its use in mass screening for PC (40–43). PC screening should be a highly individualised process and counselling on the benefits and risks offered beforehand (9,43). In the Kenyan setting, it should be done in men of African descent aged between 40 and 70 years and whose expected longevity is more than 15 years (9,44). The routine use of digital rectal examination in screening is not recommended due to its low sensitivity, specificity and positive predictive value in asymptomatic men (9,45).

Transurethral ultrasound-guided (TRUS) biopsy is the ideal method for the definitive diagnosis of PC and is indicated after abnormal DRE findings and/or an elevated serum PSA level (46). It has become increasingly important to perform a multiparametric magnetic resonance imaging (mpMRI) before TRUS biopsy to reduce instances of biopsy of clinically insignificant PC (47–49). The disadvantage of TRUS biopsy is that it is has a high prevalence of false negatives and results in complications such as infections, haematochezia, haematuria, haematospermia, fever, and acute retention (50,51). One study conducted in KNH found that minor post-TRUS biopsy complications were reported in 62.5% of participants and that they resolved within 2 weeks and did not require hospitalisation (51). Transperineal biopsy offers a safer alternative to TRUS, with fewer complications (50).

The risk stratification of PC patients is dependent on the clinical stage of disease, grade group and PSA level (52,53). Risk stratification of localised PC is very important as it informs the management and outcome reporting of PC when coupled with the life expectancy of the patient (54). Traditionally, this has employed a three-tiered stratification, that is, low risk, intermediate-risk and high-risk, however, the National Comprehensive Cancer Network (NCCN) added two tiers, very low-risk and very-high risk localised PC. (11,47).

Table 2. 1 Risk Stratification and Staging of Clinically Localised Disease

<table>
<tr><th>Group</th><th colspan="3">Features of Disease</th></tr>
<tr><td>Very-low</td><td colspan="3">T1c AND Grade group 1 AND PSA <10ng/ml AND Fewer than 3 prostate biopsy fragments/core positive, ≤ 50% cancer in each fragment/core AND PSA density <0.15ng/ml/g</td></tr>
<tr><td>Low</td><td colspan="3">T1-T2a AND Grade Group 1 AND PSA<10ng/ml</td></tr>
<tr><td rowspan="2">Intermediate</td><td rowspan="2">Has no high- or very-high-risk features and has one or more intermediate risk factors (IRF): T2b-T2c, Grade Group 2 or 3, PSA 10-20ng/ml</td><td>Favourable intermediate</td><td>1 IRF AND Grade Group 1 or 2 AND <50% biopsy core positives</td></tr>
<tr><td>Unfavourable intermediate</td><td>2 or 3 IRFs AND/OR Grade Group 3 AND/OR ≥50% biopsy cores positive</td></tr>
<tr><td>High</td><td colspan="3">T3a OR Grade Group 4 or 5 OR PSA >20ng/ml</td></tr>
<tr><td>Very-High</td><td colspan="3">T3b-T4 OR Primary Gleason pattern 5 OR >4 cores with Grade Group 4 or 5</td></tr>
</table>

Source: NCCN Prostate Cancer, Version 2.2019 Guidelines (11).

2.3 Management of Prostate Cancer

The options available for the management of PC are observation, active surveillance, surgical, radiological, hormonal, chemotherapeutic, immunotherapeutic or targeted interventions or the newer so-called focal therapies (47,48,55). The management of PC in Kenya is largely adapted from American and European guidelines (12).

The management of localised disease may be conservative (observation or active surveillance) to avoid overtreatment of disease and to maintain the patients' quality of life or for curative intent, that is, radical prostatectomy (RP), External Beam Radiation Therapy (EBRT) or brachytherapy (BT) (47,48).

Observation (watchful waiting) is reserved for frail and elderly patients whose disease presentation is not severe, who are not expected to live beyond 10 years from the time of diagnosis and whose death is more likely to result from another comorbidity other than cancer (43,48,56). Palliative Androgen Deprivation Therapy (ADT) is given to

manage disease symptoms when they appear and monitoring is done through PSA testing every 6 months without the involvement of biopsy or imaging (48,56). Active surveillance (deferred treatment) is recommended for younger patients expected to live longer than 10 years from the time of diagnosis and have very-low or low-risk disease where they are monitored with PSA every 6 months and DRE, repeat biopsy and mpMRI every 12 months with the expectation of converting to curative options once the disease progresses (48,56,57). Active surveillance has been shown to extend life more than observation but has a considerable impact on quality of life (58).

Radical Prostatectomy (RP) is a curative option used in men with clinically localised disease who have a life expectancy of more than 10 years irrespective of age, (43,48,59). Studies show that RP shows a benefit in survival, as well as a has significant reduction in bone metastasis when compared to active surveillance or watchful waiting (59–61). A 4-6 week course of ADT is of benefit in intermediate-risk disease and those with high-risk and locally advanced disease may benefit from neoadjuvant and adjuvant ADT (47).

Newer options for the management of localised disease are the so-called focal therapies that utilise minimally invasive techniques aimed at bypassing the disadvantages of whole-gland therapies (RT and RP), that is, the high incidence of complications as well as the risk of overtreatment of clinically insignificant cancers (62,63). Current focal therapies have various limitations such as the lack of available evidence of the outcomes of long-term follow-up and thus may be classified as still experimental (43,63–65).

Men who have undergone RP or RT should have regular monitoring of their PSA level to detect biochemical recurrence (PSA failure), defined as a "rise in PSA in prostate cancer patients after treatment with surgery or radiation (PSA of 0.2 ng/mL and a confirmatory value of 0.2 ng/mL or greater following radical prostatectomy and nadir + 2.0 ng/mL following radiation)" (47,66). Treatment options available for relapsing disease are salvage RT with ADT or bicalutamide (47).

Primary ADT is the standard of care for mHNPC, accomplished either surgically through orchiectomy or medically using Luteinising Hormone Releasing Hormone (LHRH) agonists or antagonists (67). Huggins and Hodges demonstrated that androgenic activity influences the growth of PC (68). Combination androgen

blockade, that is ADT combined with either non-steroidal antiandrogens, androgen-receptor targeted agents (ARTAs) or abiraterone acetate/prednisone (a CYP17 inhibitor) or a combination of docetaxel chemotherapy have been shown to improve overall survival outcomes (47,67).

CRPC is that which exhibits disease progression while on ADT, despite serum testosterone being at castration levels (47). ARTAs should be considered in non-metastatic (M0) CRPC whereas the first-line therapy for metastatic CRPC is abiraterone acetate/prednisone (47,56,67). Other options available are enzalutamide, sipuleucel-T, docetaxel, cabazitaxel, ketoconazole, diethylstilbesterol and radium ^{223} in patients with bone metastases (48,67).

Adverse effects of therapy differ with each modality. However, the most common ones are sexual dysfunction which occurs universally, urinary dysfunction occurring with RP and RT, gastrointestinal, skin effects and the increased risk of secondary malignancy that occur with RT (48,61,69–72). Apart from sexual dysfunction, other adverse effects of ADT are gynaecomastia, insulin resistance and dyslipidaemia, increased risk for cardiovascular disease and osteoporosis (48,73). Docetaxel chemotherapy is associated with hypersensitivity, bone marrow suppression, neurotoxicity and water retention (74). Abiraterone acetate adverse effects are related to mineralocorticoid excess (necessitating its use with prednisone), hepatotoxicity and hormonal effects (11).

Table 2. 2 Treatment Modalities Available for the Management of Prostate Cancer

NCCN GUIDELINES			**ESMO GUIDELINES**	
Disease stage	**Life expectancy**	**Treatment Options**	**Disease Stage**	**Treatment Option**
Very Low-Risk Localised Disease	≥20 years	Active Surveillance (preferred) **or** EBRT or BT **or** RP +/- adjuvant EBRT +/- 6-month ADT OR Observation		
	10-20 years	Active surveillance		
	<10 years	Observation		
Low-Risk Localised Disease	≥10 years	Active surveillance **or** EBRT or BT **or** RP +/- adjuvant EBRT +/- 6-month ADT OR Observation	Low-risk Localised Disease	Active Surveillance **or** BT **or** Radical RT **or** RP
	<10 years	Observation		
Favourable Intermediate-Risk Localised Disease	≥10 years	Active surveillance **or** EBRT or BT **or** RP +/- PLND +/-adjuvant EBRT +/- 6-month ADT OR Observation	Intermediate-Risk Localised Disease	RP **or** Radical RT +/- neoadjuvant ADT **or** BT **or** Active surveillance
	<10 years	EBRT or BT **or** Observation		
Unfavourable Intermediate-Risk Localised Disease	≥10 years	RP +/- PLND +/- adjuvant EBRT +/- ADT (6 months) or observation **or** EBRT +/- ADT (4 months) **or** + BT +/- ADT (4 months)		
	<10 years	EBRT + BT +/- ADT (4 months) **or** Observation (preferred)		
High or Very High-Risk Localised Disease	≥5 years or with symptoms	EBRT + ADT (1.5-3 years) **or** EBRT + BT + ADT (1-3 years) **or** RP + PLND +/- EBRT with ADT or Observation	High risk localised disease	Long-term ADT + radical RT +/- neoadjuvant

	<5 years and without symptoms	Observation **or** ADT **or** EBRT		docetaxel, **or** RP +PLND
Regional disease	≥5 years or with symptoms	EBRT + ADT (preferred) **or** EBRT + ADT + abiraterone/prednisone **or** EBRT + ADT + abiraterone/methylprednisolone **or** ADT +/- abiraterone/prednisone **or** ADT +/- abiraterone/ methylprednisolone	Locally advanced disease	Neoadjuvant ADT + radical RT + adjuvant ADT +/- neoadjuvant docetaxel**, or** RP + PLND
	<5 years and without symptoms	Observation or ADT		
Non-metastatic hormone naïve disease		Observation **or** ADT	mHNPC	ADT + abiraterone or docetaxel or enzalutamide or apalutamide **or** ADT alone for frail patients **or** RT for low volume disease **or** Bone health agents
Metastatic hormone naïve disease		ADT + docetaxel or abiraterone or apalutamide or enzalutamide or EBRT **or** ADT	M0 (non-metastatic) CRPC	ADT + apalutamide or darolutamide or enzalutamide

Metastatic CRPC (first line)		Abiraterone/prednisone, Docetaxel, Enzalutamide, Radium-223 for symptomatic bone metastases, Abiraterone/ methylprednisolone	Metastatic CRPC (first line)	Abiraterone, Docetaxel, Enzalutamide, ^{223}Ra for patients unfit for other treatments and only bone metastases
Metastatic CRPC (second line)		Docetaxel, Radium-223, Pembrolizumab, abiraterone/ prednisone. Enzalutamide, Cabazitaxel, Sipuleucel-T, Radium-223,	Metastatic CRPC (second line)	Abiraterone, Cabazitaxel, Enzalutamide, ^{223}Ra

Sources: Prostate Cancer: ESMO Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up, 2020 and NCCN Clinical Practice Guidelines for Prostate Cancer Version 4.2019 (47,48)

2.4 Health-related quality of life

Several persons and organisations have defined HRQoL in several ways, to align themselves with the WHO interpretation of a person's health, "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." (21,75–77). However, all these definitions have these aspects in common: they focus on the multidimensional nature of HRQoL and they incorporate both subjective and objective measures (78). HRQoL has been used as an outcome measure in the economic evaluation of health technologies, in the assessment of public health of the general population, in clinical trials and clinical practice (76,79,80). Several tools have been used in the assessment of HRQoL of prostate cancer patients and are either generic or disease-specific. Generic tools include the Medical Outcome Study 36-item short-form survey instrument (SF-36), the EQ-5D (EuroQol-5D), and the World Health Organisation Quality of Life BREF (WHOQOL-BREF). Tools specific to cancer and PC that have been used are the Functional Assessment of Cancer Therapy-General and -Prostate (FACT-G, FACT-P), Expanded Prostate Cancer Index Composite (EPIC), and the European Organisation for Research and Treatment of Cancer (EORTC-QLQ-30, EORTC-QLQ-PR25) (29). Regardless of the tool used, it should be "valid, appropriate, reliable, responsive, able to be interpreted, simple, quick

to complete, easy to score and provide useful clinical data"(79). Although the tools are different in their own way, they all tend to focus on the following domains or functional areas: physical, social, emotional with others adding on environmental and financial burden domains.

The incorporation of HRQoL into clinical practice may help to foster patient-physician relationships thus promoting shared decision making concerning treatment which is based on the patient's priorities, detect disease aspects that are ordinarily ignored or unnoticed and it may also help in an economic evaluation of treatment options (81,82).

HRQoL in prostate cancer as a primary outcome has proven important in the past decade due to the longer post-diagnosis life span of patients, the problem of overtreatment and overdiagnosis of PC, the apparent over-estimation of the health status of patients by physicians compared to patients themselves, the emergence of newer treatments and a need to make informed treatment decisions (29,83,84). A systematic review by Odeo and Degu concluded that the overall HRQoL of patients with PC was poor in the functional domains, more so, sexual function and that the major predictors of poor HRQoL include, but are not limited to African American race, older age, poor disease characteristics, comorbidities and neoadjuvant hormonal therapy (29). The factors that influence HRQoL in patients on management for PC are discussed below.

2.4.1 Sociodemographic characteristics

Increased age at diagnosis affects the HRQoL of patients on PC management. Older patients report more problems with physical functioning, sexual and urinary function compared to younger patients, while younger patients report fewer symptoms, sexual dysfunction and have more energy for daily life (85,86). Age is also associated with a higher occurrence of chronic diseases and their associated risk factors, more so in Kenya (87). Comorbidities in PC have an unfavourable impact on HRQoL in patients on treatment (29,88). Some studies have shown that impaired mental health, circulatory problems in lower extremities, chronic respiratory diseases and coronary artery disease negatively impact HRQoL (29,89,90). In a study conducted in Nigeria, it was found that comorbidities occur in one in four cancer patients, more so those with PC, and they affect the prognosis of these patients (91). A higher BMI is associated with increased incidence of aggressive PC, more complications after ADT,

increased risk of biochemical failure and increased PC-specific mortality and a lower HRQoL (92,93).

