ADHERENCE TO ENDOCRINE THERAPY AND ITS DETERMINANTS IN PATIENTS WITH HORMONE RECEPTOR POSITIVE BREAST CANCER AT MOI TEACHING AND REFERRAL HOSPITAL

BY

NATHAN JOHN ANJICHI

A THESIS SUBMITTED IN PARTIAL FULFILLMENT FOR AN AWARD OF THE DEGREE OF MASTER OF MEDICINE (INTERNAL MEDICINE), MOI UNIVERSITY

© 2026

DECLARATION

Candidate's Declaration

This thesis is my original work and it has not been presented for a degree in any other University. No part of this thesis may be reproduced without the prior written permission of the author and /or Moi University.

Nathan John Anjichi, MBChB

MS/MED/4906/23

Signature:…………………………………… **Date**:…………………………….

Supervisors' Declaration

This thesis report has been submitted for examination with our approval as university Supervisors.

Dr. Evangeline Njiru, MBChB, MMED (Internal Medicine), Post-Grad Cert, Oncology

Senior Lecturer, Consultant Physician

Department of Medicine

School of Medicine

Moi University

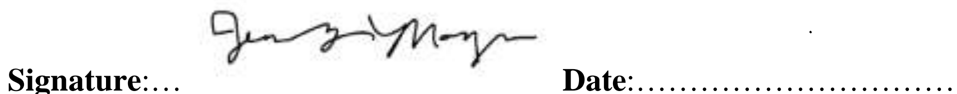
Signature: …………………………. **Date**:…………………………….

Jennifer Morgan, MD,

Visiting Oncologist

AMPATH Oncology

Moi University



Signature:… **Date**:………………………….

DEDICATION

This thesis is dedicated to my late father, Gilbert Anjichi, in profound gratitude for his wisdom, love, sacrifice, sense of humor and unwavering dedication in raising me, and for the invaluable lessons he imparted that continue to guide me to this day.

I honor the courageous patients living with hormone receptor positive breast cancer whose daily commitment to their therapy inspires hope and fuels the fight for better care.

TABLE OF CONTENTS

DECLARATION ...ii

DEDICATION ... iii

LIST OF TABLES ...vii

LIST OF FIGURES ... viii

LIST OF ABBREVIATIONS ...ix

ACKNOWLEDGEMENT ...x

ABSTRACT ...xi

CHAPTER ONE: INTRODUCTION ...1

1.1 Background ...1

1.2 Problem Statement ...4

1.3 Justification ...4

1.4 Research Questions ...5

1.5 Objectives ...6

1.5.1 Broad Objective ...6

1.5.2 Specific Objectives ...6

CHAPTER TWO: LITERATURE REVIEW ...7

2.1 Epidemiology of Breast Cancer ...7

2.1.1 The Burden of Breast Cancer ...7

2.1.2 Risk Factors ...9

2.1.3 Screening and Diagnosis ...10

2.1.4 Treatment Options ...11

2.1.5 Challenges Faced in Management ...12

2.2 Clinical Outcomes of Endocrine Therapy in Breast Cancer ...13

2.2.1 Disease-free survival ...14

2.2.2 Overall survival ...14

2.2.3 Response rates and duration of response ...14

2.2.4 Impact on recurrence, metastases and quality of life ...14

2.3 Patient Adherence to Endocrine Therapy 15
2.4 Measurement of Adherence to Endocrine Therapy 16
2.5 Determinants of Adherence 18
2.5.1 Patient related factors 18
2.5.2 Disease related factors 19
2.5.3 Therapy related factors 21
2.5.4 Healthcare system related factors 23
CHAPTER THREE: METHODOLOGY 25
3.1 Study Site and Setting 25
3.2 Study Design 25
3.3 Target Population 26
3.4 Sample Size 26
3.5 Sampling Technique and Eligibility Criteria 29
3.5.1 Sampling Technique 29
3.5.2 Eligibility Criteria 29
3.6 Study Procedure 30
3.7 Data Collection and Management 30
3.7.1 Data Collection 30
3.7.2 Data Analysis and Presentation 31
3.8 Ethical Considerations 32
3.9 Dissemination of Study Findings 33
CHAPTER FOUR: RESULTS 34
4.1 Recruitment 34
4.1.1 Socio-Demographic Characteristics of Participants 35
4.1.2 Clinical Characteristics of Participants 37
4.1.3 Health System Factors Characteristics of Participants 39

4.2 Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH 40
4.3 Determinants of Adherence Among HR+ Breast Cancer Patients at MTRH 41
4.3.1 Sociodemographic Factors as Determinants of Adherence 41
4.3.2 Clinical Factors as Determinants of Adherence 46
4.3.3 Health System Factors as Determinants of Adherence 52
CHAPTER FIVE: DISCUSSION...58
5.1 Introduction 58
5.2 Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH 58
5.3 Sociodemographic Factors as Determinants of Adherence................................60
5.4 Clinical Factors as Determinants of Adherence 63
5.5 Health System Factors as Determinants of Adherence 65
5.6 Study Strengths and Limitations 67
CHAPTER SIX..69
CONCLUSION AND RECOMMENDATIONS 69
6.1 Conclusions 69
6.1.1 Adherence to Therapy 69
6.1.2 Determinants of Adherence to Therapy...69
6.2 Recommendations 70
REFERENCES 72
APPENDIX...80
Appendix 1: STUDY DATA COLLECTION FORM 80
Appendix 2: IN-DEPTH INTERVIEW GUIDE...83
Appendix 3: Informed Consent..85
Appendix 4: Ethical Approvals 94

LIST OF TABLES

Table 1 Socio-Demographic Characteristics of Participants in the Quantitative Arm 36

Table 2 Clinical Characteristics of Participants 38

Table 3 Health System Factors Affecting Participants 39

Table 4: Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH 40

Table 5: Bivariate Analysis of Sociodemographic Factors as Determinants of Adherence 42

Table 6 Multivariate Analysis of Sociodemographic Factors as Determinants of Adherence 43

Table 7 Main themes showing Socioeconomic Factors Affecting Adherence to Treatment 45

Table 8: Bivariate Analysis of Clinical Factors as Determinants of Adherence 47

Table 9 Multivariate Analysis of Clinical Factors as Determinants of Adherence 48

Table 10: Main themes on Clinical Factors as Determinants of Adherence: Disease, Medication, and Treatment Impact 50

Table 11: Bivariate Analysis of Health System Factors as Determinants of Adherence 53

Table 12 :Multivariate Analysis of Health System Factors as Determinants of Adherence 53

Table 13: Main Themes on Health System Factors and Their Impact on Adherence . 55

LIST OF FIGURES

Figure 1: Recruitment Schema..34

Figure 2 :Distribution of age groups of the study participants 36

Figure 3: Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH..41

LIST OF ABBREVIATIONS

AET	Adjuvant Endocrine Therapy
AI	Aromatase Inhibitor
BRCA1 and 2	Breast Cancer Gene 1 and 2
ET	Endocrine Therapy
ER +	Estrogen Receptor Positive
ERP	Enterprise Resource Planning
GLOBOCAN	Global Cancer Observatory
HER-2	Human Epidermal Growth Factor Receptor 2
HR+	Hormone Receptor Positive
IHC	Immunohistochemistry staining
IREC	Institutional Research and Ethics Committee
MTRH	Moi Teaching and Referral Hospital
NHIF	National Health Insurance Fund
NIH	National Institute of Health
PR+	Progesterone Receptor Positive
SERM	Selective Estrogen Receptor Modulators

ACKNOWLEDGEMENT

I wish to express my deepest gratitude to all those who have supported and guided me throughout the course of this research and the writing of this thesis. First and foremost, I extend my profound appreciation to my supervisors, Dr. Njiru and Dr. Morgan, whose steadfast support, insightful guidance, and invaluable feedback have been instrumental from the conceptualization of this study through to its completion. Their mentorship has greatly enriched both my academic growth and research experience.

I am also deeply grateful to the dedicated team at the Breast Cancer Clinic at Moi Teaching and Referral Hospital. Your tireless commitment to patient care and your willingness to accommodate and support me during data collection were crucial to the success of this research. I thank AGC Tenwek Hospital for funding part of this work.

On a personal note, I owe immense thanks to my dearest wife, Janet, for her extraordinary patience, understanding, and unwavering support throughout this demanding journey. She has endured my long absences and moments of distraction while remaining my constant source of encouragement and strength. I am equally grateful to my dear children—Jerry, Jonathan, and Joshua—whose innocent words of wishing me luck in my studies provided moments of joy and motivation amidst the rigors of academic work.

I also wish to thank my mother, Victoria, whose consistent interest in my endeavors and steadfast belief in my potential have been a bedrock of strength. To my siblings, I am profoundly thankful for your financial support and encouragement, which eased the demands and challenges of completing this thesis.

ABSTRACT

Background: Endocrine therapy is the cornerstone of management for early-stage hormone receptor positive breast cancer with significant clinically relevant outcomes like improved disease-free and overall survival, better response rates, reduction in recurrence and distant metastases and improvement in quality of life. Adherence to endocrine therapy is the key determinant in achieving these improved outcomes. This adherence has however been reported to be sub-optimal in clinical practice globally with limited data from Africa and Moi Teaching and Referral Hospital (MTRH).

Objectives: To determine the proportion of Hormone Receptor Positive (HR+) breast cancer patients in MTRH with good adherence to endocrine therapy and to identify the determinants of adherence.

Methods: A cross-sectional, descriptive, sequential explanatory mixed-methods study was conducted at the outpatient oncology clinic of MTRH from February 2024 to February 2025. Eligible participants were adults aged 18 years or older, with documented hormone receptor positivity, Stage I–III breast cancer, on endocrine therapy for at least two months. Participants were enrolled through consecutive sampling until the target sample size of 131 was achieved. Data collection involved patient interviews, chart reviews, and prescription assessments. Quantitative adherence was assessed using the Voils DOSE non-adherence scale, with good adherence defined by a mean score of ≤1. For qualitative analysis, 11 patients participated in-depth interviews to explore determinants of adherence, and thematic analysis was employed to identify patterns and themes related to adherence to endocrine therapy.

Results: The majority of participants were female (97%), aged 40–59 years (61%), had attained secondary-level education (50.4%), and a substantial proportion (70.2%) reported having no formal employment or regular income. Overall, 72.5% of participants reported good adherence to endocrine therapy. Patients aged 50–59 years exhibited a significantly higher proportion of good adherence ($p = 0.002$), and higher educational attainment was strongly associated with good adherence. Advanced disease stage (Stage III) and use of anastrozole ($p = 0.016$) were also significantly associated with good adherence. In multivariate analysis, patients aged 50–59 years (adjusted odds ratio [aOR] = 4.21, $p = 0.040$) and those with tertiary-level education (aOR = 3.23, $p = 0.043$) were significantly more likely to demonstrate good adherence to endocrine therapy. Although travel time and transport costs were not statistically significant predictors of adherence in the quantitative analysis, qualitative findings identified these factors as substantial barriers, with participants describing the burden of long travel distances and expressing the need for more accessible treatment facilities.