Men who are married or co-habiting are more likely to present with lower metastatic disease, to receive definitive treatment, to suffer less from cancer-specific mortality and to exhibit better physical health and social relationships (85). Since it has been shown to boost HRQoL in persons with chronic illnesses, marital status may be used as a surrogate marker for the recognition of patients more prone to having a lower quality of life and provide them with a support system (89,94). The presence of a support system in the life of a cancer patient improves their quality of life (95).

Persons with a higher level of education, literacy and ability to communicate with physicians, perhaps by increasing their level of confidence, have been found to have better outcomes (96). In fact, patients who were able to seek second opinions by consulting different physicians exhibited a better quality of life (89). The level of education may influence initial treatment choice presumably due to the relationship between education and socioeconomic status, access to and ability to understand information on PC and its management and the ability to nurture a relationship between physician and patient (97). Brar *et al,* found that men with lower education status experienced greater distress over treatment-related adverse effects, perhaps due to a lesser understanding of the symptoms, but found that they improved more in their mental well-being and were more likely to benefit from oversight and counselling services (98). Higher global health status and HRQoL is associated with a higher level of education (99).

Persons with lower income or unemployment status have lower functioning scores and HRQoL partly due to poor access to healthcare or an unresponsive healthcare system (98–100). Financial toxicity associated with high out-of-pocket costs and unemployment negatively affects HRQoL (25,101). A personal income appears to influence HRQoL positively (85). A Tanzanian study found that participants reported significant financial difficulties occasioned by the extra costs that come with a cancer diagnosis and treatment (102).

2.4.2 Clinical factors

Clinical factors that may have an influence on HRQoL are the type and duration of treatment used, disease status and the presence of treatment-related adverse effects. In

studies conducted at KNH and Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) in persons with breast, prostate and cervical cancers, it was found that the more severe the cancer, the greater the impact on the quality of life (95,103). Sexual dysfunction appears to be the most common treatment-related adverse effect especially in those that undergo surgery (19,23). ADT and chemotherapy are associated with worse outcomes and HRQoL, perhaps because they are used in advanced disease (19,83,104). In a study by Shin *et al*, most functional and symptom domains recovered after 12 months of radical prostatectomy except for sexual and social functioning (23).

2.5 Overview of the Literature

PC is a neoplasm of the prostate whose often non-specific lower urinary tract symptoms present a challenge in diagnosis. Screening for PC is normally done using PSA but a TRUS biopsy is the gold standard for diagnosis. Risk stratification of patients into a predefined group informs the management of PC, which may include various combinations of conservative, pharmacological and non-pharmacological therapies. Several factors including patient and disease factors have been found to affect the HRQoL in these patients.

Individual aspects of the management of PC such as EBRT and ADT have been researched at KNH but none has looked at the overall management. Additionally, to the best of the investigator's knowledge, no study had looked at the HRQoL of these patients and its predictors. This study sought to fill this gap.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter highlights the methodological approach of the study. It outlines the details of the ethical considerations, study site and design, the target and study population, eligibility criteria, sampling method, data collection tools, techniques, and analysis.

3.2 Study design

A descriptive, cross-sectional study design was used, which allowed for the determination of both the independent variables, that is, sociodemographic characteristics of the patient and the clinical characteristics of the disease, and the dependent variable, which is the HRQoL in men under treatment for prostate cancer at the same time. This choice of study allowed for a description of the management of PC at KNH as well as the evaluation of the HRQoL of the patients from their point of view at a specific point in time without having to follow-up patients over an extended period of time.

3.3 Location of the Study

The study was conducted at the Cancer Treatment Centre (CTC) and the urology clinic (Clinic 24) of the KNH. The facility is the biggest public hospital in Kenya and is located in the Upper Hill region of Nairobi. It is a Level 7A hospital with a current bed capacity of 1800, spread over 50 wards, several surgical theatres and outpatient clinics and an Emergency Department. The facility attends to cancer patients from across the country by providing radiotherapy, brachytherapy, chemotherapy and surgical services both on an inpatient and outpatient basis.

3.4 Target and Study Population

Adult men with a diagnosis of PC and on management served as the target population in this study. The number of patients who visited the hospital for initial management of PC in the year 2020 was 122. However, the study population consisted of those who were eligible as per the set requirements.

3.5 Eligibility Criteria

3.5.1 Inclusion Criteria

1. Patients with a confirmed diagnosis of prostate cancer.
2. Patients aged 18 years and above.

3. Patients who were able to communicate effectively in English or Kiswahili languages.
4. Patients who had been on any treatment modality for PC for at least 4 weeks.

3.5.2 Exclusion criteria

1. Patients who refused to give informed consent.
2. Patients with cognitive impairment and those that were unable to comprehend the elements of the data collection tools.

3.6 Sample size and sampling technique

3.6.1. Sample size determination

The sample size of the study was calculated using the Cochran Formula for calculating sample size in descriptive studies (105).

$$n_0 = \frac{Z^2\, p(1-p)}{d^2}$$

where:

n_0= calculated sample

Z= the standard normal variate at 95% confidence interval. Its value is 1.96

p= the estimated proportion or prevalence of prostate cancer in Kenya. As per GLOBOCAN 2020, the estimated 5-year prevalence of PC is 7.1% (5)

d = the level of precision of the study, which is 0.05

Therefore,

$$n_0 = \frac{1.96^2 x\ 0.071(1-0.071)}{0.05^2}$$

n_0= 101.4 ≈ 102 participants

Since the target population at KNH was relatively small, the calculated sample size was corrected using the Cochran correction for finite populations.

$$n = \frac{n_0}{1+\frac{n_0}{N}}$$

Where:

n= adjusted sample size

$n_{0=}$ calculated sample size (102 participants)

N= the approximate number of patients on management for PC at KNH. Data obtained from the Health Records Department at KNH indicated that 122 patients with PC were managed over the period of 12 months from January to December 2020.

$$n= \frac{102}{1+\frac{102}{122}} = 55.56 \approx 56 \text{ participants}$$

To cater for non-response, missing records or poor quality of records, an additional 10% was added to the calculated sample size

$$N = n + \frac{10}{100} * n$$

$$N = 56 + \frac{10}{100} * 56 = 61.6 \approx 62 \text{ participants}$$

3.6.2 Sampling technique

The selection of participants was accomplished using simple random sampling using the lottery method. A sampling frame of patients with PC being managed at KNH was constructed from records obtained from the CTC, the oncology pharmacy, the urology clinic and the hospital's central records department. The lottery method involved assigning each member of the sampling frame sequential numbers from 1 to N. The investigator then proceeded to draw numbers from a box (without replacement) until the required sample size was achieved.

3.7 Research instruments

An eligibility screening form (*Appendix 1*) was used to determine the eligibility of participants. It contained the study and patient information, the eligibility criteria and a statement of eligibility. The participants were presented with a consent form (*Appendix 2*) that was used to obtain voluntary informed consent from those who meet the eligibility criteria. A well-structured questionnaire (*Appendix 3*) was constructed to capture details about the participant's sociodemographic characteristics, comorbidities as well as treatment and related adverse effects. The questionnaire was administered by the principal investigator in an interview with the participants. This was supplemented by the abstraction of data from the patient's treatment file in case the information was not directly available from the patient.

The questionnaire was attached to the HRQoL forms (*Appendices 4 and 5*), which were to be filled by the patient. The EORTC-QLQ-C30 form employed a Likert scale to assess the HRQoL in cancer patients. It had 30 questions that examined the global health status/QOL, level of function and the symptoms experienced by the patient. The EORTC-QLQ-PR25 was similar to the QLQ-C30 questionnaire but specific to prostate cancer. It had 25 questions and contained two scales, the symptom scale and the functional scales. The selection of the EORTC tools for this study was guided by the fact that they were readily available in both English and Kiswahili and that the tool had been validated for use in cancer patients in Kenya (106).

3.8 Pilot study and pre-testing

Copies of the questionnaires were issued to about 10% of the study population at the KNH CTC for purposes of pre-testing. This allowed for the identification of any inadequacies of questionnaires. The questionnaires were revised based on the results of the pre-test.

3.9 Validity

The study was designed to ensure that both internal and external validity were maintained. Simple random sampling was used to ensure that the sample was representative of the predefined target population. The chosen study site, KNH, was appropriate for the study as it offered services to cancer patients from all over the country. The questionnaires that were used in the study had been designed in such a way to ensure that they were arranged systematically, used simple and clear language and were relevant to the study objectives. The tools used to measure HRQoL had prior validation.

3.10 Reliability

The data collection tools will be pre-tested before the study commences. The multi-item scale items in the EORTC tools were subjected to tests for reliability. However, since they are standardised and prequalified tests, no amendments were made. The test for reliability that was used was the Cronbach alpha (α) test where the acceptable limit was 0.7.

3.11 Data collection techniques

Participants in the study were recruited from the CTC and the urology clinic on clinic days, that is, Monday through Thursday of every week. Those that were found to be

eligible were taken through the process of consenting and were required to sign the consent form after they had understood the aim of the study and its associated risks and benefits. The data was then collected from the participants using the researcher administered questionnaire and the self-administered HRQoL questionnaires. Those who were not able to fill the questionnaires themselves were assisted to do so. This process was repeated on all clinic days until the required sample size was reached. Treatment files and other medical records were reviewed and the data that was not directly available from the patient was collected from them. These files were tagged with a small coloured sticker to prevent duplication of collected data.

3.12 Data management and analysis

A unique serial number was used on each file and participant to avoid duplication during data entry. The data was entered into a Microsoft Excel 2019 spreadsheet. The data was coded before entry for ease of analysis and entered within 24 hours of collection. It was checked regularly for accuracy and completeness with any corrections made promptly. Data was cleaned and validated prior to export to STATA version 13 for data analysis. All data was backed up regularly on an external hard drive which was stored in a safe location.

Scores for the various domains were calculated as per the EORTC-QLQ-C30 version 3 and the EORTC-QLQ-PR25 scoring manuals (107,108). The raw scores were calculated and transformed as dictated by the manual and thereafter expressed as means.

$$\text{Raw Scores= } RS = \frac{I_1+I_2+\cdots+I_n}{n}$$

The transformed scores for the functional scale were calculated using the formula, $Score = \left\{1 - \frac{RS-1}{range}\right\} x\ 100$,whereby a high score is interpreted as having a greater degree of functioning and that of the symptoms and global scale were calculated as $Score = \left\{\frac{RS-1}{range}\right\} x\ 100$, where a high score represents high QoL and a high level of symptomatology.

Analysis of the data was accomplished on two levels, that is, using descriptive and inferential statistics owing to the nature of the data. A summary of continuous variables was accomplished using means and standard deviation or medians and

interquartile range while categorical variables were expressed through frequencies and percentages. Associations between variables will be assessed using tests for correlation such as Spearman's rho correlation test. Presentation of results was done using tables, graphs and figures.

3.13 Ethical and Logistical Considerations

Potential ethical issues that may have arisen in this study include ethical, institutional and organisational approval, informed voluntary consent as well as privacy, confidentiality and beneficence concerns for the participant, the fidelity of data analysis, risk of plagiarism, and conflict of interest.

Ethical approval to conduct the study was sought from the KNH/UON Ethics and Research Committee. After ethical approval has been given with the study number P85/02/2021, further approval to conduct the study in KNH was sought through the KNH Research and Programs Department and the respective departments concerned (the departments of Pharmacy and Surgery). Permission to use the EORTC-QLQ-C30 and EORTC-QLQ-PR25 was sought from the European Organisation for Research and Treatment of Cancer. This process involved making an application through the EORTC website indicating the researcher's name, email address, country of residence and the title of the study or its intended use. Permission to use the tools was granted for free on the condition that it is used only for academic purposes.

Informed consent was obtained voluntarily, using a patient information and consent form, from the participants before the administration of the questionnaires ensuring that their privacy and confidentiality was protected and that they suffered no risk of harm. All precautions against the Covid-19 pandemic, such as mask-wearing and the frequent hand washing and maintenance of social distance, where possible, were adhered to, to protect both the investigator and the participants.

A plagiarism check was conducted using the Turnitin Plagiarism Checker to ensure that the research dissertation has a similarity index of 15% or less. Data analysis was be conducted logically and scientifically to maintain the fidelity of the obtained results. The principal investigator and supervisors had conflicts or financial interests to declare.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter details the results obtained after descriptive, inferential and exploratory analysis of the data collected. It includes patients' sociodemographic profiles, clinical characteristics, their health-related quality of life and correlation analysis for the predictors of the HRQoL.

4.2 Sociodemographic characteristics

Data from 62 study participants was collected using a structured questionnaire and their sociodemographic characteristics summarised in **Table 4.1**.

The mean age of the study participants was 70.5 (± 7.36) years and it ranged from 51 to 87 years old. More than half (35, 56.5%) of the participants were aged between 65 and 74 years old. The mean body mass index (BMI) was 25.7 (±4.17) and 29 participants (53.7%) were in the pre-obesity category (25.0-29.9 kg/m^2). Most of the participants were not consumers of alcohol (57, 93.2%) or cigarettes and other tobacco products (59, 96.6%). Fifty-one (82.3%) participants were married and 27 (43.6%) were secondary level graduates. Thirty-nine (62.9%) participants were retired and 37 (61.7%) identified as being part of the low-income group, as per the 2017 Kenya National Bureau of Statistics Economic Survey. Sixty (96.8%) participants had an active medical insurance cover, of which 58 (96.7%) were covered by the National Hospital Insurance Fund.