Conclusion: A significant proportion of the HR+ patients living with breast cancer reported good adherence to endocrine therapy. Higher education level, older age, advanced disease stage and anastrozole use were associated with good adherence.

Recommendations: Develop targeted interventions for younger and less-educated patients to overcome barriers and improve endocrine therapy adherence.

CHAPTER ONE: INTRODUCTION

1.1 Background

Cancer has long represented a significant public health challenge in Kenya, ranking as the third leading cause of mortality after infectious and cardiovascular diseases. In 2012, approximately 37,000 new cancer cases were documented, accompanied by 28,500 cancer-related deaths (Macharia et al., 2019). Among the various malignancies, breast cancer emerges as the most frequently diagnosed cancer worldwide and remains the leading cause of cancer-related mortality among women. Furthermore, in Kenya, the incidence and mortality rates of breast cancer reflect these global trends, with breast cancer ranking highest in both incidence (16.1%) and mortality (11.5%) (Bray et al., 2024). A notable feature distinguishing the Kenyan context is the relatively younger age at which women are diagnosed with breast cancer. Specifically, the highest incidence occurs among women aged 40 to 49 years, in contrast to the median age of 62 years reported in the United States (Gakunga et al., 2019). This demographic pattern underscores the pressing need for effective management strategies tailored to a younger patient population in Kenya who tend to be hormone receptor positive.

Following diagnosis, the management of breast cancer necessitates a multidisciplinary approach to optimize patient outcomes. This comprehensive strategy encompasses surgical interventions, chemotherapy, radiotherapy, and endocrine therapy (Korde et al., 2021). Surgical procedures including lumpectomy, mastectomy, and axillary lymph node dissection are fundamental for removing malignant tissue and preventing disease spread. In addition, chemotherapy serves as a systemic treatment aimed at eradicating cancer cells throughout the body. It may be administered as neoadjuvant therapy to shrink tumors prior to surgery, as adjuvant therapy to eliminate residual

cancer cells postoperatively, or as palliative treatment to control disease progression in advanced stages. Moreover, radiotherapy is employed as a localized intervention to destroy remaining cancer cells, particularly following surgical resection, thereby reducing the risk of recurrence (Ramashia et al., 2024).

Endocrine therapy occupies a pivotal role in the management of hormone receptor-positive (HR+) breast cancer by blocking or inhibiting the proliferative effects of estrogen and progesterone (Krauss & Stickeler, 2020). The primary agents employed include selective estrogen receptor modulators (SERMs), such as tamoxifen, commonly prescribed for premenopausal women, and aromatase inhibitors (AIs), such as anastrozole, typically used in postmenopausal patients. By targeting hormone-sensitive tumors, endocrine therapy has been shown to significantly improve survival outcomes, lower recurrence rates, and enhance patients' quality of life. Notably, HR+ breast cancer accounts for approximately 75% of all breast cancer cases and is generally associated with a more favorable prognosis and responsiveness to endocrine treatments. In contrast, triple-negative breast cancer lacks hormone receptors, exhibits a more aggressive course, and presents fewer therapeutic options (Sayed et al., 2014).

Despite the well-established efficacy of endocrine therapy, adherence remains a substantial concern in clinical practice. Although the initiation of endocrine therapy is typically high, long-term adherence often declines over time. For example, while adherence in the first year may reach approximately 93%, it decreases sharply to about 57% by the fifth year, according to a registry data in Italy (Cavazza et al., 2020). Non-adherence may result from patient-related factors—including adverse side effects, financial burdens, and inadequate understanding of treatment benefits—or from prescriber-related factors such as insufficient patient counseling. This non-adherence undermines the potential benefits of therapy and highlights the need for

consistent monitoring and the implementation of targeted interventions aimed at sustaining adherence. Furthermore, while extensive global research has explored adherence to endocrine therapy, there remains a paucity of data from low-resource settings, including Kenya. This research gap provided the impetus for the present study, which seeks to evaluate adherence levels and identify determinants of non-adherence among breast cancer patients attending the oncology clinic at Moi Teaching and Referral Hospital (MTRH). Fertility concerns are a significant consideration for younger women diagnosed with hormone receptor-positive breast cancer, as endocrine therapy often requires prolonged treatment that may delay or compromise future childbearing (Lambertini et al., 2017). The desire to preserve fertility or pursue pregnancy has been shown to contribute to intentional treatment interruption or early discontinuation, thereby negatively affecting adherence rates (Collin et al., 2021)

In recent decades, significant advances in breast cancer diagnosis and treatment have led to earlier detection and improved survival rates. Consequently, the growing population of breast cancer survivors necessitates ongoing surveillance to address gaps in survivorship care and further reduce the burden of disease. In 2022, approximately 22% of cancer survivors in the United States were female breast cancer survivors, representing the largest cohort among all cancer survivors (Tonorezos et al., 2024). As breast cancer prognosis continues to improve, the optimal duration of endocrine therapy typically ranges from five to ten years, depending on individual disease characteristics. However, understanding the multifaceted challenges of adherence in diverse settings particularly in Kenya remains essential to improving outcomes for women with hormone receptor-positive breast cancer. This study,

therefore, aims to contribute valuable insights into the barriers to adherence and to inform strategies for enhancing adherence within Kenyan healthcare contexts.

1.2 Problem Statement

Endocrine therapy has become a standard of care in managing HR+ breast cancer, but in low-resource settings, including Kenya, its use has been hindered by low prescription rates and poor patient adherence to prescribed medications. This resulted in poor clinical outcomes and prevented many patients from benefiting fully from the therapy (Onwusah et al., 2023). Non-adherence translates to increased risk of breast cancer recurrence, higher mortality, more complex treatments, increased hospitalizations and greater burden on the limited resources at MTRH. To date, few studies have systematically evaluated adherence to endocrine therapy in Kenya. Several factors had limited the initiation and continued use of endocrine therapy, including side effects, perceived lack of benefits, low health literacy, high pill burdens, cognitive or physical impairments, and barriers to consistent medication access such as high drug costs or unavailability (Cavazza et al., 2020). This study aimed to assess adherence to endocrine therapy among HR+ breast cancer patients at Moi Teaching and Referral Hospital (MTRH) and identify the factors contributing to non-adherence in this context.

1.3 Justification

The justification for this study arose from the fact that Moi Teaching and Referral Hospital (MTRH) sees over 400 patients with breast cancer annually, making it a key facility for cancer treatment in the region. Despite the regular prescription of endocrine therapy for early hormone receptor-positive breast cancer patients, little was known about how well these treatments were followed. Furthermore, the factors contributing to non-adherence remained unclear. In resource-constrained settings like

Kenya, adherence to endocrine therapy has been reported as low, with few studies from similar regions addressing this issue (Onwusah et al., 2023). Socioeconomic challenges, including the high cost of medication, lack of consistent access to treatments, and low health literacy, play a significant role in restricting adherence. These factors, younger age and fertility related concerns, combined with the common barriers faced by cancer patients, highlight the urgent need for a closer look at adherence patterns in this context.

This study aimed to provide local data on patient-reported adherence to endocrine therapy, offering a clear understanding of the factors influencing adherence in Kenya. By identifying barriers such as cost, accessibility, and patient knowledge, this research could guide the development of targeted quality improvement initiatives. The goal was to improve patient outcomes at MTRH and strengthen the support provided for cancer survivorship care. By addressing the specific obstacles faced by patients in this setting, the study sought to ensure that more patients could benefit fully from endocrine therapy, ultimately leading to better clinical outcomes and long-term health for breast cancer patients.

1.4 Research Questions

i. What is the proportion of Hormone Receptor positive (HR+) breast cancer patients with good adherence to endocrine therapy in at MTRH?

ii. What are the determinants of adherence to endocrine therapy in Hormone Receptor positive (HR+) breast cancer patients at MTRH?

1.5 Objectives

1.5.1 Broad Objective

To assess the adherence to endocrine therapy and its determinants in patients with Hormone Receptor positive (HR+) breast cancer at MTRH

1.5.2 Specific Objectives

i. To determine the proportion of HR+ breast cancer patients with good adherence to endocrine therapy at MTRH

ii. To identify the determinants of adherence to endocrine therapy in HR+ breast cancer patients at MTRH

CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology of Breast Cancer

2.1.1 The Burden of Breast Cancer

Breast cancer remains a significant health concern, affecting millions of women worldwide with significant disparities in high and low middle income countries. There has been a notable increase in newly diagnosed cases in high income countries and drastic reductions in mortality rates. In 2018 alone, it was estimated that 2.1 million new breast cancer cases would be diagnosed globally, with over a quarter-million cases expected in the United States. However, in middle- and low-income countries, both incidence and mortality cases continue to increase. Over the past decade, there has been a substantial increase in the total number of breast cancer cases, indicating changing trends possibly influenced by factors such as population dynamics, screening methods, and therapies (Coughlin, 2019).

Despite an increase in new cases, deaths from breast cancer have increased only somewhat, indicating advances in therapy and higher survival rates. According to estimates, there were 268,670 new cases of breast cancer in the United States in 2019, up from 194,280 instances a decade earlier. However, from 40,610 in 2009 to 41,400 in 2019 (Coughlin, 2019), the estimated death toll has only marginally increased. Positive progress has been made in the reduction of mortality as a percentage of breast cancer incidence. In 2009, estimated deaths accounted up 21.11% of new cases; and in 2019 they accounted for 15.41%. According to this, the ratio of deaths to new cases has decreased by 27% during that ten-year period. However, breast cancer caused 684,996 deaths worldwide in 2020, with a mortality rate of 13.6 per 100,000 after adjusting for age. Although industrialised areas had the greatest incidence rates, Asia and Africa were responsible for 63% of all breast cancer fatalities in the same year

(Łukasiewicz et al., 2021). The mortality-to-incidence ratio (MIR), reflecting 5-year survival rates, was 0.30 globally for breast cancer in 2020. When considering the clinical extent of the disease, countries with developed healthcare systems reported higher survival rates, such as 89.6% for localized breast cancer and 75.4% for regional breast cancer in locations like Hong Kong, Singapore, and Turkey. Less developed countries like Costa Rica, India, the Philippines, Saudi Arabia, and Thailand had lower survival rates, 76.3% for localized breast cancer and 47.4% for regional breast cancer (Łukasiewicz et al., 2021).

Exciting patterns emerge from a closer look at the annual variations in breast cancer incidence and fatalities. Following the findings of the Women's Health Initiative (WHI) study, postmenopausal hormone therapy use was decreased in the early 2000s, which led to a decrease in the incidence of breast cancer. The decrease, however, was short-lived, and starting in 2007, incidence rates started to rise once more. When it comes to deaths, they originally went down between 2009 and 2012 but have since started to rise (Coughlin, 2019). Depending on the income level of the nation, there are considerable differences in the breast cancer survival rates.

Breast cancer incidence rates have rapidly increased in Sub-Saharan Africa, particularly in nations like Malawi, Nigeria, and the Seychelles. North Africa has the highest overall incidence, whereas East Africa has the largest increase in incidence rates between 2008 and 2012. Institutional statistics show that between 2013 and 2019 there was an increase in the incidence of breast cancer in Southern Ethiopia (Adewale Adeoye, 2023). While the average prevalence rate in the Central African Republic has been rising, incident rates have been steadily rising in Nigeria over time. Sub-Saharan Africa has seen a sharp rise in the incidence of breast cancer, particularly in countries like Malawi, Nigeria, and the Seychelles. The total incidence is highest in North

Africa, whereas the increase in incidence rates between 2008 and 2012 was greatest in East Africa. According to institutional data, the incidence of breast cancer increased in Southern Ethiopia between 2013 and 2019 (Adewale Adeoye, 2023). While incident rates have increased continuously in Nigeria over time, the average prevalence rate in the Central African Republic has been rising.

2.1.2 Risk Factors

Breast cancer risk factors involve a complex interplay of genetic, environmental, lifestyle, and reproductive influences. Genetic predisposition plays a critical role, with mutations in the BRCA1 and BRCA2 genes significantly increasing the risk of breast cancer. Family history, particularly having a first-degree relative with breast cancer, raises the risk by four to five times compared to the general population (Sayed et al., 2021). Reproductive factors, such as early menarche, late menopause, and nulliparity, are also linked to an increased risk due to prolonged exposure to estrogen and progesterone (Liu et al., 2022; Mao et al., 2023). Environmental and occupational exposures, including radiation and night-shift work, have been identified as emerging concerns for breast cancer risk (FENGA, 2016). Lifestyle factors, including obesity, physical inactivity, poor diet, and smoking, contribute significantly to the development of breast cancer (Ji et al., 2021). Protective factors, such as breastfeeding and multiple term pregnancies, have been shown to reduce the risk, suggesting the importance of considering both positive and negative lifestyle choices in risk assessment (Liu et al., 2022).

In addition to these well-known risk factors, emerging research has highlighted the need for a more nuanced understanding of breast cancer's causes, particularly in terms of environmental exposures and the timing of these exposures. Several studies suggest that sedentary behavior, chronic hyperinsulinemia, and a diet high in refined

carbohydrates, red meat, and animal fats significantly contribute to breast cancer development (Ji et al., 2021). Moreover, carcinogen exposure, including pesticides and radiation, continues to be a growing concern in both occupational and everyday environments (Roheel et al., 2023). Preventive strategies that focus on lifestyle modification, such as regular exercise, maintaining a healthy weight, and dietary changes, have been shown to reduce the risk of breast cancer. Chemoprevention strategies, including selective estrogen receptor modulators, offer additional protective benefits, but their utilization remains underexplored (García-Sancha et al., 2025). As breast cancer risk factors vary significantly by geographical region and molecular subtype, future research should focus on identifying exposure pathways, understanding the timing of these exposures, and developing targeted interventions to reduce the burden of breast cancer across diverse populations (Terry & Colditz, 2023).

2.1.3 Screening and Diagnosis

Recent literature highlights the critical role of early breast cancer screening and diagnosis in improving survival rates. Screening mammography has been shown to reduce breast cancer mortality by up to 40% in women aged 40-74 who participate regularly (Seely & Alhassan, 2018). Annual mammography, starting at age 40, is recommended to decrease mortality, as it enhances early detection and timely treatment (Destounis & Santacroce, 2018). Despite its benefits, screening remains a subject of debate due to concerns about overdiagnosis, which is estimated to occur in 0-50% of cases. In addition to mammography, other screening methods such as breast self-examination, clinical breast examination, digital breast tomosynthesis, ultrasonography, and MRI are commonly employed (Shah & Guraya, 2017). Advances in technology, including thermal imaging and computer-aided detection,

hold promise for improving early diagnosis (Milosevic et al., 2018). However, balancing the advantages of screening with the risks of overdiagnosis and unnecessary treatment remains a challenge. Despite these concerns, breast cancer screening has undeniably contributed to early detection and better survival outcomes (Ahmad, 2019).

Although early detection is vital for improving breast cancer prognosis, several barriers hinder the widespread adoption of screening programs. Lack of awareness, fear of screening procedures, limited access to healthcare facilities, financial constraints, and cultural attitudes can all obstruct the utilization of screening methods (Gakunga et al., 2019). Breast cancer diagnosis involves a comprehensive approach, including physical examinations, imaging tests, and biopsy. Imaging modalities like mammography and ultrasound are commonly used, and in cases where local tumor expansion is suspected, additional tests such as chest X-rays, CT scans, and MRIs may be employed (Mann et al., 2020). Core-needle biopsies are then used to establish the tumor's histological features and hormone receptor status, helping guide treatment decisions. Multidisciplinary collaboration is crucial for refining screening techniques and diagnostic methods, as combining expertise from various medical fields enhances the accuracy and effectiveness of early detection (Barba et al., 2021). Ultimately, while breast cancer screening remains essential for reducing mortality, it is crucial to address the barriers to its use and improve access to these life-saving services (Alsammak & Khattabi, 2023).

2.1.4 Treatment Options

Breast cancer treatment is multidisciplinary and includes a variety of techniques. Surgery plays a vital role in the treatment of breast cancer and is frequently employed in various facilities. Surgical techniques for MTRH are based on the breast mass's

features. Modified radical mastectomy (MRM) and breast-conservative treatment are common operations. Depending on the stage and the characteristics of the tumour, drugs including chemotherapy and hormone treatment may be employed. The effectiveness of treatment can be increased by using targeted therapy against tumours that express particular proteins, including HER-2. Endocrine treatment effectively treats tumours that express hormone receptors. Radiotherapy is applied after surgery or as part of breast-conservative therapy (Ramashia et al., 2024). It is also used in patients with bleeding tumors or suspected spinal metastasis (O'Neil et al., 2019). Finally, palliative and supportive treatment is ideal for stage four disease. Palliation aims to make patients comfortable and improve their quality of life. Supportive measures include psychological counseling, pain management, nutrition, antiemetics, social support, and rehabilitation. Many patients require a combination of the treatment options making the process difficult and challenging.

Endocrine therapy is a primary treatment for hormone receptor-positive breast cancer, but resistance remains a significant challenge (Nabieva & Fasching, 2021; Rugo et al., 2017). Extended endocrine therapy and ovarian suppression have shown benefits in selected patients (Glassman et al., 2017). However, endocrine therapy remains underutilized, particularly in elderly patients who may opt for primary endocrine therapy over surgery, potentially increasing the risk of treatment failure (Thomas et al., 2018). Ongoing research focuses on identifying biomarkers and developing new combination therapies to improve outcomes and overcome resistance in hormone receptor-positive breast cancer (Haque & Desai, 2019).

2.1.5 Challenges Faced in Management

Developing nations frequently struggle to offer thorough breast cancer therapy due to a lack of infrastructure and finances. To offer patients with the best care possible,

low-resource nations must have adequate diagnostic facilities, qualified people, and treatment methodologies. According to Gakunga, Kinyanjui, et al. (2019), these facilities lack specialised care such multidisciplinary departments dedicated to offering breast cancer patients quality care. In order to give the best care, many facilities could lack a surgeon, medical or radiological oncologists, and palliative team specialists. Due to a lack of standardised treatment protocols and patient follow-up, a fragmented healthcare system may cause a lack of coordination among healthcare team members, which may impact care delivery. Also, late presentation is a big challenge as most patients present with advanced disease associated with poor outcomes. The main reasons for late presentation are a lack of proper education and poor health-seeking behavior that may be influenced by cultural beliefs (Sayed et al., 2019). Stigma and social misconceptions play a role, as patients with breast cancer will not seek help due to society's negative perception of breast cancer.

2.2 Clinical Outcomes of Endocrine Therapy in Breast Cancer

In order to lower the risk of recurrence and metastasis, improve disease-free and overall survival, and maintain or improve patients' quality of life, endocrine therapy is a key treatment for hormone receptor positive breast cancer (Alnaim, 2022). Endocrine therapy comes in a variety of forms and is used to treat breast cancer. Among the most often given endocrine therapy for breast cancer are selective oestrogen receptor modulators (SERMs), including Tamoxifen and Raloxifene. They function in breast tissue as an oestrogen antagonist, preventing the development of oestrogen receptor-positive breast cancer cells. Nonsteroidal Aromatase Inhibitors (AIs) like Anastrozole and Letrozole are also used in breast cancer treatment. They suppress estrogen biosynthesis by inhibiting the enzyme aromatase, which converts

androgens to estrogens. It is commonly used as adjuvant therapy in postmenopausal women with hormone-positive breast cancer (Barroso-Sousa et al., 2016)

2.2.1 Disease-free survival

The amount of time following therapy during which there are no visible signs or symptoms of cancer is known as disease-free survival. Endocrine therapy greatly prolongs life without disease, according to studies that show this time and time again. Patients who underwent endocrine therapy for breast cancer had a 10th percentile disease-free survival rate that was 23.85 months higher than that of those who did not (Yazdani & Haghighat, 2022).

2.2.2 Overall survival

Overall survival refers to the length of time from the start of treatment until death from any cause. Endocrine therapy has been shown to improve overall survival in hormone receptor-positive breast cancer patients (Gao et al., 2021).

2.2.3 Response rates and duration of response

In women with hormone receptor-positive breast cancer, endocrine therapy can enhance symptoms or quality of life while also eliciting objective and subjective reactions. Endocrine therapy has demonstrated encouraging response rates, with a sizable percentage of patients stabilising. Endocrine therapy can help many patients maintain long-term illness control, albeit the length of response varies from person to person (Krauss & Stickeler, 2020).

2.2.4 Impact on recurrence, metastases and quality of life

In hormone receptor-positive breast cancer, endocrine therapy significantly lowers the chance of cancer recurrence and metastasis. It encourages long-term disease control and aids in stopping the spread of cancer cells. Because ET normally has lower side

effects and does not induce hair loss or severe systemic toxicity like chemotherapy, a meta-analysis found that it is generally associated with a higher quality of life than chemotherapy (Alnaim, 2022)

2.3 Patient Adherence to Endocrine Therapy

The degree to which a patient's behavior-taking endocrine therapy complies with approved advice from a healthcare professional is known as adherence. A significant clinical problem that results in unfavourable and subpar outcomes is poor adherence to ET. It is crucial that ET is recommended to all patients without contraindications in order to get the greatest benefits from it, and that patients follow the approved ET regimen. Regarding patients' compliance with prescription ET, studies have shown conflicting findings. Only 50% of patients in high-income countries complete a five-year course of endocrine therapy, despite adjuvant trials showing strong adherence rates (Chlebowski et al., 2014). It's interesting that in adjuvant and therapeutic practise, adherence to endocrine therapy for primary breast cancer prevention is similar (Chlebowski et al., 2014). Endocrine therapy adherence is influenced by patient, societal, economic, and drug-related factors, much like with all other medications. Poor medication adherence was caused by a number of factors, including side effects, younger age, fertility concerns, ineffective patient-physician treatments, prescription costs, and a lack of social support. However, in Sub-Saharan Africa, a lack of social support and inadequate patient education regarding the availability and benefits of the medication are the key variables that adversely affect overall medication adherence (Macquart de Terline et al., 2019). Endocrine therapy is less expensive and has less side effects than other treatment techniques (Mohamed & Elamin, 2020a). The adherence to endocrine therapy in Khartoum Oncology Hospital revealed an adherence rate of 93% for both tamoxifen and aromatase inhibitors,

supporting the aforementioned findings. As a result, there was a link between taking medications as prescribed and living a disease-free life (Mohamed & Elamin, 2020).