Table 4. 1 Sociodemographic Characteristics (n=62)

Variable	n (%)	Mean ± SD
Age (years)		70.5 (7.35)
<55	2 (3.2)	
55-64	10 (16.1)	
65-74	**35 (56.5)**	
75-84	12 (19.4)	
>84	3 (4.8)	
BMI (kg/m^2)		25.7 (4.17)
Underweight	3 (4.8)	
Normal weight	18 (29.0)	
Pre-obese	**29 (46.8)**	
Obese	4 (6.5)	
Missing	8 (12.9)	
Current alcohol consumption		
No	**57 (91.9)**	
Yes	4 (6.5)	
Unknown	1 (1.6)	
Current cigarette and other tobacco product use		
No	**59 (95.2)**	
Yes	2 (3.23)	
Missing	1 (1.6)	
Marital status		
Married	**51 (82.3)**	
Separated	4 (6.5)	
Widowed	7 (11.3)	
Highest level of education		
No formal education	1 (1.6)	
Primary	26 (41.9)	
Secondary	**27 (43.6)**	
Tertiary	8 (12.9)	
Employment status		
Unemployed	6 (9.7)	
Employed	4 (6.5)	
Self-employed	13 (21.0)	
Retired	**39 (62.9)**	
Income group		
Low income	**39 (62.9)**	
Middle income	20 (32.3)	
Upper income	3 (4.8)	
Medical insurance cover		
Yes	**60 (96.8)**	
No	2 (3.2)	
Type of medical insurance cover		
Public (national scheme)	**58 (96.7)**	
Public (civil servants and special groups)	1 (1.7)	
Public and Private	1 (1.7)	
Missing	2 (3.2)	

4.2 Clinical characteristics

Most (41, 66.1%) participants had Stage IV disease at diagnosis **(Table 4.2)**. However, 12 (19.4%) of them had no staging data. At diagnosis, 52 (83.9%) had a level of PSA greater than 20 ng/ml while 21 (33.9%) were in Gleason grade group 5. Thirty (48.4%) participants were diagnosed with PC between 1 and 3 years ago.

It was not possible to tell from the records whether patients with stage IV disease had mHNPC or mCRPC.

Table 4. 2 Clinical characteristics of PC at diagnosis

Variable	n (%)	Median [IQR]
Cancer stage at diagnosis		
Stage III	9 (14.5)	
Stage IV	**41 (66.1)**	
Missing	12 (19.4)	
PSA at diagnosis (ng/ml)		
<10	3 (4.8)	
10-20	4 (6.5)	
>20	**52 (83.9)**	
Missing	3 (4.8)	
Gleason Grade Group at diagnosis		
Grade Group 1 (GS 3+3=6)	4 (6.5)	
Grade Group 2 (GS 3+4=7)	8 (12.9)	
Grade Group 3 (GS 4+3=7)	11 (17.7)	
Grade Group 4 (GS 4+4, 5+3=8)	14 (22.6)	
Grade Group 5 (GS 4+5, 5+5= 9, 10)	**21 (33.9)**	
Missing	4 (6.5)	
Duration since diagnosis (years)		2 [0.83, 3]
<1	19 (30.7)	
1-3	**30 (48.4)**	
>3	13 (21.0)	

Forty-two (67.7%) of the participants had at least one comorbid disease. Most (43.6%) had one comorbid disease, while 13 (21.0%) and 2 (3.2%) had two and three comorbidities respectively. As illustrated in **Figure 4.1**, the most common comorbidities were hypertension (37, 59.7%) followed by diabetes mellitus (10, 16.1%). Of the participants that had hypertension, 23 (71.9%) had had it for a duration of 3 months-10 years.

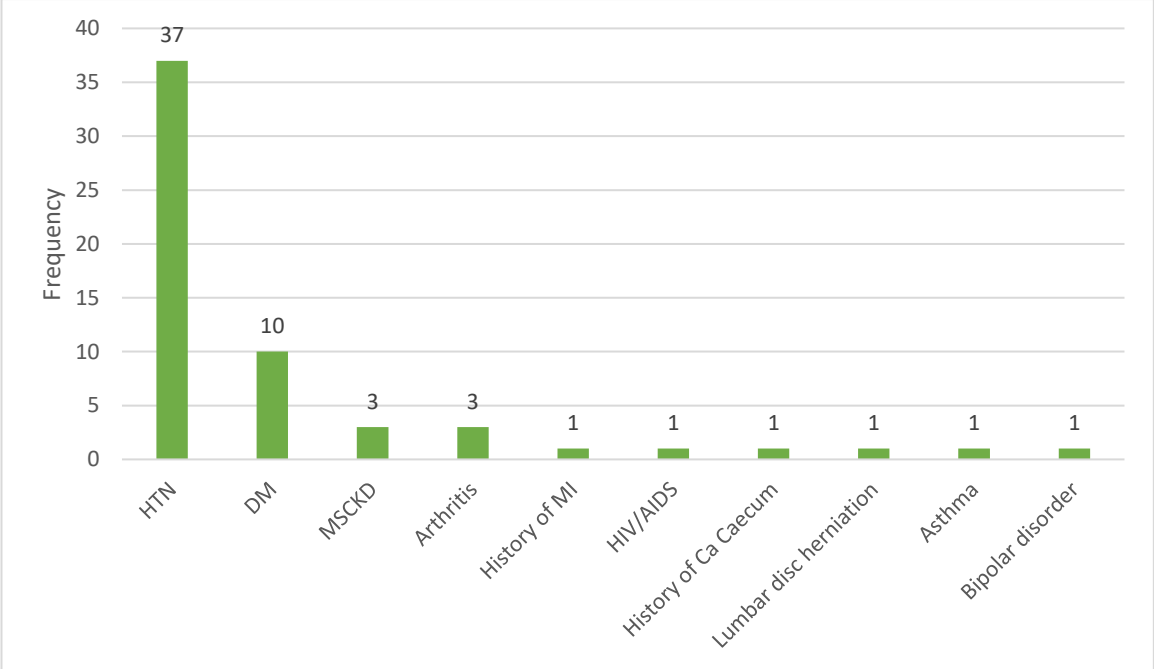
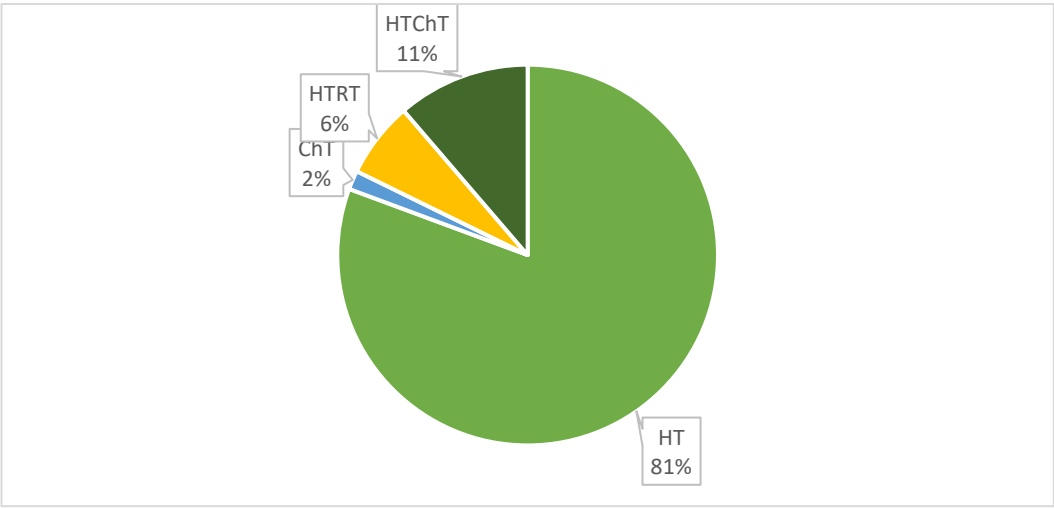


Figure 4. 1 Comorbidities among Prostate cancer patients

Key: *HTN- Hypertension, DM- Diabetes mellitus, MSCKD- Moderate to Severe Chronic Kidney Disease, MI- Myocardial Infarction, HIV/AIDS- Human Immunodeficiency Virus/Acquired Immunodeficiency syndrome*

4.3 Management of prostate cancer

The majority (50, 80.7%) of the participants were on hormonal therapy for the management of their disease **(Figure 4.2)**.



Key: *HT-Hormonal therapy, HTChT- Hormonal therapy plus chemotherapy, HTRT- Hormonal therapy plus radiation therapy, ChT- Chemotherapy*

Figure 4. 2 Treatment modalities employed in the management of PC (n= 62)

Seven (11.3%) were on a combination of hormonal therapy and chemotherapy, four (6.5%) with a combination of hormonal and radiation therapy and one (1.6%) was being managed with chemotherapy alone. More specifically, 19 (30.7%) participants were managed with androgen deprivation therapy (ADT) alone, either medically with goserelin or surgically with orchiectomy **(Table 4.3).** Twenty-nine (46.8%) were managed using a combination of ADT plus either an androgen receptor blocker or a CYP17 inhibitor or both. Almost all patients (26, 89.7%) who were on combined androgen blockade had Stage IV disease at diagnosis while those on ADT alone were almost equally distributed across the stages of the disease.

While the majority of the patients had not been exposed to other surgical or radiological procedures, five (8.1%) had previous exposure to EBRT.

Table 4. 3 Therapeutic combinations used in the management of PC (n=62)

Management	**n (%)**
Current therapy	
CAB	**29 (46.8)**
ADT alone	19 (30.7)
ADT + chemotherapy	4 (6.5)
ADT + EBRT	4 (6.5)
CAB + chemotherapy	3 (4.8)
Abiraterone acetate/prednisolone alone	2 (3.2)
Chemotherapy/prednisolone alone	1 (1.6)
Previous therapy	
None	**48 (77.4)**
Previous EBRT	5 (8.1)
Previous prostatectomy	3 (4.8)
Previous orchiectomy	2 (3.2)
Previous orchiectomy and EBRT	2 (3.2)
Previous prostatectomy and EBRT	1 (1.6)
Previous orchiectomy, prostatectomy and EBRT	1 (1.6)

Key: *ADT- Androgen deprivation therapy, CAB- Combined androgen blockade, EBRT- External beam radiation therapy*

During their treatment, some patients were managed using a bisphosphonate drug, that is, 27 (43.5%) were using zoledronic acid and 2 (3.2%) were using alendronic acid (**Table 4.4**).

Table 4. 4 Additional biphosphonate therapy for patients with (n=29)

	Bisphosphonates	
	Zoledronic acid (n= 27)	**Alendronic acid (n=2)**
Current therapy		
CAB	**17 (63.0)**	1 (50.0)
ADT alone	5 (18.5)	0 (0.0)
CAB + chemotherapy	3 (11.1)	0 (0.0)
ADT + chemotherapy	1 (3.7)	0 (0.0)
Abiraterone acetate/prednisolone alone	1 (3.7)	0 (0.0)
ADT + EBRT	0 (0.0)	0 (0.0)
Chemotherapy/prednisolone alone	0 (0.0)	1 (50.0)

Key: *ADT- Androgen deprivation therapy, CAB- Combined androgen blockade, EBRT- external beam radiation therapy*

As illustrated in **Table 4.5**, the most common drug combination was goserelin with bicalutamide and zoledronic acid (16, 26.2%) while about a quarter of the participants were using goserelin alone. Majority of the participants were either on dual (22, 36.1%) or triple (20, 32.8%) drug therapy.

Table 4. 5 Drug combinations in the management of PC (n=61)

Drug combinations	**n (%)**
Goserelin + Bicalutamide + Zoledronic acid	16 (26.2)
Goserelin alone	15 (24.6)
Goserelin + Abiraterone acetate/prednisolone	6 (9.8)
Goserelin + Zoledronic acid	5 (8.2)
Goserelin + Bicalutamide	5 (8.2)
Goserelin + Docetaxel/prednisolone + Bicalutamide + Zoledronic acid	3 (4.9)
Goserelin + Abiraterone acetate/prednisolone	2 (3.3)
Goserelin + Docetaxel/prednisolone	1 (1.6)
Goserelin + Docetaxel/prednisolone + Zoledronic acid	1 (1.6)
Goserelin + Cabazitaxel/prednisolone	1 (1.6)
Goserelin + Bicalutamide + Docetaxel/prednisolone	1 (1.6)
Goserelin + Abiraterone acetate/prednisolone + Alendronic acid	1 (1.6)
Goserelin + Bicalutamide + Abiraterone acetate/prednisolone	1 (1.6)
Docetaxel/prednisolone + Alendronic acid	1 (1.6)
Abiraterone acetate/prednisolone + Zoledronic acid	1 (1.6)
Abiraterone acetate/prednisolone alone	1 (1.6)

The most commonly prescribed medications were goserelin (58, 93.6%) and bicalutamide (26, 41.9%) as shown in **Table 4.6**.

Table 4. 6 Medications prescribed in the management of PC

Class	Medication	N (%)
LHRH agonists	Goserelin	**58 (93.6)**
Androgen receptor antagonists	Bicalutamide	26 (41.9)
CYP17 inhibitors	Abiraterone/prednisolone	12 (9.4)
Taxanes	Docetaxel/prednisolone	7 (11.3)
	Cabazitaxel/prednisolone	1 (1.6)
Bisphosphonates	Zoledronic acid	27 (43.6)
	Alendronic acid	2 (3.2)

Key: *LHRH- Luteinising hormone-releasing hormone*

4.4 Disease and treatment-associated signs and symptoms

All the interviewed participants reported having experienced some signs and symptoms since their diagnosis and the start of management, as shown in **Table 4.7**. The most commonly reported were erectile dysfunction (46, 74.2%), loss of libido (42, 67.7%), urinary frequency (47, 50.0%), hot flushes (45, 72.6%) and fatigue (42, 67.7%).

Table 4. 7 Disease and treatment-associated signs and symptoms

System	Adverse effect	n (%)
Gastrointestinal tract	Nausea	**14 (22.6)**
	Vomiting	11 (17.7)
	Diarrhoea	6 (9.7)
	Haematochezia	3 (4.8)
Sexual dysfunction	Erectile dysfunction	**46 (74.2)**
	Loss of libido	42 (67.7)
Urinary system	Frequency	**47 (75.8)**
	Urgency	31 (50.0)
	Incontinence	17 (27.4)
	Dysuria	6 (9.7)
	Haematuria	2 (3.2)
Hormonal effects	Hot flushes	**45 (72.6)**
	Fatigue	42 (67.7)
	Weight gain	22 (35.5)
	Memory loss	13 (21.0)
	Gynaecomastia	10 (16.1)
	Mood swings/depression	5 (8.1)
Nervous system	Peripheral neuropathy	**16 (25.8)**
Metabolic derangements	Abnormal liver function	2 (3.2)
	Impaired glucose tolerance	1 (1.6)
Haematological derangements	Anaemia	**14 (22.6)**
Dermatological system	Alopecia	**7 (11.3)**
	Pruritus	3 (4.8)

4.5 Health-related quality of life scores

The mean HRQoL scores are shown in **Table 4.8**. The higher the score in the functional scales and the global health status, the better the level of functioning and quality of life, while a high score among the symptom scales/items indicates high symptomatology or a poorer state.

The multi-item scales in the EORTC tools were subjected to the Cronbach alpha (α) test for reliability whose cut-off was 0.7 which is described as good. All scales met this cut off except for cognitive functioning, pain, bowel function, hormone-related treatment effects and sexual activity.

Table 4. 8 Health-Related Quality of Life Scores

Scale/Item	Mean (± SD)
EORTC-QLQ-C30	
Quality of Life/ Global health status (QOL)	**65.1 (22.1)**
Functional scale	
Physical functioning (PF2)	68.3 (24.6)
Role functioning (RF2)	70.7 (35.1)
Emotional functioning (EF)	**88.4 (19.8)**
Cognitive functioning (CF)	82.8 (23.3)
Social functioning (SF)	70.2 (36.5)
Symptom scale/items	
Fatigue (FA)	35.4 (29.9)
Nausea and Vomiting (NV)	9.1 (22.7)
Pain (PA)	35.5 (32.7)
Dyspnoea (DY)	8.6 (23.3)
Insomnia (SL)	24.1 (33.2)
Appetite loss (AP)	12.9 (26.5)
Constipation (CO)	16.7 (32.4)
Diarrhoea (DI)	4.8 (16.9)
Financial difficulties (FI)	**70.9 (38.0)**
EORTC-QLQ-PR25	
Symptom scale/items	
Urinary symptoms (URI)	30.0 (23.0)
Incontinence aids (AID, conditional, n=3)	58.5 (42.0)
Bowel symptoms (BOW)	7.9 (9.4)
Hormone-related symptoms (HTR)	23.9 (15.5)
Functional scales	
Sexual activity (SAC)	**10.7 (17.8)**
Sexual functioning (SFU, conditional, n=4)	61 (5.2)

The overall quality of life mean score was 65.1 (± 21.1). Among the functional scales, emotional functioning and cognitive functioning had the highest scores at 88.4 (± 19.8)

and 82.8 (± 23.3) respectively. The lowest score for the functional scales was recorded for sexual activity as it was 10.7 (± 17.8).

Among the symptom scales, financial difficulties had the highest score of 70.9 (± 38.0) followed by incontinence aids (58.5 ± 42.0), fatigue (35.4 ± 29.9), pain (35.5 ± 32.7), and urinary symptoms (30.0 ± 23.0).

4.6 Predictors of Health-related quality of life

All scales and items of the HRQoL data were tested for normal distribution using the Shapiro-Wilk test and histograms. It was found to be skewed. The Spearman rank correlation test (r_s) was therefore used to assess for associations between the HRQoL scales and the independent variables. The level of significance (α) was set at 0.05.

4.6.1 Predictors of Physical functioning

Physical functioning (PF) refers to the ability of a person to perform strenuous activities with ease, walk short and/or long distances and perform activities of self-care without any help. There was a statistically significant positive correlation between PF and the level of education ($r_s = 0.2668$, $p = 0.0361$) as in **Table 4.9** meaning that individuals with a higher level of education were able to perform physical activities with ease.

Table 4. 9 Associations between sociodemographic characteristics and physical functioning

Variable	Spearman's rho (r_s)	p value
Age	0.0052	0.9681
Body Mass Index	0.0019	0.9892
Current alcohol consumption	0.2024	0.1178
Current cigarette and other tobacco product use	0.0631	0.6290
Marital status	0.1548	0.2295
Level of education	0.2668	**0.0361***
Employment status	0.0003	0.9981
Income group	0.2115	0.0989
Insurance status	0.0385	0.7666

Key: *-statistically significant

However, as shown in **Table 4.10**, there was a negative correlation between PF and urinary incontinence (r_s= -0.2580, p=0.0429), mood swings/depression (r_s= -0.3777,

p=0.0025), fatigue (r_s= -0.4313, *p*=0.0005) and memory loss (r_s= 0.3083, *p*=0.0148). The presence of these symptoms decreased physical functioning.

Table 4. 10 Associations between signs and symptoms and physical functioning

Variable	Spearman's rho (r_s)	*p* value	Variable	Spearman's rho (r_s)	*p* value
Diarrhoea	0.0751	0.5619	Mood swings/ depression	-0.3777	**0.0025***
Nausea	-0.1279	0.3219	Gynaecomastia	-0.1059	0.4125
Vomiting	-0.2028	0.1139	Weight gain	-0.1619	0.2086
Haematochezia	-0.1815	0.1578	Fatigue	-0.4313	**0.0005***
Erectile dysfunction	-0.1533	0.2344	Memory loss	-0.3083	**0.0148***
Loss of libido	-0.0630	0.6266	Peripheral Neuropathy	-0.1232	0.3400
Urinary incontinence	-0.2580	**0.0429***	Impaired glucose tolerance	0.0216	0.8678
Urinary frequency	-0.2179	0.0888	Abnormal LFTs	-0.0077	0.9527
Urinary urgency	-0.1468	0.2549	Anaemia	-0.0975	0.4508
Dysuria	-0.0920	0.4772	Alopecia	-0.0229	0.8597
Haematuria	-0.0949	0.4632	Pruritus	-0.0380	0.7693
Hot flushes	-0.0091	0.9438			

Key: *-statistically significant

4.6.2 Predictors of Role functioning

Role functioning (RF) refers to the ability to perform activities of daily life as well as any leisure activities without any limitation.

There was a positive correlation between RF and marital status (r_s= 0.2742, *p*=0.0311) as shown in **Table 4.11**. Married participants were more able to perform their daily activities compared to those who were not. A negative correlation was found between RF and the presence of fatigue (r_s= -0.3758, *p*=0.0026).

Table 4. 11 Associations between sociodemographic characteristics and role functioning

Variable	Spearman's rho (r_s)	*p* value
Age	-0.1215	0.3468
Body Mass Index	0.0154	0.9119
Current alcohol consumption	0.1008	0.4040
Current cigarette and other tobacco product use	0.1736	0.1808
Marital status	0.2742	**0.0311***
Level of education	0.2356	0.0653
Employment status	-0.0654	0.6133
Income group	0.1176	0.3627
Insurance status	-0.1743	0.1754

Key: *-statistically significant

Table 4. 12 Associations between signs and symptoms and role functioning

Variable	Spearman's rho (r_s)	*p* value	Variable	Spearman's rho (r_s)	*p* value
Diarrhoea	-0.0423	0.7439	Mood swings/ depression	-0.0795	0.5389
Nausea	-0.2291	0.0733	Gynaecomastia	-0.0013	0.9919
Vomiting	-0.2822	**0.0263***	Weight gain	-0.0443	0.7327
Haematochezia	-0.2445	0.0555	Fatigue	-0.3758	**0.0026***
Erectile dysfunction	-0.0275	0.8320	Memory loss	-0.0284	0.8267
Loss of libido	-0.1369	0.2886	Peripheral Neuropathy	-0.1452	0.2602
Urinary incontinence	-0.1154	0.3716	Impaired glucose tolerance	-0.0573	0.6582
Urinary frequency	-0.1090	0.3990	Abnormal LFTs	-0.0436	0.7366
Urinary urgency	-0.2281	0.0745	Anaemia	0.0414	0.7491
Dysuria	-0.1628	0.2062	Alopecia	-0.0380	0.7692
Haematuria	-0.0627	0.6286	Pruritus	-0.1749	0.1738
Hot flushes	0.0788	0.5429			

Key: *-statistically significant

4.6.3 Predictors of emotional functioning

Emotional functioning (EF) refers to feelings of anxiety, tension, worry, depression and irritability and lack thereof.

An increase in BMI was associated with a decrease in EF (r_s= -0.2756, *p*= 0.0437). Similarly, persons who had mood swings/depression had lower EF (r_s= -0.4125, *p*= 0.0009).

Table 4. 13 Associations between sociodemographic characteristics and emotional functioning

Variable	Spearman's rho (r_s)	*p* value
Age	0.2456	0..0543
Body Mass Index	-0.2756	**0.0437***
Current alcohol consumption	-0.1570	0.2269
Current cigarette and other tobacco product use	0.0262	0.8412
Marital status	-0.2170	0.0902
Highest level of education	-0.0564	0.6632
Employment status	0.0925	0.4744
Income group	-0.0515	0.6909
Insurance status	0.1397	0.2789

Key: *-statistically significant

Table 4. 14 Associations signs and symptoms and emotional functioning

Variable	Spearman's rho (r_s)	*p* value	Variable	Spearman's rho (r_s)	*p* value
Diarrhoea	0.1908	0.1374	Mood swings/ depression	-0.4125	**0.0009***
Nausea	0.0325	0.8019	Gynaecomastia	-0.0233	0.8575
Vomiting	-0.0672	0.6036	Weight gain	-0.1326	0.3041
Haematochezia	0.1831	0.1554	Fatigue	-0.0011	0.9934
Erectile dysfunction	0.2049	0.1102	Memory loss	-0.1707	0.1846
Loss of libido	0.1347	0.2967	Peripheral Neuropathy	0.0679	0.6000
Urinary incontinence	0.1152	0.3728	Impaired glucose tolerance	0.1040	0.4214
Urinary frequency	-0.1258	0.3298	Abnormal LFTs	0.1482	0.2502
Urinary urgency	0.0786	0.5438	Anaemia	0.1000	0.4394
Dysuria	0.1908	0.1374	Alopecia	-0.1973	0.1242
Haematuria	0.0228	0.8603	Pruritus	0.0493	0.7036
Hot flushes	-0.0948	0.4634			

Key: *-statistically significant

4.6.4 Predictors of Cognitive functioning

Cognitive functioning (CF) refers to the ability to maintain concentration while performing activities and/or memory loss.

There was a negative correlation between memory loss (r_s = -0.4127, p= 0.0009) and vomiting (r_s = -0.2695, p= 0.0342) and CF. Those who exhibited these signs and symptoms had reduced cognition.

Table 4. 15 Associations between sociodemographic characteristics and cognitive functioning

Variable	Spearman's rho (r_s)	*p* value
Age	-0.1777	0.1671
Body Mass Index	0.0331	0.8124
Current alcohol consumption	0.1545	0.2344
Current cigarette and other tobacco product use	0.1696	0.1914
Marital status	0.0135	0.9172
Highest level of education	0.1675	0.1932
Employment status	-0.1363	0.2907
Income group	0.0086	0.9471
Insurance status	0.0137	0.9156

Table 4. 16 Associations between signs and symptoms and cognitive functioning

Variable	Spearman's rho (rs)	p value	Variable	Spearman's rho (rs)	p value
Diarrhoea	-0.0460	0.7226	Mood swings/ depression	-0.1623	0.2076
Nausea	-0.1893	0.1406	Gynaecomastia	-0.1703	0.1857
Vomiting	-0.2695	**0.0342***	Weight gain	-0.0589	0.6495
Haematochezia	-0.0407	0.7533	Fatigue	-0.2129	0.0966
Erectile dysfunction	-0.0155	0.9046	Memory loss	-0.4127	**0.0009***
Loss of libido	-0.0280	0.8287	Peripheral Neuropathy	-0.2153	0.0929
Urinary incontinence	0.0740	0.5675	Impaired glucose tolerance	-0.0501	0.6989
Urinary frequency	-0.1587	0.2178	Abnormal LFTs	-0.0797	0.5380
Urinary urgency	-0.1690	0.1892	Anaemia	0.2288	0.0737
Dysuria	-0.0493	0.7037	Alopecia	-0.1918	0.1353
Haematuria	-0.0550	0.6713	Pruritus	0.0249	0.8477
Hot flushes	0.0762	0.5561			

Key: *-statistically significant

4.6.5 Predictors of social functioning

Social functioning (SF) refers to the interference of the disease and its management with family life and/or social relationships and activities.

There was a decrease in SF due to urinary incontinence (r_s= -0.2631, *p*= 0.0389), urinary frequency (r_s= -0.2718, *p*= 0.0326), urinary urgency (r_s= -0.2936, *p*= 0.0205), dysuria (r_s= -0.3202, *p*= 0.0112), mood swings/ depression (r_s = -0.2643, *p*= 0.0379), weight gain (r_s= -0.2614, *p*= 0.0401), fatigue (r_s= -0.4669, *p*= 0.0001) and memory loss (r_s= -0.2990, *p*=0.0183) as shown in **Table 4.18**.

Table 4. 17 Associations between sociodemographic characteristics and social functioning

Variable	**Spearman's rho (r_s)**	**p value**
Age	-0.0745	0.5649
Body Mass Index	-0.0323	0.8167
Current alcohol consumption	0.1719	0.1853
Current cigarette and other tobacco product use	0.0084	0.9486
Marital status	-0.0029	0.9821
Highest level of education	-0.0314	0.8083
Employment status	0.0245	0.8500
Income group	0.0048	0.9905
Insurance status	0.1613	0.2105

Table 4. 18 Associations between signs and symptoms and social functioning

Variable	Spearman's rho (rs)	p value	Variable	Spearman's rho (rs)	p value
Diarrhoea	0.1045	0.4187	Mood swings/ depression	-0.2643	**0.0379***
Nausea	0.1028	0.4266	Gynaecomastia	-0.1668	0.1952
Vomiting	-0.0898	0.4879	Weight gain	-0.2614	**0.0401***
Haematochezia	-0.1350	0.2954	Fatigue	-0.4669	**0.0001***
Erectile dysfunction	-0.0750	0.5621	Memory loss	-0.2990	**0.0183***
Loss of libido	-0.0671	0.6041	Peripheral Neuropathy	-0.1192	0.3561
Urinary incontinence	-0.2631	**0.0389***	Impaired glucose tolerance	0.1188	0.3576
Urinary frequency	-0.2718	**0.0326***	Abnormal LFTs	0.0738	0.5687
Urinary urgency	-0.2936	**0.0205***	Anaemia	0.0474	0.7147
Dysuria	-0.3202	**0.0112***	Alopecia	-0.0565	0.6629
Haematuria	-0.0137	0.9160	Pruritus	-0.0923	0.4757
Hot flushes	-0.1299	0.3143			

Key: *-statistically significant

4.6.6 Predictors of financial difficulties

Financial difficulties (FI) refer to the financial toxicity caused by or associated with the disease and its management.