The Ethiopian healthcare system chose to focus heavily on patient education in order to increase survival and encourage adherence. The healthcare professionals informed patients about breast cancer, screening procedures, treatment options, the advantages of endocrine therapy, and potential side effects. The average adherence rate increased from 80% to 93%. Additionally, patients who had outstanding therapy provider contact were 4.6 times more likely than those who did not to stick to their drug regimens (Wako et al., 2021).

2.4 Measurement of Adherence to Endocrine Therapy

Recent literature indicates that adherence to adjuvant endocrine therapy (AET) in breast cancer patients remains suboptimal. Studies from 2018 onwards report adherence rates ranging from 50% to 85% for tamoxifen and 31% to 73% for aromatase inhibitors over a five-year course (Montagna et al., 2021). Non-adherence is associated with lower survival rates and higher recurrence risk. Factors contributing to poor adherence include side effects, lack of shared decision-making, and socioeconomic issues (Sawesi et al., 2014). Various methods are used to assess adherence, with indirect methods like prescription refills and questionnaires being more common than direct methods such as blood tests (Montagna et al., 2021). Improving adherence requires multimodal interventions integrated into healthcare pathways, focusing on personalized approaches and better identification of at-risk patients. Nurses play a crucial role in promoting adherence through patient education and addressing underlying causes of non-adherence (Miaskowski et al., 2008).

For measuring ET adherence in breast cancer, there is no "gold-standard". Studies evaluating drug adherence have used a variety of methods (Jelínek et al., 2021). The objective measurements consist of serum biomarkers, electronic monitoring, prescription database, and pill count. Interviews, surveys, and questionnaires are examples of self-report measurements. Refill times can be substituted in electronic medical records by using the prescription database. A measurement such as the proportion of days covered or the medication possession ratio is calculated and used as a proxy for medication adherence over the same period as the quantity of medications the patient is in possession of based on refills over time (Khan et al., 2021). In our setting, where there are manual health records, this strategy is not practical. As a result, most studies in low- and middle-income countries have utilised various questionnaires such as Voils DOSE non-adherence questionnaire (Genberg et al., 2021);(Mercer et al., 2019), the Morisky Adherence Assessment tools (e.g. MAQ, MMAS-4, MMAS-8) (Fetensa et al., 2019)and the Medication Adherence Rating Scale-5 (MARS-5) tool(Ling et al., 2020).

In two ongoing clinical trials for cardiovascular disease and HIV treatment adherence monitoring in Western Kenya (Genberg et al., 2021; Mercer et al., 2019), the Voils DOSE non-adherence questionnaire (Voils et al., 2019) was used. It has also been used to assess adherence to endocrine therapy for breast cancer in Europe (Smith et al., 2023). Two components of the questionnaire are used to evaluate the level of adherence and the causes of non-adherence among patients who report non-adherence. The first section of the questionnaire consists of three questions that represent the non-use of medications during the previous seven days. Each item receives a score between 1 and 5, with higher scores indicating worse adherence. The three questions are then combined to get a mean score, which can range from 3 to

15(Voils et al., 2019). Only patients who report non-adherence are given the second portion of the questionnaire, which is used to identify the causes of non-adherence from a list of common causes. There is also room to add or remove potential causes from the original list as may be necessary for a given situation. There is a validated Kiswahili version of this questionnaire. The two sections have been used successfully in the past among patients in this proposed study setting (Genberg et al., 2021; Mercer et al., 2019). Qualitative methods are increasingly employed to complement these approaches by exploring patient experiences, perceptions, and contextual factors that are not adequately captured through quantitative measures alone.

2.5 Determinants of Adherence

2.5.1 Patient related factors

Patient demographics, psychological factors, and social support significantly influence medication adherence in breast cancer treatment. Factors such as age, occupation, literacy levels, and marital status play key roles in determining a patient's ability to follow their prescribed therapy. Studies indicate that younger patients often demonstrate better adherence due to better access to technology, stronger health beliefs, and more proactive health-seeking behaviors (Paranjpe et al., 2019). On the other hand, individuals residing in rural areas often face challenges accessing medications, leading to lower adherence rates. Patients with demanding jobs also struggle to maintain their regimen, as work-related stress can distract them from prioritizing treatment. Marital status is also a crucial factor, as married patients or those in stable relationships tend to have better adherence due to increased family involvement. Family members support the patient by accompanying them to clinic visits and reminding them to take medications, significantly enhancing adherence (Yussof et al., 2022). Additionally, low literacy levels can hinder understanding of

medication instructions, adverse effects, and the importance of consistent treatment. Psychological factors such as depression and anxiety can also negatively impact adherence, with patients becoming overwhelmed by the disease and neglecting their treatment (Wako et al., 2021).

In addition to personal and psychological factors, medication adherence is influenced by drug-related, socioeconomic, and healthcare system factors. Side effects and allergies to medications can hinder adherence, as patients may stop treatment to avoid these symptoms (Haji-Hersi et al., 2022). Socioeconomic factors, including the ability to afford medications, are also critical. High treatment costs can prevent patients from acquiring their prescribed drugs, leading to interrupted medication regimens (Haji-Hersi et al., 2022; Ingwu et al., 2019). Furthermore, the quality of the patient-provider relationship and the timing of clinic visits play a vital role in adherence. Strong, supportive communication between patients and healthcare providers can motivate patients to adhere to their treatment plans. Interestingly, prior adjuvant chemotherapy has been associated with better adherence to adjuvant endocrine therapy, suggesting that past treatment experiences may influence future adherence behaviors (Davies & Voutsadakis, 2022). Interventions aimed at improving adherence should focus on enhancing self-efficacy, addressing side effects, and providing psychological support (Toivonen et al., 2020; Yang et al., 2023). Additionally, exercise programs have been shown to improve adherence, particularly in patients with higher baseline muscle strength, highlighting the potential benefits of a holistic approach to improving medication compliance (Lund et al., 2019).

2.5.2 Disease related factors

Disease-related factors significantly influence adherence to adjuvant endocrine therapy (AET) in breast cancer patients. One of the most prominent factors is the side

effects associated with AET, which can severely impact a patient's quality of life. Studies have consistently found that these side effects are closely linked to non-adherence, especially when they cause discomfort or interfere with daily activities (Brett et al., 2018; Yang et al., 2023; Toivonen et al., 2020). The severity and burden of side effects often lead to intentional non-adherence, as patients may choose to stop taking their medications to avoid worsening symptoms (Brett et al., 2018). Patients' beliefs about the necessity of long-term therapy also influence adherence. When patients perceive the therapy as unnecessary or ineffective, their commitment to following the treatment plan diminishes (Brett et al., 2018; Yang et al., 2023). Additionally, self-efficacy and a positive decisional balance are strongly associated with better adherence, as patients who feel confident in their ability to manage their therapy are more likely to continue it (Toivonen et al., 2020; Toivonen et al., 2021). Interestingly, prior adjuvant chemotherapy has been linked to better adherence to AET, as patients who have experienced the rigors of chemotherapy may feel more motivated to complete their treatment regimen (Voutsadakis & Davies, 2022).

Beyond the direct effects of treatment, patients’ overall health status and comorbidities significantly impact their ability to adhere to AET. Cancer treatments, such as surgery and chemotherapy, often leave patients with diminished functionality, making it harder for them to perform daily tasks or manage their health independently. This lack of independence can decrease adherence, as patients with poor performance status may struggle to maintain a consistent medication regimen (Paranjpe et al., 2019). Cognitive deficiencies, which are sometimes associated with poor performance status, can also hinder patients’ ability to follow their treatment plan effectively. Moreover, patients with comorbid conditions, such as hypertension, diabetes, or neurological impairments, face additional challenges in adhering to AET.

The high pill burden and potential side effects from multiple medications can be overwhelming, leading to a higher likelihood of non-adherence (Yussof et al., 2022). Hospitalizations, which are sometimes required due to the progression of cancer or complications from treatment, can also disrupt adherence. These interruptions to treatment can negatively impact a patient's commitment to their medication regimen, necessitating modifications to the treatment plan or additional support to maintain continuity in therapy. Understanding these disease-related factors is essential for developing tailored interventions that can improve adherence and, ultimately, breast cancer outcomes (Haji-Hersi et al., 2021; Montagna et al., 2021).

2.5.3 Therapy related factors

Therapy-related factors significantly influence adherence to endocrine therapy in breast cancer patients. One of the most significant barriers is the burden of side effects, which can be severe enough to lead to non-adherence. Side effects such as nausea, hair loss, and fatigue are common and can interfere with daily life, diminishing the patient's quality of life (Sawesi et al., 2014; Brett et al., 2018). The duration of treatment also plays a role, as long-term therapy can interfere with patients' lifestyles, causing frustration and leading to decreased adherence (Sawesi et al., 2014). The type of medication prescribed, whether tamoxifen or aromatase inhibitors, can affect adherence rates. Tamoxifen is teratogenic and deters young women of reproductive age from taking the medication. These medications come with varying side effects and levels of patient tolerance, influencing their decision to continue treatment (Sawesi et al., 2014; Verma et al., 2011). Drug allergies and adverse events are also significant predictors of non-adherence, as patients may stop taking the medication to avoid discomfort (Haji-Hersi et al., 2021). Managing these side effects through patient education, support, and control can significantly improve

adherence (Brett et al., 2018). Furthermore, disease severity and the presence of advanced-stage cancer increase the likelihood of treatment discontinuity, especially when patients experience multiple hospitalizations.