As shown in **Table 4.19**, there was a negative correlation between FI and alcohol consumption (r_s= -0.3616, *p*= 0.0042). Participants who consumed alcohol had financial difficulties compared with those who did not. FI increased with the presence of urinary frequency (r_s= 0.3235, *p*= 0.0103), urinary urgency (r_s= 0.2670, *p*= 0.0359) and fatigue (r_s= 0.3354, *p*= 0.0077).

Table 4. 19 Associations between sociodemographic characteristics and financial difficulties

Variable	Spearman's rho (r_s)	*p* value
Age	0.0605	0.6405
Body Mass Index	-0.0523	0.7072
Current alcohol consumption	-0.3616	**0.0042***
Current cigarette and other tobacco product use	0.0321	0.8058
Marital status	0.0613	0.6362
Highest level of education	-0.0039	0.9761
Employment status	0.0917	0.4786
Income group	0.0490	0.7051
Insurance status	0.0801	0.5358

Key: *-statistically significant

Table 4. 20 Associations between signs and symptoms and financial difficulties

Variable	Spearman's rho (r_s)	*p* value	Variable	Spearman's rho (r_s)	*p* value
Diarrhoea	0.0582	0.6535	Mood swings/ depression	0.1300	0.3139
Nausea	-0.0943	0.4658	Gynaecomastia	0.2172	0.0899
Vomiting	-0.0212	0.8702	Weight gain	0.1163	0.3682
Haematochezia	-0.0047	0.9710	Fatigue	0.3354	**0.0077***
Erectile dysfunction	0.0069	0.9573	Memory loss	0.1963	0.1263
Loss of libido	0.1147	0.3748	Peripheral Neuropathy	0.2219	0.0830
Urinary incontinence	0.2018	0.1158	Impaired glucose tolerance	0.1044	0.4195
Urinary frequency	0.3235	**0.0103***	Abnormal LFTs	-0.0801	0.5358
Urinary urgency	0.2670	**0.0359***	Anaemia	-0.0726	0.5751
Dysuria	0.1950	0.1288	Alopecia	0.1949	0.6629
Haematuria	0.1488	0.2483	Pruritus	0.0848	0.5121
Hot flushes	0.2086	0.1038			

Key: *-statistically significant

4.6.7 Predictors of sexual activity

Sexual activity (SAC) refers to the degree of sexual interest and/or activity. There was a negative correlation between SAC and the income group of the participants (r_s= -0.2748, *p*= 0.0306), erectile dysfunction (r_s= -0.4072, *p*=0.001) and loss of libido (r_s =

-0.6724, p= <0.0001). Those who complained of these symptoms had lower levels of sexual activity.

Table 4. 21 Associations between sociodemographic characteristics and sexual activity

Variable	Spearman's rho (rs)	p value
Age	-0.1045	0.4189
Body Mass Index	0.1255	0.3659
Current alcohol consumption	0.1122	0.3891
Current cigarette and other tobacco product use	0.0748	0.5669
Marital status	-0.0005	0.9969
Highest level of education	0.1255	0.3312
Employment status	-0.0045	0.9724
Income group	-0.2748	**0.0306***
Insurance status	-0.1128	0.3829

Key: *-statistically significant

Table 4. 22 Associations between signs and symptoms and sexual activity

Variable	Spearman's rho (rs)	p value	Variable	Spearman's rho (rs)	p value
Diarrhoea	-0.0112	0.9310	Mood swings/ depression	-0.0711	0.5827
Nausea	-0.0318	0.8064	Gynaecomastia	-0.1956	0.1276
Vomiting	0.0304	0.8144	Weight gain	-0.1365	0.2902
Haematochezia	0.0077	0.9524	Fatigue	-0.0237	0.8551
Erectile dysfunction	-0.4072	**0.0010***	Memory loss	-0.0530	0.6824
Loss of libido	-0.6724	**<0.0001***	Peripheral Neuropathy	-0.1366	0.2898
Urinary incontinence	-0.1427	0.2687	Impaired glucose tolerance	-0.0835	0.5190
Urinary frequency	-0.1357	0.2930	Abnormal LFTs	-0.1190	0.3569
Urinary urgency	-0.2070	0.1065	Anaemia	-0.1271	0.3251
Dysuria	-0.1011	0.4344	Alopecia	-0.1276	0.3228
Haematuria	-0.1190	0.3569	Pruritus	0.1006	0.4367
Hot flushes	0.0583	0.6526			

Key: *-statistically significant

4.6.8 Predictors of Global health status/ Overall quality of life

As shown in **Table 4.24**, urinary urgency (r_s= -0.3628, p= 0.0038) and fatigue (r_s = -0.3519, p= 0.005) caused a decrease in the overall quality of life scores.

Table 4. 23 Associations between sociodemographic characteristics and global health status

Variable	Spearman's rho (r_s)	*p* value
Age	0.0603	0.6416
Body Mass Index	-0.1636	0.2371
Current alcohol consumption	0.0419	0.7484
Current cigarette and other tobacco product use	0.1404	0.2806
Marital status	0.0203	0.8757
Highest level of education	0.1722	0.1808
Employment status	-0.0805	0.5337
Income group	0.0705	0.5862
Insurance status	-0.1112	0.3896

Table 4. 24 Associations between signs and symptoms and global health status

Variable	Spearman's rho (r_s)	*p* value	Variable	Spearman's rho (r_s)	*p* value
Diarrhoea	-0.0433	0.7384	Mood swings/ depression	-0.1191	0.3564
Nausea	-0.2022	0.1151	Gynaecomastia	-0.0025	0.9847
Vomiting	-0.1698	0.1869	Weight gain	-0.2359	0.0650
Haematochezia	0.0830	0.5211	Fatigue	-0.3519	**0.0050***
Erectile dysfunction	-0.1880	0.1435	Memory loss	-0.1830	0.1547
Loss of libido	-0.0694	0.5920	Peripheral Neuropathy	-0.1859	0.1481
Urinary incontinence	-0.1649	0.2003	Impaired glucose tolerance	-0.0145	0.9109
Urinary frequency	-0.1792	0.1633	Abnormal LFTs	-0.1112	0.3896
Urinary urgency	-0.3628	**0.0038***	Anaemia	-0.1180	0.3609
Dysuria	-0.0680	0.5995	Alopecia	-0.1978	0.1223
Haematuria	-0.0440	0.7344	Pruritus	0.0830	0.5211
Hot flushes	-0.1014	0.4329			

Key: *-statistically significant

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses the findings of this research and gives the conclusions and recommendations made based on those research findings.

5.2 Discussion

In this study, most patients were in the age group of 65-74 years, which is in line with existing literature (8,9). Age is usually associated with a decline in physical, social, cognitive and sexual function. However, this study did not find any associations between age and any of the HRQoL scales, unlike others (86,88,99,109,110). Majority of the participants were married, retired, low-income earners and had a secondary level of education similar to studies conducted in Taiwan, Canada and Finland (19,83–85,90).

Comorbid diseases were common in this population. At least a third of the participants had other diseases with the most prevalent being hypertension and diabetes mellitus. While age is a risk factor for these comorbidities, hypertension and hyperglycaemia are adverse effects of long-term ADT use. However, it could not immediately be established if they were as a consequence of or worsened by the presence of these comorbidities. Most of the participants had at least one comorbidity similar to other studies (97,111).

A higher proportion of participants had a higher PSA level, poorly differentiated cancers and metastatic disease at diagnosis (112,113). This means that patients had more advanced and aggressive disease at presentation.

The most common side effects of therapy were erectile dysfunction, loss of libido, urinary frequency and urgency, hot flushes and fatigue. Venderbos *et al,* found that fatigue was a common complaint, although their highest score in the fatigue symptom scale was lower than in this study (19). They also found that the deterioration of sexual function was a universal complaint, regardless of the treatment modality, as did other studies (19,98,114,115). Downing *et al,* found that hot flushes were also a common complaint in patients who were on ADT, although their prevalence was lower than for this population (115).

Hormonal therapy is the most common treatment modality utilised in this population, specifically ADT or CAB because of the advanced nature of the disease. A survey conducted in Europe, the USA and Australia found that the use of ADT in non-metastatic disease was at 38.4% (116). Cassell *et al,* found that the use of surgical orchiectomy was more common in most countries in Africa, which is in contrast to the findings of this study(13). In some instances however, management deviated from established treatment guidelines (11,12,47,66).

This study sought to determine the functional capacity, the intensity of symptoms and the overall quality of life of these patients. Physical and role functioning are closely related, as they both refer to the ability to perform either activities involved in self-care, daily life, leisure or those requiring on to exert themselves, and as such, they differed only by a few percentage points. While both scales were above average, at 68.3 for physical functioning and 70.7 for role functioning, they represented a mild decrease in the patient's performance status.

A higher level of education increased the level of physical functioning, similar to one study conducted in the US (96). This may be due to the fact that education equips a person with knowledge and skills, which allows them to be more open-minded and gives them the ability to overcome physical challenges. Conversely, urinary incontinence, mood swings/depression and memory loss had a negative effect on physical functioning. Incontinence, mood swings, depression and memory loss limit physical functioning in that they may decrease one's ability to perform tasks by either reducing their movement or mental capacity to do said tasks.

Marital status was found to increase role functioning. Being married acts as a proxy marker for having a support system that may help improve the acceptance of the disease condition, improve surveillance of adverse effects and enable one to gain the confidence to perform work-related or leisure activities. Kao *et al*, found that patients' marital/cohabitation status was beneficial in the area of activities of daily life (85). In this study, participants who had a history of vomiting were found to have lower role functioning scores. Vomiting, which is more common in patients who have undergone chemotherapy or radiotherapy, often leads to a person's incapacitation.

Fatigue was shown to limit both physical and role functioning in this study. The fatigue score was also higher than in other studies (83,117). Davda *et al* found that fatigue and role functioning had a high negative correlation (106). Being one of the most common adverse effects of hormonal therapy, it predictably affects one's ability to perform even simple tasks. It is also a vicious cycle as lack of physical activity in PC is negatively correlated with fatigue and physical functioning (117).

Emotional and cognitive functioning scored the highest, that is 88.4 and 82.8 respectively, among the functional scales and were only slightly affected. These parameters represent the state of one's mental health and ability to cope with the disease and the effects of its treatment. A higher BMI and reports of mood swings and depression, which are adverse effects associated with hormonal therapy, negatively affect emotional functioning. However, this was in contrast with a study conducted among breast cancer patients in China whereby a higher BMI was associated with better HRQoL including emotional functioning (118). Obesity may reduce a person's self-esteem and introduce issues concerned with one's body image. A higher BMI may also have a negative prognostic value on the survival from prostate cancer (119).

Social functioning had a mean score of 70.2, which was moderate. The social functioning scale assessed the patient's relationships with family and society. The level of social functioning was significantly reduced by adverse urinary symptoms, mood swings or depression, weight gain, fatigue and memory loss. Adverse urinary symptoms of incontinence, frequency, urgency and dysuria reduce one's ability to socialise with others due to the fear of stigma or the need to be near sanitation facilities. Memory loss also impairs one's ability to form meaningful familial and social connections.

Financial difficulties were a big problem for participants in this study, with a score of 70.9, despite almost all of them being under national health insurance. Comorbidities may also contribute to financial deprivation due to the increase in pill burden and cost of treatment. This was higher than for the most quality of life studies (19,84,99,110). However, it was comparable to studies conducted in Kenya and Tanzania, although that looked at cancers in general (102,106). This may be due to the fact that the participants were from low to middle-income countries. Financial difficulties were observed to increase with urinary frequency and urgency as well as fatigue. This may

be explained by the fact that lack of energy can limit one's ability to generate income and therefore result in financial problems.

Deficits in sexual activity are a known side effect of treatment of PC, either through hormonal or radiation therapy, and may be as a result of the disease itself. At a score of 10.9, sexual activity was very poor for this cohort and was comparable to other studies (83,110). One study conducted in Taiwan found that the sexual activity score was worse for patients on hormonal therapy than those who had surgery for the management of their PC (120). It was negatively associated with income group, erectile dysfunction and loss of libido.

The overall quality of life score for this cohort was 65.1. It was lower than a study conducted by Silva *et al* (117). The only variables that significantly affected HRQoL were fatigue and urinary urgency. Fatigue, in limiting physical and role functioning, invariably lowers the participants overall HRQoL. In a study by Torvinen *et al*, they found that fatigue lowered HRQoL in both localised and advanced PC (84).

Being a cross-sectional study, the major limitation was that HRQoL could only be assessed at one period of time, although it has been established that quality of life is dynamic. Additionally, incomplete records were a major limitation.

5.3 Conclusion

The majority of the patients with PC were managed with hormonal therapy. The most common treatment modality used was the combination of ADT using goserelin and either bicalutamide or abiraterone acetate/prednisolone. Hot flushes, fatigue, urinary frequency and urgency and sexual dysfunction were the most common disease and treatment-related symptoms within this population.

The highest and lowest scoring functional scales were emotional functioning and sexual activity respectively. The financial difficulties had the highest score among the symptom scales. Fatigue appeared to be the most important predictor of HRQoL as it affected several scales.

5.4 Recommendations

5.4.1 Recommendations for Policy and Practice

1. Patients within this study mainly presented with advanced disease. Therefore, public health education to sensitise men on the need for screening for PC and early diagnosis and treatment is recommended.
2. While the majority of patients were on hormonal therapy, individual management was highly heterogeneous and some were not adherent to treatment guidelines. Efforts should be made to ensure consistency in the management of PC such as streamlining the institution's treatment practices.
3. There was a high prevalence of drug-related adverse effects. A modified HRQoL tool specifically for PC patients should be integrated into patient care and these disease or drug effects assessed comprehensively at every clinic visit and managed to reduce suffering and improve quality of life.
4. The degree of financial difficulties was high among the participants. Patients at risk for financial toxicity, even with national health insurance schemes, should be identified as soon as possible and directed towards patient assistance programs.

5.4.2 Recommendations for Further Research

1. A prospective long-term cohort quality of life study should be carried out among patients with PC, where they are assessed before, during and after treatment to identify long-term changes in HRQoL and identify gaps in management.
2. A study to assess the degree of adherence to treatment guidelines should be done and strategies to eliminate any discordance developed.