Various therapy-related factors, such as high pill burden and the severity of side effects, greatly impact adherence. A complex regimen with a high pill load or a combination of medications is often overwhelming for patients, leading to non-adherence (Yussof et al., 2022). Common side effects, ranging from minor issues like mucositis and nausea to severe complications like febrile neutropenia and deep venous thrombosis, exacerbate this challenge, increasing the likelihood of discontinuation (Yussof et al., 2022). Patients undergoing concurrent chemotherapy are particularly affected by the intensity of side effects, which further complicate adherence to endocrine therapy. Additionally, financial constraints, such as the high cost of prescriptions and limited insurance coverage, can result in treatment interruptions. In Kenya, the National Health Insurance Fund (NHIF) provides coverage for many patients, but the amount is restricted based on the services rendered and premiums paid, which may lead to disruptions in care (Yang et al., 2023). There was a transition to Social Health Authority (SHA) on 1st October 2024 and this offers new possibilities for cancer treatment coverage (*Https://Www.Health.Go.Ke/Kenya-Officially-Launch-Social-Health-Authority-October-1-2024*, n.d.). Prolonged treatment with chemotherapy or surgery often results in patients becoming less compliant due to the extended duration and the financial burden (Yang et al., 2023). Thus, refining prescription strategies and improving insurance coverage are necessary to enhance adherence and ensure continuity in treatment (Haji-Hersi et al., 2021; Montagna et al., 2021).

2.5.4 Healthcare system related factors

Healthcare system-related factors are crucial in determining adherence to breast cancer therapy, particularly in African countries, where resources and access to care can be limited. Several barriers affect adherence, including difficulties in accessing healthcare services, diagnostic errors, poor management, and high treatment costs (Gbenonsi et al., 2021). These challenges are compounded by inadequate patient-provider communication, which leads to misunderstandings about treatment and the management of side effects (Brett et al., 2018). Follow-up care provided by general practitioners, rather than oncologists, has been associated with lower adherence, as general practitioners may lack the specialized knowledge required for managing complex cancer care (Murphy et al., 2012). Healthcare system interventions that can improve adherence include providing timely information on side effects and medication management strategies, enhancing patient-centered communication, and implementing innovative care pathways, such as primary care nurse cancer reviews (Brett et al., 2018; Yang et al., 2023). Addressing financial barriers through universal health coverage policies and improving healthcare workers' clinical competencies are also essential for ensuring timely diagnosis and appropriate care, particularly in sub-Saharan Africa (Gbenonsi et al., 2021). These factors emphasize the need for healthcare reforms and targeted interventions to improve adherence to therapy and enhance breast cancer outcomes.

The components of the healthcare system must work together to guarantee high-quality patient care, as disruptions in any component can negatively impact service delivery and patient adherence. A strong patient-provider relationship is critical for improving adherence, as patients who feel supported by their healthcare providers are more likely to follow their prescribed treatment plans. Healthcare providers who view

the patient holistically, offering emotional support and clear guidance, foster better adherence (Wako et al., 2021). Furthermore, patients who receive continuous, personalized care and regular monitoring are more likely to stay committed to their treatment regimens. This ongoing relationship with healthcare providers builds trust and encourages patients to adhere to their prescribed therapy. Adequate insurance coverage also plays a pivotal role in ensuring adherence. Without proper coverage, patients may face difficulties accessing prescriptions or follow-up appointments, leading to treatment interruptions that can further decrease adherence and compromise outcomes. Limited access to breast cancer centers and long distances to treatment facilities exacerbate these issues. While MTRH and Kenyatta National Hospital offer the best breast cancer treatment in Kenya, many patients struggle with delays and extended wait times due to the high disease burden and distance to these centers (Petricca et al., 2023). These logistical challenges underscore the need for improved access to care and a more streamlined healthcare system to enhance patient adherence and outcomes.

CHAPTER THREE: METHODOLOGY

3.1 Study Site and Setting

This study was conducted in the outpatient oncology clinic at Moi Teaching and Referral Hospital (MTRH), which is the leading referral hospital in western Kenya. Located in Eldoret town, approximately 320km northwest of Nairobi, MTRH serves as a critical healthcare hub for the region. It also functions as a training institution for Moi University, supporting the School of Medicine, Nursing, Dentistry, and Public Health. The hospital has a substantial catchment population of approximately 21 million people, making it a key player in the healthcare system of western Kenya. The breast cancer clinic, held every Thursday, catered to an average of 400 patients annually. The clinic was staffed by a team of experienced professionals, including consultant oncologists, internal medicine registrars, and medical and clinical officers, ensuring comprehensive care for the patients.

3.2 Study Design

This was a cross-sectional descriptive sequential explanatory mixed methods study design. The design combined both quantitative and qualitative approaches, allowing for a comprehensive exploration of the research topic. The quantitative phase, conducted first, involved collecting numerical data to assess patient-reported adherence to endocrine therapy among breast cancer patients. This phase provided clear, objective insights into adherence patterns and allowed for the identification of key factors influencing patient behavior. Following this, the qualitative phase was implemented, involving in-depth interviews to explore in more depth the personal experiences and perceptions of patients regarding their adherence to treatment. This phase helped to contextualize the quantitative findings by revealing the underlying

reasons for non-adherence, such as psychological, social, and healthcare system-related barriers. The mixed methods design was particularly effective for this study as it not only quantified adherence rates but also provided a richer, more detailed understanding of the factors influencing adherence, facilitating the development of targeted interventions to improve patient outcomes.

3.3 Target Population

The target population for this study was outpatients with Stage I-III Hormone Receptor Positive (HR+) breast cancer receiving care at the oncology clinic in Moi Teaching and Referral Hospital (MTRH). These patients were selected as they are typically prescribed adjuvant endocrine therapy as part of their treatment regimen. By focusing on this group, the study aimed to assess adherence to endocrine therapy and identify the factors influencing patient compliance. Patients in this category are crucial to understanding the effectiveness of treatment and the challenges they face in following prescribed regimens. The inclusion of patients at various stages of breast cancer (Stage I-III) provided a comprehensive perspective on adherence patterns across different stages of treatment, ensuring that the findings were relevant to a broad population of HR+ breast cancer patients. This specific group was chosen to yield insights that are applicable to other similar healthcare settings. Stage IV patients were excluded because their management is primarily palliative, and adherence patterns differ from those in curative treatment settings.

3.4 Sample Size

To determine the proportion of good adherence to endocrine therapy among Stage I-III HR+ breast cancer patients at MTRH, we used Fisher's formula for sample size calculation. Since the proportion of good adherence is unknown in our local setting, we assume a 50% adherence rate, based on comparable studies that have reported

adherence rates ranging from 25% to 80% (Getachew et al., 2022; Reibold et al., 2021; Wako Z et al., 2019). The sample size formula is as follows:

$$n = \frac{(Z\alpha/2)^2 x\ P\ (1-P)}{d^2}$$

Where:

N is the desired sample size

$Z\alpha/2$ is the standardized score corresponding to a two-sided 95% confidence interval and I equivalent to 1.96

P is the estimated proportion and corresponds to 0.5 (50%)

d is the margin of error (precision) and corresponds to 0.05 (5%)

Substituting in the above equation gives:

$$n = \frac{(1.96)^2 x\ 0.5\ (1-0.5)}{0.05^2} = 384$$

A suitable adjustment was performed to the final sample size because the Stage I-III HR+ breast cancer population at MTRH is small

For the second objective, using multivariate logistic regression to identify clinical and patient demographic factors associated with good adherence to endocrine therapy was not easy. First, using the rule of thumb (Bujang et al., 2018) n=100+Xin = 100 + Xin=100+Xi, where 100 was the fixed sample size predetermined to avoid overestimating the odds ratio(Concato et al., 1995; Peduzzi et al., 1995) XXX represented the events per variable and was minimally placed at 10, as suggested by Concato et al. (1995) and (Concato et al., 1995; Peduzzi et al., 1995) iii referred to the number of independent covariates. Given the 10 independent variables we aimed to collect using our questionnaire, and applying the formula, a sample size of 200 (i.e., 100+10×10100 + 10 \times 10100+10×10) was deemed sufficient to estimate significant associations.

In an ideal world, the 384 samples would have been the best choice; however, we aimed to collect data from active patients seeking care services at MTRH. It had been established that roughly 400-450 breast cancer patients were seen annually at the hospital, with 40% of them being Stage IV and 25% having HR- (Toroitich et al., unpublished 2023). Each month, between 25-40 new patients qualified for endocrine therapy, which resulted in a finite population of approximately 150-240 patients over a 4–6-month period. This smaller, more focused population influenced the sample size calculation and sampling strategy for the study.

Where:

N is the adjusted sample size

n is the originally calculated sample size corresponding to 200

F is the finite population corresponding to 240(maximum over a 6-month period)

Substituting the above equation gives:

$$N = \frac{F\,x\,n}{n+F-1} = \frac{240\,x\,200}{200+240-1} = 109$$

An adjustment for non-response at 20%. 109*1.2 = 131

The target sample size for the study was therefore set at 131 participants. Given the study's time limitations and the relatively small population, we proposed using a consecutive sampling approach. It is well known that a small sample size can still be efficient in detecting large effect sizes. With a sample size of 100+ participants, factors that are strongly associated with adherence to endocrine therapy would be identified (Bujang et al., 2018). We would also report the power to detect significant associations in our final analysis. To account for potential biases from the small sample size, bootstrapped confidence intervals, which are free from such biases,

would be used to detect significant factors and we would triangulate the quantitative findings with qualitative interview findings. If the confidence interval does not cover 1, the factor would be considered significant.

3.5 Sampling Technique and Eligibility Criteria

3.5.1 Sampling Technique

Patients who met the study's eligibility criteria were approached for consent using a consecutive sampling approach from February 2024 to February 2025. This approach involved recruiting all eligible patients who visited the oncology clinic during this time, ensuring that no patient was excluded. Consecutive sampling allowed for the collection of data from a real-time cohort of patients, providing an accurate reflection of adherence patterns within the population. The process continued until the target sample size of 131 participants was achieved. This method proved efficient, given the finite number of eligible patients, and ensured adequate representation within the study's timeframe.

3.5.2 Eligibility Criteria

Inclusion Criteria

- Patients 18 years or older
- Documentation of HR Positivity (Either ER+ or PR+) regardless of HER-2 status
- Stage I-III breast cancer
- Patients on endocrine therapy for at least two months
- Having completed curative treatment as indicated (surgery with or without chemotherapy)
- Able and willing to provide informed consent

Exclusion Criteria

- Patients actively receiving chemotherapy
- Recurrent or newly metastatic breast cancer

3.6 Study Procedure

The electronic medical records were screened for breast cancer clinic attendees during their routine scheduled visits to identify patients who met the eligibility criteria. The eligible patients were approached by the Principal Investigator or a trained research assistant and informed about the study. Once informed, they were taken to a private room where written informed consent procedures were administered. This process ensured that patients fully understood the nature of the study, their participation requirements, and their rights before consenting. The research team adhered to ethical guidelines, ensuring patient privacy and confidentiality throughout the procedure.