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APPENDICES

APPENDIX 1: ELIGIBILITY CRITERIA

All participants who are to be enrolled into the study must meet the eligibility criteria based on the inclusion/exclusion criteria that is detailed in this form.

I) Study Information

Title	Management and Health-Related Quality of Life Among Patients with Prostate Cancer at Kenyatta National Hospital: A descriptive cross-sectional study
KNH/UoN-ERC Number	**P85/02/2021**
Principal Investigator	Dr. Wairimu Karaihira

II) Subject Information

Subject Name/ID	

III) Inclusion/Exclusion Criteria

Inclusion Criteria	**Yes**	**No**
1.Patients with a histologically confirmed diagnosis of prostate cancer.		
2. Adult patients aged 18 years and above		
3. Patients who can communicate effectively in English or Kiswahili		
4. Patient on treatment for PC for at least 4 weeks		
Exclusion Criteria	**Yes**	**No**
1.Patient refuses to offer informed consent		
2.Patient has cognitive impairment or is unable to comprehend the elements of the data collection tools		

IV) Statement of Eligibility

This subject is **ELIGIBLE** ☐ / **NOT ELIGIBLE** ☐ to participate in this study.

Reason:

_____

Signature:	Date:
Name	

APPENDIX 2A: PATIENT INFORMATION AND CONSENT FORM

Title of Study: Management and Health-Related Quality of Life Among Patients with Prostate Cancer at Kenyatta National Hospital: A descriptive cross-sectional study

Principle Investigator: Dr. Wairimu Karaihira

Supervisors: Dr. Peter N. Karimi (1), Dr. Irene Weru (2)

Institution(s): (1) Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi, (2) Kenyatta National Hospital

Introduction:

I would like to inform you about a study being conducted by the above listed researchers. This consent form will give you the information you will need to help you decide whether or not to be a participate in the study. Do not hesitate to ask any questions about the intended purpose of the research, what happens if you choose to participate, the possible risks and benefits, your rights as a volunteer, and anything else that you may be unsure about. When all your questions have been answered satisfactorily, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form.

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. P85/02/2021.

The role of the KNH-UON ERC is to review the research proposal so as to ensure that it adheres to ethical standards and scientific principles of research with the aim of protecting potential participants.

What is the study about?

The researcher will be interviewing individuals who are on management for prostate cancer. The purpose of the interview is to find out the management of prostate cancer at KNH and the health-related quality of life of these patients. Participants in this research study will be asked questions about their sociodemographic characteristics, what treatment options they are on, any adverse effects experienced as a consequence of their treatment and their physical, social and mental well-being. The findings of the study will be used to improve the management of the disease, taking into consideration the general well-being of the patient.

Procedure: If you agree to participate in this study, I will interview you in a private area where you feel comfortable answering questions. Your medical file will also be accessed for purposes of retrieving information regarding your disease, laboratory tests and management. The interview will last approximately 30 minutes.

Risks or Costs: Since no medication or intervention is being administered to you, the study carries no risks. You will also not incur any costs in the course of the study.

Benefits: While you will not receive any direct benefits, all information that will improve your quality of care will be shared with your healthcare provider(s). Any information will also be a contribution to the body of knowledge concerned with the management of prostate cancer.

Assurance of Confidentiality: All information that you provide will be treated with the utmost confidence. A serial number will be used to identify you, instead of your name and other personal identifiers, and it will be kept in a password-protected computer database. All paper records will be kept under lock and key.

Your rights as a participant

1. Your participation in this study is strictly voluntary
2. You may withdraw from the study at any time without necessarily providing a reason for your withdrawal. You will not suffer any injustice or loss of benefit as a result.
3. Your refusal to participate will not affect your ability to access and benefit from services at this health facility or others.
4. You have the right to both privacy and confidentiality.
5. You may seek clarification on any part of this form.
6. A copy of this form will be given to you for your records.

Contacts: If you have any questions during the course of the study, you can contact the following:

1. Dr. Wairimu Karaihira,
   Department of Pharmaceutics and Pharmacy Practice,
   School of Pharmacy, University of Nairobi

Mobile: 0716120963, Email: wkaraihira@gmail.com

2. Dr. P.N. Karimi, PhD
   Department of Pharmaceutics and Pharmacy Practice,
   School of Pharmacy, University of Nairobi
   P. O. Box 19676-00200, Nairobi.
3. The Secretary, KNH-UON Ethics and Research Committee. Telephone numbers 2726300 Ext 44102. Email: uonknh_erc@uonbi.ac.ke Website: http://www.erc.uonbi.ac.ke

STATEMENT OF CONSENT

Participant's Statement

I have read this consent form. I have had the chance to discuss this research study and I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I have also understood that all efforts will be made to keep information regarding my personal identity confidential.

Name of participant _____ Date _____

Study number _____ Signature of participant _____

Researcher's Statement

I, the researcher, can confirm that I have explained the details of the study to the participant, that they have understood and have given their consent voluntarily.

Name of researcher _____ Date _____

Signature of researcher _____

APPENDIX 2B: RIDHAA YA KUSHIRIKI KATIKA UTAFITI

Kichwa cha Utafiti: Utibabu na Hali ya Maisha ya Kiafya miogoni mwa wangojwa wanaougua Saratani ya Kibofu katika Hospitali ya Kitaifa ya Kenyatta: Utafiti wa maelezo wa sehemu nzima.

Mtafiti Mkuu: Dkt. Wairimu Karaihira

Wasimamizi: Dkt. Peter. N. Karimi (1), Dkt. Irene Weru (2)

Taasisi: (1) Idara ya mazoezi ya Famasia, Shule ya Famasia katika Chuo Kikuu cha Nairobi, (2) Hospitali ya Kitaifa ya Kenyatta

Utangulizi:

Ningependa kukujulisha kuhusu utafiti utakaofanywa na waliotajwa hapo juu. Umuhimu wa mazungumzo haya ni kukufahamisha zaidi kuhusu utafiti huu ili uweze kufanya uamuzi wa hekima kushiriki au kutoshiriki katika utafiti huu. Usisite kuuliza swali lolote kuhusu kusudi za utafiti huu, kitakachofanyika utakapo kubali kushiriki, hatari na manufaa ya utafiti, haki zako kama mshiriki na mengine yote usiyokuwa na uhakika nayo. Maswali yako yote yatakapokuwa yamejibiwa, utaweza kuamua kama utashiriki au la. Mchakato huu unaitwa “idhini ya habari”. Utakapoelewa mambo haya na ukubali kushiriki, nitakuliza utie sahihi na majina yako kwa ukurasa huu hapo chini. Utafiti huu umeidhinishwa na Kamati ya Adili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta ikishirikiana na Chuo Kikuu cha Nairobi Nambari ya Itifaki

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Jukumu la Kamati ya Adili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta ikishirikiana na Chuo Kikuu cha Nairobi ni kupitia pendekezo hii ya utafiti ili kuhakikisha ya kwamba inazingatia maadili na kanuni za utafiti wa kisayansi kwa lengo la kuwalinda wanaoshiriki katika utafiti huu.

Utafiti huu unahusu nini?

Mchunguzi atakuwa akiwahoji washiriki wa utafiti huu wanaotibiwa kwa ugonjwa wa saratani ya kibofu. Sababu ya kufanya utafiti huu ni kuweza kutambua ugonjwa huu wa saratani ya kibofu unavyotibiwa katika hospitali ya Kitaifa ya Kenyatta na hali ya maisha ya kiafya ya waliougua saratani ya kibofu. Washiriki katika utafiti huu wataulizwa maswali kuhusu sifa zao za kijamii, wanavyotibiwa na madhara ya

matibabu hayo na uzima wao wa kimwili, kijamii na kiakili. Matokeo ya utafiti huu yataweza kutumika kuboresha matibabu ya saratani ya kibofu ikizingatia uzima wa mgonjwa kikamilifu.

Mtindo: Ukikubali, nitakuuliza maswali kwa njia ya kisiri. Faili yako ya hospitali itakaguliwa ili kupata habari kuhusu ugonjwa unaougua, majibu ya maabara na unavyotibiwa. Mahojiano haya yatakaa kwa muda wa dakika kama thelathini.

Hatari au gharama: Hakuna hatari yoyote utakayoponzwa nayo kwa maana hakuna matibabu au kiingilia kati utakayopata. Vile vile, hakuna gharama yoyote utakayopata kwa muda wa utafiti huu.

Manufaa: Hakuna manufaa utakayopata moja kwa moja lakini matokeo ya utafiti kwako yatajadiliwa pamoja na madaktari wanaokutibu ili ugonjwa wako ueleweke kwa ndani ndiposa uweze kutibiwa zaidi. Maelezo utakayotoa yataweza kuongeza maarifa kuhusu usimamizi wa saratani ya kibofu.

Dhibitisho la usiri: Habari zote utakazotueleza zitalindwa kwa siri kuu. Hakutakuwepo wakati wowote ambapo jina lako litatumika wala kutajwa wakati wa kutayarisha matokeo ya utafiti huu. Badala ya jina lako, nambari tambulishi ndio itakayotumika na itawekwa katika hifadhidata ya kompyuta itakayolindwa na nywili.

Haki zako kama mshiriki

1. Kushiriki kwako kwa utafiti huu ni kwa hiari yako.
2. Unaweza kujiondoa wakati wowote bila kushurutishwa kutoa maelezo ya kufanya hivyo. Hautakosa manufaa au kudhulumiwa.
3. Kutoshiriki kwako katika utafiti huu hakutaadhiri huduma unazopaswa kupata kwa hospitali ama ingine iwayo.
4. Una haki ya faragha na usiri.
5. Una uhuru wa kuuliza swali lolote baada ya kusoma na kuelewa ujumbe huu ili upate habari kamili kuhusu utafiti wenyewe.
6. Tutakupa nakala yako ili ujiwekee kwa manufaa yako binafsi.

Nambari za mawasiliano ya baadaye: Ukiwa na swali lolote baadaye, unaweza wasiliana na:

1. Dkt. Wairimu Karaihira, Idara ya mazoezi ya Famasia, Shule ya Famasia katika Chuo Kikuu cha Nairobi. Nambari ya simu: 0716120963. Barua pepe: wkaraihira@gmail.com
2. Dkt. P. N. Karimi. Idara ya mazoezi ya Famasia, Shule ya Famasia katika Chuo Kikuu cha Nairobi. S.L.P 19679-00200, Nairobi.
3. Katibu, Kamati ya Adili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta ikishirikiana na Chuo Kikuu cha Nairobi. Nambari ya simu: 2726300 EXT 44102. Barua pepe: uonknh_erc@uonbi.ac.ke Tovuti: http://www.erc.uonbi.ac.ke

FOMU YA RIDHAA

Taarifa ya mshiriki

Nimesoma na pia kupokea maelezo katika ridhaa hii na nimeyaelewa kikamilifu. Maswali na haja zangu kuhusu utafiti yamejibiwa. Nimepata kuelezewa manufaa na hatari zozote. Nimefahamu ya kwamba kushiriki kwangu ni kwa hiari na nina uhuru wa kujiondoa bila dhuluma. Nimekubali kushiriki katika utafiti huu. Nimefahamu ya kwamba juhudi zote zitafanywa kuweka habari zote kunihusu siri.

Jina la mshiriki: _____ Tarehe: _____

Nambari ya utafiti: _____ Sahihi ya mshiriki: _____

Andiko la Mtafiti Mkuu

Mimi, kama mtafiti mkuu, nadhibitisha ya kwamba nimemueleza habari zote anazopaswa kujua kuhusu utafiti hu una amepeana ridhaa yake kwa hiari yake.

Jina la mtafiti mkuu: _____ Tarehe: _____

Sahihi ya mtafiti mkuu _____

APPENDIX 3: STRUCTURED QUESTIONNAIRE

PATIENT BIODATA

Patient serial number _____ Study number P85/02/2021

Patient's initials _____ Date of enrolment _____

SOCIODEMOGRAPHIC CHARACTERISTICS

1. What is your age in years? _____
2. Patient's age category (*please tick one*)

Age category (years)	[ ] <55	[ ] 55-64	[ ] 65-74	[ ] 75-84	[ ] >84
Code	0	1	2	3	4

3. Weight in kilograms? _____
4. Height in centimetres? _____
5. Patient's BMI category (*Please tick one*)

BMI	[ ] <18.5	[ ] 18.5-24.9	[ ] 25.0 – 29.9	[ ] ≥ 30
Category	Underweight	Normal weight	Pre-obesity	Obese
Code	0	1	2	3

6. What is your marital status? (*Please tick one*)

Marital status	[ ] Single	[ ] Married	[ ] Separated	[ ] Divorced	[ ] Widowed
Code	0	1	2	3	4

7. What is your highest level of education? *(Please tick one*)

Level of education	[ ] None	[ ] Primary	[ ] Secondary	[ ] Tertiary
Code	0	1	2	3

8. What is your employment status? (*Please tick one*)

Employment status	[ ] Unemployed	[ ] Employed	[ ] Self-employed	[ ] Retired
Code	0	1	2	3

9. What is your total monthly expenditure?

Monthly expenditure (Kshs.)	[ ] ≤23,670	[ ] 23,671-119,999	[ ] ≥120,000
Income group	Low income	Middle income	Upper income
Code	0	1	2

10. Do you have a medical insurance cover? [ ] No (0) [ ] Yes (1)
11. If yes, what type of medical insurance cover do you have?

Insurance cover	[ ] Public (national scheme)	Public (civil servant scheme or another special group)	[ ] Private	[ ] Public and private
Code	0	1	2	3

12. Do you consume alcohol? [ ] No (0) [ ] Yes (1)
13. Do you smoke cigarettes or use tobacco products? [ ] No (0) [ ] Yes (1)

COMORBIDITIES

14. Do you suffer from any other illness (comorbidities)? [ ] No (0) [ ] Yes (1)

If yes, what illnesses is the patient currently suffering from or has a history of?