3.7 Data Collection and Management

3.7.1 Data Collection

With the aid of a pre-designed structured data collection tool (Appendix 1), pertinent socio-demographic, clinical, and medical history data were gathered, as well as information from patient interviews, reviews of their medical records, and prescriptions written during the most recent clinic visit. Initially, a patient interview was conducted to collect demographic information (birth date, gender, educational attainment, income, and insurance status) and medical history (date of breast cancer diagnosis, histologic subtype, staging, immunohistochemistry staining, menopausal status, performance status, hospitalizations, and comorbidity indices). The clinician's prescription provided additional details on the medications prescribed at the latest clinic visit. To assess adherence to endocrine therapy for specific objective 1, the

Voils DOSE non-adherence survey was administered. Participants who reported not following their endocrine therapy regimen were asked why they had not adhered, in line with specific objective 2.

Participants exhibiting very high non-adherence (mean score ≥ 4) and good adherence (mean score ≤ 1) on the Voils DOSE were prioritized for in-depth interviews, aimed at identifying factors influencing adherence. 11 patients were selected to participate in these interviews, which were conducted at a later stage with transport facilitation, following an explanatory sequential design. A trained research assistant, skilled in conducting in-depth interviews, asked open-ended, follow-up, and closing questions, and the interview was audio recorded. Additionally, three patients with Stage I-III HR+ breast cancer who were unable to participate in the trial helped pilot test the data collection tools. For patients indicating non-adherence, counseling was provided, along with a reminder to follow up with their healthcare provider for a more thorough assessment.

3.7.2 Data Analysis and Presentation

The collected data was de-identified and entered into a password-protected REDCAP database, accessible only to approved research personnel. The researcher prepared the data for analysis by a licensed biostatistician, ensuring it was cleaned and properly exported for further analysis. Descriptive statistics were used for categorical variables, reporting frequencies and percentages, while continuous variables were summarized using means and medians, along with the relevant standard deviations and interquartile ranges.

For specific objective 1, a cut-off mean score of 1 on the Voils DOSE Scale was used to calculate the proportion (and corresponding 95% confidence interval) of adherence

to endocrine medication. A mean score of 1 denoted good adherence, while a score above 1 indicated poor adherence. For specific objective 2, the frequency of determinants influencing adherence was reported using descriptive statistics, and logistic regression was applied to explore the associations between various factors and adherence.

The qualitative data were transcribed and analyzed using thematic content analysis with the help of Nvivo software. Themes and patterns in adherence to endocrine therapy were identified and categorized. The qualitative and quantitative findings were compared to identify areas of convergence or divergence, offering a comprehensive understanding of the factors affecting adherence. Data was coded under relevant themes, and as new patterns emerged during analysis, they were incorporated into existing or new themes. The final write-up included summaries, interpretations, and textual excerpts to support the analysis.

3.8 Ethical Considerations

Written informed consent was obtained from all eligible study participants. Before participation, each participant was provided with a detailed informed consent document that clearly outlined the study's purpose, procedures, potential risks, benefits, and the voluntary nature of participation. Emphasis was placed on ensuring participants understood their right to withdraw at any time without consequences. The study procedures were streamlined to minimize the duration of hospital visits while maintaining the accuracy and comprehensiveness of data collection. For participants indicating non-adherence to their treatment regimen, counseling was provided, along with a reminder to schedule a follow-up visit with both the clinician and counselor for a more thorough assessment. Ethical approval for the study was sought from the Moi Teaching and Referral Hospital/Moi University Institutional Research and Ethics

Committee (IREC) and from National Commission for Science, Technology and Innovation (NACOSTI). Permission to conduct the study was also obtained from the MTRH Chief Executive Officer and from the Duke University for the use of Voils DOSE tool. All study data were kept confidential, stored in a password-protected database, and access was limited to authorized research personnel only. No incentives were used to recruit participants.

3.9 Dissemination of Study Findings

The findings of this study will be disseminated through multiple channels to ensure wide accessibility and impact. A presentation of the results will be made at the College of Health Sciences, Moi University, to inform faculty, students, and healthcare professionals about the study’s outcomes. Additionally, an abstract will be submitted for consideration at the Kenya Society of Hematology and Oncology Conference, as well as at the National Cancer Summit, where key stakeholders in cancer care and policy will have the opportunity to engage with the research. A manuscript summarizing the study's findings will be developed for publication in a peer-reviewed journal to ensure that the results contribute to the broader scientific community. These dissemination efforts aim to raise awareness about the barriers to adherence to endocrine therapy and support future initiatives for improving breast cancer care in Kenya.

CHAPTER FOUR: RESULTS

4.1 Recruitment

Chapter four presents the results of the study on adherence to endocrine therapy and its determinants among hormone receptor-positive (HR+) breast cancer patients at Moi Teaching and Referral Hospital (MTRH). This chapter provides a detailed analysis of the data collected from 131 participants in the quantitative arm and 11 participants in the qualitative arm. The findings are organized according to the study objectives, focusing on the proportion of patients adhering to endocrine therapy and the factors influencing their adherence. A total of 227 participants with breast cancer were screened at the breast cancer clinic. Ninety-two participants did not meet the inclusion criteria and were excluded. 57 participants had metastatic or recurrent disease, 21 had ongoing concomitant chemotherapy and 14 had hormone receptor negative status. Four participants declined to participate in the study.

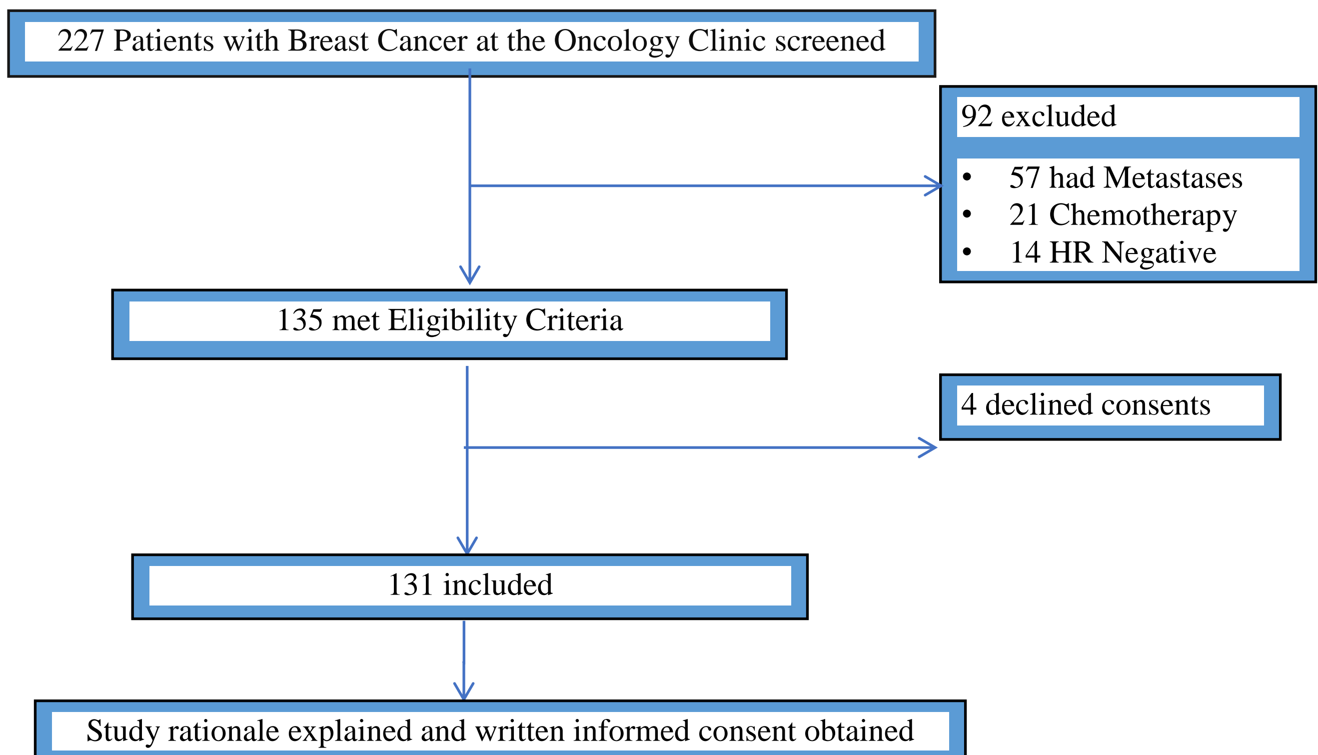


Figure 1: Recruitment Schema

4.1.1 Socio-Demographic Characteristics of Participants

The demographic characteristics of the participants in the quantitative arm were as follows. In terms of age, the majority of participants were aged between 40 and 59 years, with 40 participants (30.5%) in both the 40-49 and 50-59 age groups. The next largest group was the 30-39 years category, with 20 participants (15.3%), followed by the 60-69 years group, which included 16 participants (12.2%). A smaller proportion of participants were in the 70-79 years group, with 9 participants (6.9%), while only 6 participants (4.6%) were aged below 30 years. Regarding gender, there was a significant predominance of females, with 127 participants (96.9%) female and only 4 participants (3.1%) male. In terms of education, most participants had completed secondary education (66 participants, 50.4%), followed by tertiary education (45 participants, 34.4%), which included college and university graduates. Only 20 participants (15.3%) reported completing primary education.

The socio-economic data showed that a large proportion of participants had no job or income, with 92 participants (70.2%) falling into this category. The remaining participants had varying income levels, with 21 participants (16.0%) earning above 5000 Ksh, 10 participants (7.6%) earning between 1000 and 5000 Ksh, and 8 participants (6.1%) earning below 1000 Ksh. Regarding health insurance, the vast majority had NHIF coverage, with 119 participants (90.8%) reporting this, while 6 participants (4.6%) had private insurance, and another 6 participants (4.6%) had no health insurance. In terms of marital status, 92 participants (70.2%) were married, while 23 participants (17.6%) were single. The remaining participants had private insurance (14 participants, 10.7%) or other types of coverage (2 participants, 1.5%).

Table 1: Socio-Demographic Characteristics of Participants in the Quantitative Arm

Variable	Categories	Frequency (n)	Percentage (%)
Age Group	Below 30 Years	6	4.6
	30 to 39 Years	20	15.3
	40 to 49 Years	40	30.5
	50 to 59 Years	40	30.5
	60 to 69 Years	16	12.2
	70 to 79 Years	9	6.9
Gender	Female	127	96.9
	Male	4	3.1
Highest Education Level	Primary	20	15.3
	Secondary	66	50.4
	Tertiary (College/University)	45	34.4
Monthly Income (Ksh)	No Job/Income	92	70.2
	Below 1000	8	6.1
	1000 to 5000	10	7.6
	Above 5000	21	16.0
Active Health Insurance	No Insurance	6	4.6
	NHIF	119	90.8
	Private Insurance	6	4.6
Marital Status	Single	23	17.6
	Married	92	70.2
	Separated	14	10.7
	Other	2	1.5
Occupation	Employed	20	15.3
	Self Employed/Business	43	32.8
	Unemployed	68	51.9

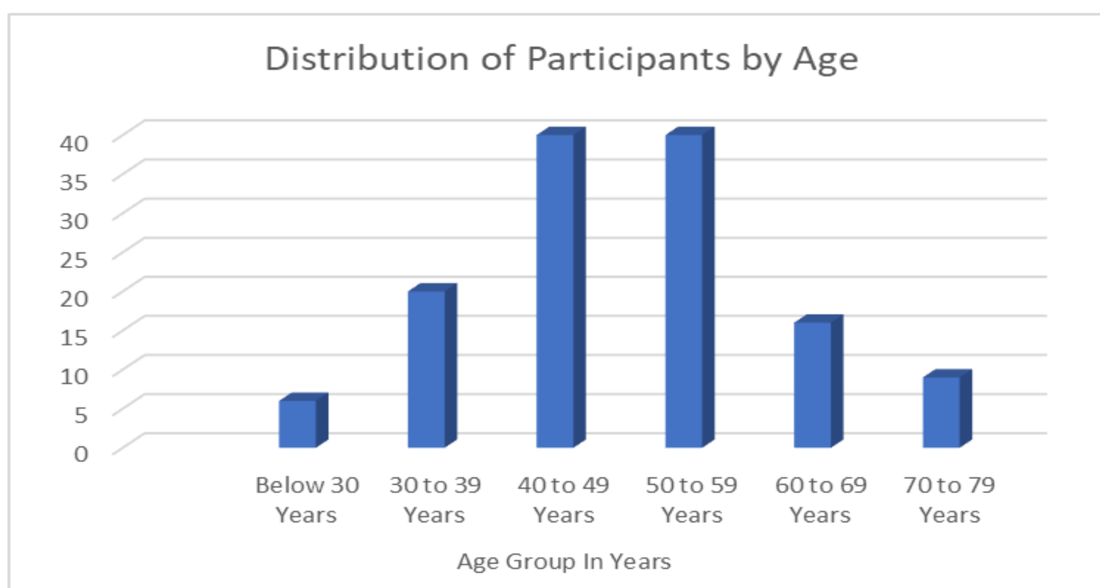


Figure 2: Distribution of age groups of the study participants

4.1.2 Clinical Characteristics of Participants

The clinical characteristics of the participants in the quantitative arm were reported as follows. Regarding the years with breast cancer, the majority of participants had been diagnosed for less than 5 years, with 86 participants (65.6%) falling into this category. The remaining participants were diagnosed between 5 to 9 years (33 participants, 25.2%) and more than 10 years (12 participants, 9.2%). For the stage at diagnosis, most participants were diagnosed at Stage III (70 participants, 53.4%), followed by Stage II (55 participants, 42.0%). A small proportion were diagnosed at Stage I (4 participants, 3.1%) and Stage 0 (2 participants, 1.5%).

Concerning the current stage at time of recruitment, most participants were in Stage III (75 participants, 57.3%) or Stage II (44 participants, 33.6%). Fewer participants were in Stage 0 (6 participants, 4.6%) and Stage I (6 participants, 4.6%). In terms of family history of breast cancer, most participants (101, 77.1%) did not have a family history, while 30 participants (22.9%) had a family history of breast cancer. Regarding menopausal status, 77 participants (58.8%) were menopausal, and 54 participants (41.2%) were not. Performance status indicated that 84 participants (64.1%) had normal activity (PS 0), while 45 participants (34.4%) had some symptoms but were still ambulatory (PS 1), and 2 participants (1.5%) had less than 50% performance (PS 2). Regarding hospitalisation in the last year, 109 participants (83.2%) had not been hospitalised, while 22 participants (16.8%) had been. Regarding comorbidities, only 7 participants (5.3%) had a history of heart disease, 30 participants (22.9%) had hypertension, and 8 participants (6.1%) had diabetes. Finally, regarding endocrine therapy medication, 68 participants (51.9%) were prescribed Tamoxifen, 51 participants (38.9%) were prescribed Anastrozole, and 10

participants (7.6%) were prescribed Letrozole and 37 participants (28.2%) reported running out of medication while awaiting their next clinic visit.

Table 2: Clinical Characteristics of Participants

Variable	**Categories**	**Frequency (n)**	**Percentage (%)**
Years with Breast Cancer	Below 5 Years	86	65.6
	5 to 9 Years	33	25.2
	More than 10 Years	12	9.2
Stage at Diagnosis	Stage 0	2	1.5
	Stage I	4	3.1
	Stage II	55	42.0
	Stage III	70	53.4
Current Stage	Stage 0	6	4.6
	Stage I	6	4.6
	Stage II	44	33.6
	Stage III	75	57.3
Family History of Breast Cancer	Yes	30	22.9
	No	101	77.1
Menopausal Status	Yes	77	58.8
	No	54	41.2
Performance Status	PS 0: Normal Activity	84	64.1
	PS 1: Some Symptoms but Near Fully Ambulatory	45	34.4
	PS 2: Less than 50%	2	1.5
Hospitalization in Last Year	Yes	22	16.8
	No	109	83.2
History of Heart Disease	Yes	7	5.3
	No	124	94.7
History of Hypertension	Yes	30	22.9
	No	101	77.1
History of Diabetes	Yes	8	6.1
	No	123	93.9
Other Chronic Disease on Medication	Yes	2	1.5
	No	129	98.5
Tamoxifen	Yes	68	51.9
	No	63	48.1
Anastrozole	Yes	51	38.9
	No	80	61.1
Letrozole	Yes	10	7.6
	No	121	92.4
Running out of Medication Awaiting Next Clinic	Yes	37	28.2
	No	94	71.8

4.1.3 Health System Factors Characteristics of Participants

Regarding monthly medical costs, the majority of participants, 98 (74.8%), reported spending more than Ksh 400, while 19 participants (14.5%) spent between Ksh 100 and 400, and 14 participants (10.7%) spent up to Ksh 100. In terms of travel time to the health facility, most participants, 113 (86.3%), spent more than 60 minutes traveling, with 14 participants (10.7%) traveling between 30 and 60 minutes, and only 4 participants (3.1%) spent less than 30 minutes. Transport costs were high for most participants, with 119 (90.8%) reporting costs above Ksh 100, while 12 participants (9.2%) spent between Ksh 0 and 100. Additionally, 38 participants (29.0%) missed refills or appointments due to cost-related reasons, while 93 participants (71.0%) did not face such issues.

Table 3: Health System Factors Affecting Participants

Variable	Categories	Frequency (n)	Percentage (%)
Monthly Medical Costs	Up to Ksh 100	14	10.7
	Ksh 100 to 400	19	14.5
	Above Ksh 400	98	74.8
Travel Time to Health Facility (One Way)	Less than 30 mins	4	3.1
	30 to 60 mins	14	10.7
	Above 60 mins	113	86.3
Transport Cost to Health Facility (One Way)	Ksh 0 to 100	12	9.2
	Above Ksh 100	119	90.8
Missed Refills or Appointments Caused by Cost	Yes	38	29.0
	No	93	71.0

4.2 Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH

The results for adherence to endocrine therapy showed that out of 131 participants, 95 (72.5%) demonstrated good adherence, as indicated by a mean score of 1 on the Voils DOSE non-adherence scale. The remaining 36 participants (27.5%) were categorized as having poor adherence, with a mean score greater than 1. These findings reflected the distribution of adherence levels among the study population, with a larger proportion of patients adhering to their prescribed endocrine therapy. The adherence status was measured using the Voils DOSE scale, where a mean score of 1 signified good adherence, and a score greater than 1 indicated non-adherence. The overall adherence rate for this cohort, based on the data collected, highlighted the varying degrees of adherence to endocrine therapy in the studied population.

Table 4: Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH

Adherence Status	Frequency (n)	Percent (%)
Poor Adherence	36	27.5
Good Adherence	95	72.5
Total	**131**	**100.0**

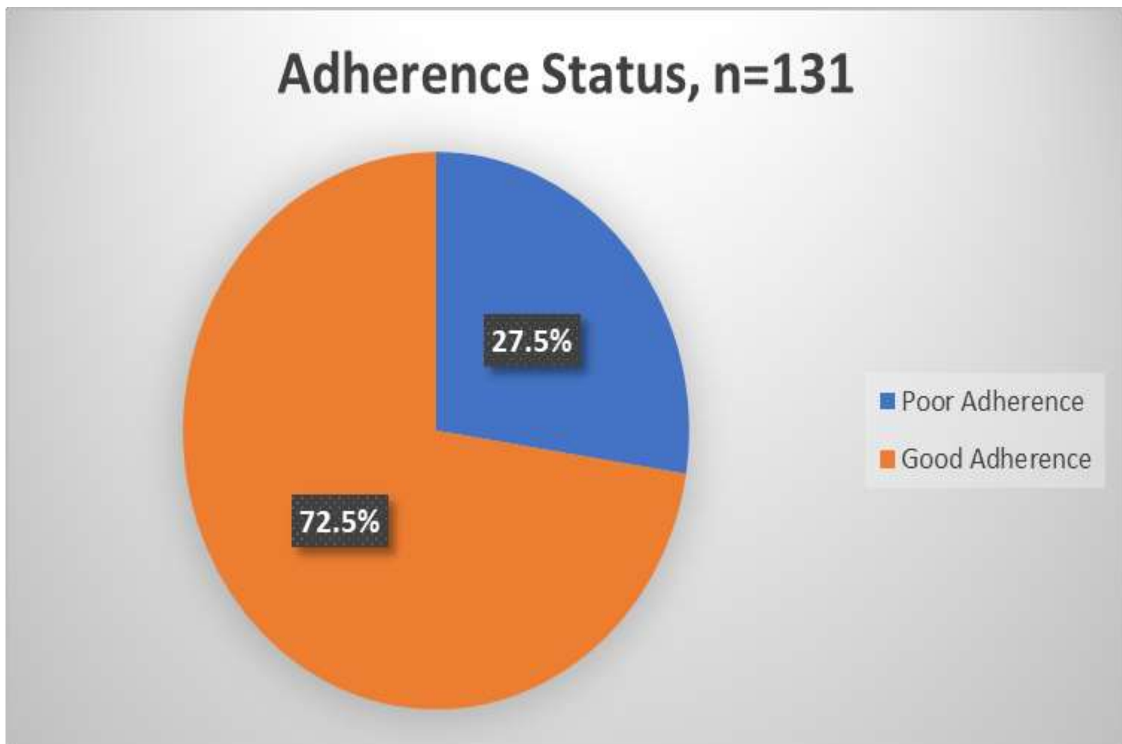


Figure 3: Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH

4.3 Determinants of Adherence Among HR+ Breast Cancer Patients at MTRH

4.3.1 Sociodemographic Factors as Determinants of Adherence

The bivariate analysis revealed significant associations between adherence levels and several sociodemographic factors. The age group variable demonstrated a significant association with adherence ($p = 0.002$), with adherence rates increasing among older age groups. Education level was also significantly associated with adherence, where those with primary education had the lowest adherence ($p < 0.000$), whereas higher education levels, such as secondary and university, showed better adherence. Monthly income, marital status, occupation, and active health insurance were not significantly associated with adherence, as their p-values were above the 0.05 threshold, indicating no strong relationship with adherence behavior.