No.	Comorbidity	Present	Absent	Duration (years)
15.	History of Myocardial Infarction	1	0	
16.	Congestive Heart Failure	1	0	
17.	Peripheral Vascular Disease	1	0	
18.	Cerebrovascular Accident or Transient Ischaemic Attack	1	0	
19.	Dementia	1	0	
20.	Chronic Obstructive Pulmonary Disease	1	0	
21.	Connective Tissue Disease	1	0	
22.	Peptic Ulcer Disease	1	0	
23.	Mild Liver Disease	1	0	
24.	Moderate to severe Liver disease	1		
25.	Uncomplicated diabetes	1	0	
26.	Diabetes with end organ damage	1		
27	Hypertension	1	0	
28.	Hemiplegia	1	0	
29.	Moderate to severe chronic kidney disease	1	0	

30.	Localised solid tumour (apart from prostate cancer)	1	0	
31.	Leukaemia	1	0	
32.	Lymphoma	1	0	
33.	Metastatic solid tumour (apart from prostate cancer)	1	0	
34.	HIV/AIDS	1	0	
35.	Other (specify) _____	1	0	

36. Number of comorbidities _____

CLINICAL CHARACTERISTICS

What was the severity of disease at diagnosis?

37. Prostate specific antigen _____ ng/ml

PSA level (ng/ml)	[ ] <10	[ ] 10-20	[ ] >20
Code	0	1	1

38. Tumour staging (Is this present in the file? [ ] Yes [ ] No)

Primary Tumour (T)	Lymph node (N)	Metastasis (M)
[ ] T1-T2a	[ ] Nx	[ ] Mx
[ ] T2b-T2c	[ ] N0	[ ] M0
[ ] T3a	[ ] N1	[ ] M1
[ ] T3b-T4		

39. Disease stage (*Tick as appropriate*)

Stage	Stage 1	Stage II	Stage III	Stage IV
Code	0	1	2	3

40. Tumour Grading (*Tick as appropriate*)

Grade Group	[ ] G1 (GS 6)	[ ] G2 (GS 3+4=7)	[ ] G3 (GS 4+3 = 7)	[ ] G4 (GS 8)	[ ] G5 (GS 9-10)
Code	0	1	2	3	4

41. When was the patient diagnosed with prostate cancer (Month and Year)

_____

Choice of Treatment Option

How is the patient's disease currently managed? (*Tick as appropriate)*

No.	Treatment Modality	Yes	No	Duration
42.	Observation	1	0	
43.	Active Surveillance	1	0	
44.	External Beam Radiation Therapy (EBRT)	1	0	
45.	Brachytherapy (BT)	1	0	
46.	Radical Prostatectomy (RP)	1	0	
47.	Hormonal Therapy (HT)	1	0	
48.	Chemotherapy	1	0	
49.	Radiation Therapy + Radical Prostatectomy	1	0	
50.	Hormonal Therapy + Radiation Therapy	1	0	
51.	Hormonal Therapy + Chemotherapy	1	0	
52.	Radiation Therapy + Chemotherapy	1	0	

Medications prescribed in prostate cancer

No.	Class	Specific medication	Yes	No
53	LHRH agonists	Leuprolide	1	0
		Goserelin	1	0
54	LHRH antagonists	Degarelix	1	0
55	Non-steroidal antiandrogens	Bicalutamide	1	0
		Flutamide	1	0
56.	ARTAs	Enzalutamide	1	0
		Apalutamide	1	0
57.	CYP17 inhibitors	Abiraterone/prednisone	1	0
58.	Taxanes	Docetaxel/prednisolone	1	0
		Cabazitaxel/prednisolone	1	0
59.	Bone Modifying Agents	Pamidronate	1	0
		Zoledronate	1	0
		Alendronate	1	0
		Ibandronate	1	0
60	Oestrogens	Diethylstilbesterol/ Aspirin	1	0
61.	Other drugs		1	0

62. Previous treatment _____

Treatment Related Adverse Effects

63. Have you experienced any adverse effects since you started your treatment? [ ] No (0) [ ] Yes (1)

If yes, which ones have you experienced? *Tick as appropriate*

System	Symptom	Yes	No
Gastrointestinal	64. Diarrhoea	1	0
	65. Nausea	1	0
	66. Vomiting	1	0
	67. Haematochezia	1	0
Sexual dysfunction	68.Erectile dysfunction	1	0
	69. Loss of libido	1	0
Urinary system	70.Urinary incontinence	1	0
	71.Urinary frequency	1	0
	72. Urinary urgency	1	0
	73. Dysuria	1	0
	74.Haematuria	1	0
Hormonal effects	75. Hot flashes	1	0
	76. Mood swings/ depression	1	0
	77. Memory loss	1	0
	78. Gynaecomastia	1	0
	79. Loss of muscle mass	1	0
	79. Weight gain	1	0
	80. Alopecia	1	0
	81. Fatigue	1	0
	82. Reduced bone density and/or fractures	1	0
Nervous System	83.Peripheral neuropathy	1	0
	84. Seizures	1	0
Haematological and Biochemical derangement (s)	85. Dyslipidaemia	1	0
	86. Impaired glucose tolerance	1	0
	87. Abnormal liver enzyme levels	1	0
	88. Anaemia	1	0
	89. Neutropenia	1	0

SCORES FOR HRQOL TOOLS

EORTC-QLQ-C30		**EORTC-QLQ-PR25**	
Scale	Score	Scale	Score
Functional scales			
Physical functioning		Sexual activity	
Role functioning		Sexual functioning	
Emotional functioning			
Cognitive functioning			
Social functioning			
Symptom scales/items			
Fatigue		Urinary symptoms	
Nausea and vomiting		Incontinence aids	
Pain		Bowel symptoms	
Dyspnoea		Hormonal- treatment related symptoms	
Insomnia			
Appetite			
Constipation			
Diarrhoea			
Financial difficulties			

APPENDIX 4A: EORTC-QLQ-C30 version 3 (English Version)

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: _____

Your birthdate (Day, Month, Year): _____

Today's date (Day, Month, Year): 31 _____

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

APPENDIX 4B: EORTC-QLQ-C30 version 3 (Kiswahili Version)

EORTC QLQ-C30 (toleo la 3)

Tunapenda kujua mambo kadhaa kukuhusu wewe na afya yako. Tafadhali jibu maswali yote wewe mwenyewe kwa kuzungushia duara kwenye nambari inayokueleleza zaidi wewe. Hakuna jibu "zuri" au "baya". Taarifa utakazotoa zitabaki kuwa siri.

Tafadhali jaza herufi za kifupi cha majina yako:
Tarehe ya kuzaliwa (Siku, Mwezi, Mwaka):
Tarehe ya leo (Siku, Mwezi, Mwaka): 31

		Hapana	Kidogo tu	Kiasi	Sana
1.	Unapata shida yoyote unapofanya kazi ngumu, kama vile kubeba mifuko mikubwa ya kununulia vitu au sanduku?	1	2	3	4
2.	Una tatizo lolote unapotembea umbali mrefu?	1	2	3	4
3.	Unapata shida yoyote utembeapo umbali mfupi nje ya nyumba?	1	2	3	4
4.	Unahitaji kupumzika kitandani au kwenye kiti wakati wa mchana?	1	2	3	4
5.	Unahitaji msaada wakati wa kula, kuvaa, kuoga au kwenda msalani?	1	2	3	4

Katika kipindi cha wiki moja iliyopita:		**Hapana**	**Kidogo tu**	**Kiasi**	**Sana**
6.	Umekuwa ukishindwa kufanya kazi zako au shughuli za kila siku ipasavyo?	1	2	3	4
7.	Umekuwa ukishindwa kuendelea kufanya mambo yako unayoyapenda au shughuli zako za wakati wa mapumziko?	1	2	3	4
8.	Ulishindwa kupumua vizuri?	1	2	3	4
9.	Ulikuwa na maumivu?	1	2	3	4
10.	Ulihitaji mapumziko?	1	2	3	4
11.	Umekuwa na matatizo ya kupata usingizi?	1	2	3	4
12.	Umejisikia dhaifu?	1	2	3	4
13.	Umekosa hamu ya chakula?	1	2	3	4
14.	Umesikia kichefuchefu?	1	2	3	4
15.	Ulitapika?	1	2	3	4
16.	Umekuwa na tatizo la kufunga choo?	1	2	3	4

Tafadhali endelea ukurasa unaofuata

Katika kipindi cha wiki moja iliyopita:	**Hapana**	**Kidogo tu**	**Kiasi**	**Sana**
17. Umeharisha?	1	2	3	4
18. Umejisikia mchovu?	1	2	3	4
19. Maumivu yaliingilia shughuli zako za kila siku?	1	2	3	4
20. Umekuwa na shida ya kuwa makini na vitu? Kwa mfano kusoma gazeti au kuangalia televisheni kwa umakini?	1	2	3	4
21. Umekuwa ukijisikia hali ya kukasirika kwa upesi?	1	2	3	4
22. Umekuwa na wasiwasi?	1	2	3	4
23. Ulijisikia kukasirika?	1	2	3	4
24. Umejisikia kuvunjika moyo?	1	2	3	4
25. Umekuwa ukipoteza kumbukumbu ya mambo yaliyopita, pia kusahau kufanya mambo unayotakiwa kufanya?	1	2	3	4
26. Hali yako ya kiafya au matibabu vimeingilia maisha yako ya kifamilia?	1	2	3	4
27. Hali yako ya kiafya au matibabu vimeingilia maisha yako ya kijamii?	1	2	3	4
28. Hali yako ya kiafya au matibabu vimekusababishia matatizo ya kifedha?	1	2	3	4

Kwa maswali yafuatayo tafadhali zungushia duara kwenye namba kati ya 1 mpaka 7 ambayo inakueleleza zaidi wewe

29. Unaweza kuitathmini vipi hali yako ya kiafya katika kipindi cha wiki moja iliyopita?

1 2 3 4 5 6 7

Mbaya sana Nzuri sana

30. Kwa ujumla unaweza kutathmini vipi hali yako ya maisha au mwenendo wa maisha yako katika kipindi cha wiki moja iliyopita?

1 2 3 4 5 6 7

Mbaya sana Nzuri sana

APPENDIX 5A: EORTC-QLQ-PR25 (English Version)

ENGLISH

EORTC QLQ - PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	Not at all	A little	Quite a bit	Very much
31. Have you had to urinate frequently **during the day**?	1	2	3	4
32. Have you had to urinate frequently **at night**?	1	2	3	4
33. When you **felt the urge** to pass urine, did you have to hurry to get to the toilet?	1	2	3	4
34. Was it difficult for you to **get enough sleep**, because you **needed** to get up frequently at night to urinate?	1	2	3	4
35. Have you had difficulty going out of the house because you **needed** to be close to a toilet?	1	2	3	4
36. Have you had any **unintentional release** (leakage) of urine?	1	2	3	4
37. Did you have **pain** when you urinated?	1	2	3	4
38. Answer this question only if you wear an incontinence aid: Has wearing an incontinence aid been a problem for you?	1	2	3	4
39. Have your daily activities been limited by your urinary problems?	1	2	3	4
40. Have your daily activities been limited by your bowel problems?	1	2	3	4
41. Have you had any **unintentional release** (leakage) of stools?	1	2	3	4
42. Have you had blood in your stools?	1	2	3	4
43. Did you have a **bloated feeling** in your abdomen?	1	2	3	4
44. Did you have hot flushes?	1	2	3	4
45. Have you had sore or enlarged nipples or breasts?	1	2	3	4
46. Have you had swelling in your legs or ankles?	1	2	3	4

Please go to the next page

During the last 4 weeks:	Not at all	A little	Quite a bit	Very much
47. Has weight loss been a problem for you?	1	2	3	4
48. Has weight gain been a problem for you?	1	2	3	4
49. Have you felt less masculine as a result of your illness or treatment?	1	2	3	4
50. To what extent were you interested in sex?	1	2	3	4
51. To what extent were you sexually active (with or without intercourse)?	1	2	3	4

PLEASE ANSWER THE NEXT FOUR QUESTIONS ONLY IF YOU HAVE BEEN SEXUALLY ACTIVE OVER THE LAST 4 WEEKS:

52. To what extent was sex enjoyable for you?	1	2	3	4
53. Did you have difficulty getting or maintaining an erection?	1	2	3	4
54. Did you have ejaculation problems (eg dry ejaculation)?	1	2	3	4
55. Have you felt uncomfortable about being sexually intimate?	1	2	3	4

APPENDIX 5B: EORTC-QLQ-PR25 (Kiswahili Version)

SWAHILI

EORTC QLQ - PR25

Wagonjwa wakati mwingine huelezea kwamba wana dalili au matatizo yafuatayo. Tafadhali onyesha ni kwa kiwango gani umekuwa ukipata dalili au matatizo kwa wiki iliyopita. Tafadhali jibu kwa kuzungushia duara namba ambayo ni bora zaidi kwako.

Katika kipindi cha wiki moja iliyopita:	Hapana	Kidogo	Kiasi	Sana
31. Je umekuwa ukikojoa mara kwa mara wakati wa mchana?	1	2	3	4
32. Je umekuwa ukikojoa mara kwa mara usiku?	1	2	3	4
33. Je uliposikia haja ndogo, umekuwa ukilazimika kulifanya haraka kwenda msalani?	1	2	3	4
34. Je ilikuwa vigumu kwako kupata usingizi wa kutosha, kwa sababu umekuwa ukilazimika kuamka mara kwa mara usiku kwenda kukojoa?	1	2	3	4
35. Je imekuwa vigumu kutoka nje ya nyumba yako kwa sababu ulihitaji kuwa karibu na msalani?	1	2	3	4
36. Je umekua ukipata hali ya kutoka mkojo (kuvuja) bila kukusudia?	1	2	3	4
37. Je umepata maumivu wakati ulikojoa?	1	2	3	4
38. Jibu swali hili ikiwatu unavaa kifaa cha kuzuia kujikojolea: Je kuvaa kifaa cha kuzuia kujikojolea imekuwa tatizo kwako?	1	2	3	4
39. Je shughuli zako za kila siku imekua vigumu kuzifanya kwa sababu ya tatizo lako la mkojo?	1	2	3	4
40. Je shughuli zako za kila siku imekua ni vigumu kuzifanya kwa sababu ya matatizo yako ya kupitisha haja kubwa?	1	2	3	4
41. Je umekuwa na hali ya kutokwa na haja kubwa (kuvuja) bila kukusudia?	1	2	3	4
42. Je umewahi kupata choo chenye damu?	1	2	3	4
43. Je umeshawahi kuwa na hali ya kujaa kwa tumbo?	1	2	3	4
44. Je ulijisikia mwili kupata joto ghafla?	1	2	3	4
45. Je umeshawahi kuwa na maumivu au kuvimba kwa chuchu au matiti?	1	2	3	4
46. Je umeshawahi kuvimba kwenye miguu au vifundo vya miguu?	1	2	3	4

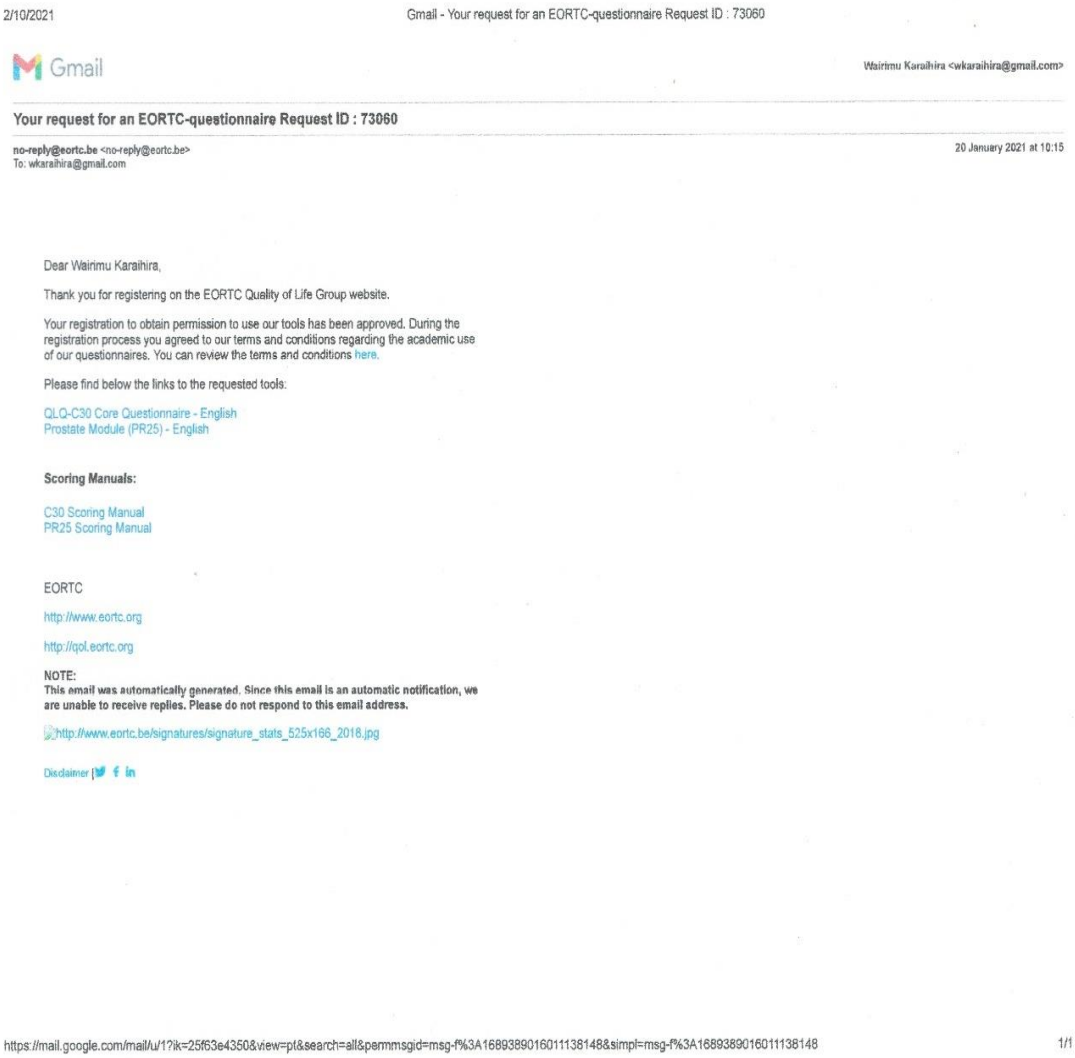
Tafadhali endelea na ukurasa unaofuata

Katika kipindi cha wiki nne zilizopita:	Hapana	Kidogo	Kiasi	Sana
47. **Je kupungua** uzito imekuwa ni tatizo kwako?	1	2	3	4
48. **Je kuongezeka** uzito imekuwa tatizo kwako?	1	2	3	4
49. Je ulijisikia si mwenyewe uliyekamilika kwa sababu ya ugonjwa wako au matibabu?	1	2	3	4
50. Je ni kwa kiwango gani ulipenda kufanya tendo la ndoa?	1	2	3	4
51. Je ni kwa kiwango gani ulifanya tendo la ndoa (kwa kuingiliana au la)?	1	2	3	4

TAFADHALI JIBU MASWALI NNE YAFUATAYO IKIWA TU ULIFANYA TENDO LA NDOA KATIKA KIPINDI CHA WIKI 4 ZILIZOPITA

52. Je ni kwa kiwango gani umekuwa ukifurahia tendo la ndoa?	1	2	3	4
53. Je ulishawahi kupata ugumu kuweza kuendelea kusimamisha mume?	1	2	3	4
54. Je umeshawahi kupata tatizo la kutoa manii? (kwa mfano, manii kutotoka wakati wa tendo la ndoa)	1	2	3	4
55. Je umekuwa ukijisikia vibaya kuwa na urafiki wa kimapenzi?	1	2	3	4

APPENDIX 6: APPROVAL FOR USE OF EORTC-QLQ-C30 AND EORTC-QLQ-PR25 TOOLS



2/10/2021 Gmail - Your request for an EORTC-questionnaire Request ID : 73060

Gmail Wairimu Karaihira <wkaraihira@gmail.com>

Your request for an EORTC-questionnaire Request ID : 73060

no-reply@eortc.be <no-reply@eortc.be> 20 January 2021 at 10:15
To: wkaraihira@gmail.com

Dear Wairimu Karaihira,

Thank you for registering on the EORTC Quality of Life Group website.

Your registration to obtain permission to use our tools has been approved. During the registration process you agreed to our terms and conditions regarding the academic use of our questionnaires. You can review the terms and conditions here.

Please find below the links to the requested tools:

QLQ-C30 Core Questionnaire - English
Prostate Module (PR25) - English

Scoring Manuals:

C30 Scoring Manual
PR25 Scoring Manual

EORTC

http://www.eortc.org

http://qol.eortc.org

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APPENDIX 7: KNH-UON ERC APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/171

17th May 2021

Dr. Wairimu Karaihira
Reg. No.U56/33451/2019
Dept. of Pharmaceutics and Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 17 MAY 2021 KNH/UoN-ERC P.O. BOX 20723 - 00202 NAIROBI

Dear Dr.Wairimu

RESEARCH PROPOSAL –MANAGEMENT AND HEALTH RELATED QUALITY OF LIFE AMONG PATIENTS WITH PROSTATE CANCER AT KENYATTA NATIONAL HOSPITAL: A DESCRIPTIVE CROSS-SECTIONAL STUDY (P85/02/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 17th May 2021 – 16th May 2022.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise
e. e that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
f. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
h. Submission of an *executive summary* report within 90 days upon completion of the study.

Protect to discover

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

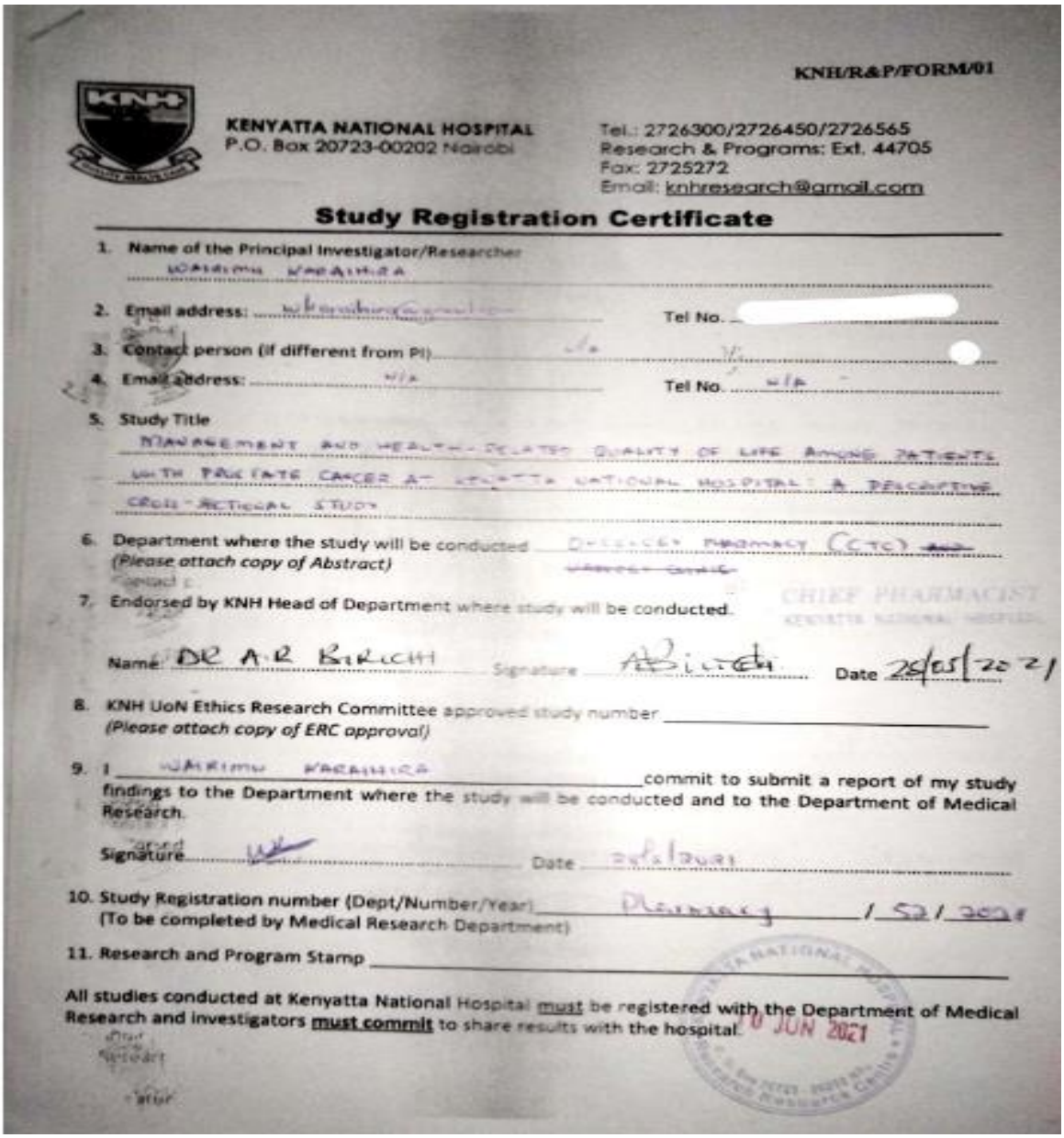
For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept, KNH
The Dean, School of Pharmacy, UoN
The Chair, Dept. of Pharmaceutics and Pharmacy Practice, UoN
Supervisors: Dr. Peter N. Karimi, Dept. of Pharmaceutics and Pharmacy Practice, UoN
Dr. Irene W. Weru, Deputy Chief Pharmacist, KNH

APPENDIX 8A: INSTITUTIONAL APPROVAL



KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   WAIRIMU KARANJA
2. Email address: [redacted] Tel No. [redacted]
3. Contact person (if different from PI) N/A
4. Email address: N/A Tel No. N/A
5. Study Title
   MANAGEMENT AND HEALTH-RELATED QUALITY OF LIFE AMONG PATIENTS WITH PANCREATIC CANCER AT KENYATTA NATIONAL HOSPITAL: A PROSPECTIVE CROSS-SECTIONAL STUDY
6. Department where the study will be conducted DIRECTOR PHARMACY (CCTC) AND ONCOLOGY CLINIC
   (Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.
   Name: DR A.R BIRICH Signature [signature] Date 28/05/2021
   CHIEF PHARMACIST KENYATTA NATIONAL HOSPITAL
8. KNH UoN Ethics Research Committee approved study number _____
   (Please attach copy of ERC approval)
9. I WAIRIMU KARANJA commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.
   Signature [signature] Date 28/5/2021
10. Study Registration number (Dept/Number/Year) Pharmacy / 521 / 2021
    (To be completed by Medical Research Department)
11. Research and Program Stamp _____

All studies conducted at Kenyatta National Hospital must be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.

10 JUN 2021

APPENDIX 8B: INSTITUTIONAL APPROVAL

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723, 00202 Nairobi

Tel.: 2726300/2726450/2726550
Fax: 2725272
Email: knhadmin@knh.or.ke

Ref.KNH/HOD/GEN-SURG/7/VOL.I

Date: 4th June 2021

Dr.Wairimu Karaihira
Department of Pharmaceutics and Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Wairimu

RE: APPROVAL TO COLLECT DATA FROM KNH GENERAL SURGERY DEPARTMENT

We acknowledge your request on the above, together with a study registration form and a KNH/UON ERC approval letter on your study titled ***"Management and health related quality of life among patients with prostate cancer at Kenyatta National Hospital."***

Approval has been granted for you to collect data from Urology unit, General Surgery Department at Kenyatta National Hospital.

By a copy of this letter, ACN in-charge Surgical Outpatient clinic No.24 is informed and requested to facilitate.

Note, we would like you to forward a copy of the study report to the undersigned after completion of the study.

Dr. Gibson Musila
HOD, GENERAL SURGERY

Cc. ACN In-charge
SOPC No.24
KNH

KABinki 18/11/2021

PLAGIARISM REPORT 18/11/2021

MANAGEMENT AND HEALTH RELATED QUALITY OF LIFE AMONG PATIENTS WITH PROSTATE CANCER AT KENYATTA NATIONAL HOSPITAL: A DESCRIPTIVE CROSS-SECTIONAL STUDY

ORIGINALITY REPORT

12%	10%	7%	3%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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3	ir.lib.uwo.ca Internet Source	1%
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