Table 5: Bivariate Analysis of Sociodemographic Factors as Determinants of Adherence

Variable	Category	Poor Adherence (Count & %)	Good Adherence (Count & %)	p-value
Age Group	Below 30 years	4 (11.2)	2 (33.3)	0.002
	30 to 39 Years	2 (5.6)	18 (90.0)	
	40 to 49 Years	6 (15.0)	34 (85.0)	
	50 to 59 Years	14 (35.0)	26 (65.0)	
	60 to 69 Years	4 (25.0)	12 (75.0)	
	70 to 79 Years	6 (66.7)	3 (33.3)	
Highest Education	Primary	16 (80.0)	4 (20.0)	0.000
	Secondary	10 (15.2)	56 (84.8)	
	University	10 (36.4)	35 (63.6)	
Monthly Income	No Job/Income	30 (32.6)	62 (67.4)	0.178
	Below 1000 Ksh	2 (25.0)	6 (75.0)	
	1000 to 5000 Ksh	2 (20.0)	8 (80.0)	
	Above 5000 Ksh	2 (9.5)	19 (90.5)	
Active Health Insurance	No Insurance	2 (33.3)	4 (66.7)	0.893
	NHIF	32 (26.9)	87 (73.1)	
	Private Insurance	2 (33.3)	4 (66.7)	
Marital Status	Single (Reference)	2 (8.7)	21 (91.3)	0.109
	Married	30 (32.6)	62 (67.4)	
	Separated	4 (28.6)	10 (71.4)	
	Other	0 (0.0)	2 (100.0)	
Occupation	Employed	4 (18.2)	18 (81.8)	0.417
	Self Employed/Business	10 (23.3)	33 (76.7)	
	Unemployed	22 (33.3)	44 (66.7)	

The multivariate analysis revealed several significant findings. The 50 to 59 years age group showed a statistically significant association with adherence, with an odds ratio (OR [4.212]) and a p-value (p [0.040]), indicating a moderate but statistically significant relationship with good adherence. Educational level also played a statistically significant role in adherence, with individuals having secondary education showing an odds ratio (OR [0.195]) and a p-value (p [0.003]), while those with university education had an odds ratio (OR [3.238]) and p-value (p [0.043]). These results emphasized that age and education were statistically significant factors influencing adherence, with clear differences in likelihood based on these variables. Other variables did not show statistically significant results (p values above 0.05).

Table 6 Multivariate Analysis of Sociodemographic Factors as Determinants of Adherence

Variable	Category	Poor Adherence (n & %)	Good Adherence (n & %)	Adjusted Odds Ratios	Sig.	95% CI for Exp(B)
Age Group	Below 30 Years (Reference)	4 (11.2%)	0 (0.0%)			
	30 to 39 Years	2 (5.6%)	18 (90.0%)	2.223 E+28	0.998	0.000 – .
	40 to 49 Years	6 (15.0%)	34 (85.0%)	6.479	0.203	0.365 – 115.074
	50 to 59 Years	14 (35.0%)	26 (65.0%)	4.212	0.040	1.114 – 110.723
	60 to 69 Years	4 (25.0%)	12 (75.0%)	1.705	0.665	0.153 – 19.033
	70 to 79 Years	6 (66.7%)	3 (33.3%)	2.860	0.435	0.205 – 39.886
Highest Education Level	Primary (Reference)	16 (80.0%)	4 (20.0%)			
	Secondary)	10 (15.2%)	56 (84.8%)	0.195	0.003	0.033 – 0.963
	University	10 (36.4%)	35 (63.6%)	3.238	0.043	0.696 – 15.062
Monthly Income (Ksh)	No Job/Income (Reference)	30 (32.6%)	62 (67.4%)			
	Below 1000 Ksh	2 (25.0%)	6 (75.0%)	0.000	0.998	0.000 – .
	1000 to 5000 Ksh	2 (20.0%)	8 (80.0%)	1.686	1.000	0.000 – .
	Above 5000 Ksh	2 (9.5%)	19 (90.5%)	3.060	1.000	0.000 – .
Active Health Insurance	No Insurance (Reference)	2 (33.3%)	4 (66.7%)	0.000	0.998	0.000 – .
	NHIF	32 (26.9%)	87 (73.1%)	0.000	0.999	0.000 – .
	Private Insurance	2 (33.3%)	4 (66.7%)			
Marital Status	Single (Reference)	2 (8.7%)	21 (91.3%)			
	Married	30 (32.6%)	62 (67.4%)	3.332 E+8	1.000	0.000 – .
	Separated	4 (28.6%)	10 (71.4%)	1.000	1.000	0.000 – .
	Other	0 (0.0%)	2 (100.0%)	0.223	1.000	0.000 – .
Occupation	Other (Reference)	22 (33.3)	44 (66.7)			
	Employed	4 (18.2%)	18 (81.8%)	0.000	0.998	0.000 – .
	Self Employed/Business	10 (23.3%)	33 (76.7%)	1.411	0.633	0.344 – 5.792
Constant				0.000	0.998	

The socioeconomic factors influencing treatment adherence were closely tied to financial constraints, healthcare accessibility, and family dynamics.

Financial barriers, such as the high costs of medication and treatment, were often mentioned as a key issue, with patients like Participant 11 expressing the financial stress caused by the cost of treatment, stating, *"Ksh. 250 is a lot of money."* (Participant 11). Financial support, either from family or the community, helped alleviate some of these barriers, as highlighted by Participant 9, who mentioned, *"I*

borrowed my friends who instead managed to raise Ksh. 20000." (Participant 9). However, financial constraints also led to significant challenges, with patients like Participant 9 noting that, *"It has no side effects on me, it only just stresses me out when I do not have money."* (Participant 9).

Healthcare accessibility was another concern, particularly with NHIF issues and out-of-pocket costs, which could delay treatment and impact adherence, as described by Participant 9, who feared, *"I fear to come get admitted at Chandaria as I am afraid the card may not help with the remaining treatments."* (Participant 9). Additionally, societal and cultural barriers, such as stigma surrounding cancer treatment, affected adherence, as patients were sometimes discouraged by others, as seen in Participant 1's comment, *"The stigma, knowing you have to take medicine daily, I take mine daily."* (Participant 1).

Family support played a crucial role in improving adherence, with patients like Participant 7 highlighting the positive impact of reminders, saying, *"My kids would remind me now."* (Participant 7). However, lack of family support could hinder adherence, as noted by Participant 2, who stated, *"I have not been getting any support."* (Participant 2). Emotional tolls, such as the stress from treatment costs and the desire to stop treatment, were also significant, with Participant 9 sharing, *"I told the sisters that after the 20 sessions they should just leave me as I had no otherwise."* (Participant 9). Work-related challenges, such as reduced capacity to work, also impacted financial stability and medication adherence, as seen with Participant 2, who shared, *"It has affected my capacity to work."* (Participant 2). Overall, these socioeconomic factors significantly influenced patients' ability to adhere to treatment, with financial, familial, and emotional elements playing a central role.

Table 7 Main themes showing Socioeconomic Factors Affecting Adherence to Treatment

Main Theme	Sub-Theme	Description	Sample Quote
Financial Constraints	**Financial burden of treatment**	High treatment costs can delay or prevent patients from continuing their medication and treatment.	"Ksh. 250 is a lot of money." (Participant 11)
	Difficulty in managing treatment costs	Financial constraints lead to difficulty in covering treatment-related costs, affecting adherence.	"It has no side effects on me; it only just stresses me out when I do not have money." (Participant 9)
	Financial support for treatment	Support from family, community, or programs can assist patients in managing financial barriers to treatment.	"I borrowed my friends who instead managed to raise Ksh. 20000." (Participant 9)
	Cost of medication	High medication costs can lead to discontinuation or delay in treatment, affecting adherence.	"It costs 200Ksh per tablet but I was being sold at 172Ksh per tablet." (Participant 4)
	Transportation challenges for treatment	The high cost of travel to healthcare facilities can be a barrier to consistent treatment adherence.	"The transport to here has really brought me down." (Participant 9)
Healthcare Accessibility	**NHIF challenges and out-of-pocket costs**	Issues with NHIF approval, including delays and limited coverage, can increase out-of-pocket costs and affect adherence.	"I fear to come get admitted at Chandaria as I am afraid the card may not help with the remaining treatments." (Participant 9)
	Use of NHIF for treatment	NHIF coverage can make it easier for patients to access treatment, enhancing adherence.	"I have NHIF which pays for it." (Participant 8)
	Challenges with NHIF registration and approval	NHIF registration and approval issues can delay access to medications and treatment.	"Sometimes you come, get the card and pay since now you have to pay NHIF does not cover that..." (Participant 10)
Societal and Cultural Barriers	**Stigma surrounding cancer treatment**	Stigma associated with cancer and its treatment may deter some patients from adhering to prescribed regimens.	"The stigma, knowing you have to take medicine daily, I take mine daily." (Participant 1)
	Traditional medicine suggestion	Suggestions to use traditional medicine can conflict with medical treatment, reducing adherence.	"There was one who came before I had begun chemo, a traditional one. They told me to use traditional drugs." (Participant 7)
	Reliance on faith due to financial constraints	Some patients rely on faith or wait for external support when financial resources are insufficient to continue treatment.	"I decided to wait and let God protect me." (Participant 11)
Family Support and Dynamics	**Family support for medication adherence**	Family members' encouragement and involvement in medication adherence significantly improve treatment outcomes.	"My kids would remind me now." (Participant 7)
	Dependence on family for financial support	Patients who rely on family for financial support are often more likely to continue treatment if support is provided.	"My eldest son has been with me through this journey, even my NHIF he is the one who pays for it." (Participant 4)
	Lack of family support	Lack of financial or emotional support from family can hinder a patient's ability to adhere to treatment.	"I have not been getting any support." (Participant 2)
	Family advice and support	Supportive family advice can enhance patients' adherence by reinforcing positive attitudes toward treatment.	"I went home and talked to the people close to me, told them what the doctors had explained and they advised me to do as the doctor says." (Participant 8)
Emotional Impact	**Emotional toll of treatment costs**	The financial burden of treatment can increase stress, potentially affecting adherence to the prescribed regimen.	"I thought that it was the end of life." (Participant 9)
	Willingness to stop treatment due to financial strain	Patients who face severe financial difficulties may express a desire to stop treatment due to the costs involved.	"I told the sisters that after the 20 sessions they should just leave me as I had no otherwise." (Participant 9)
Work and Earnings Impact	**Impact on work ability**	Illness and treatment side effects can reduce a patient's ability to work, affecting financial stability and treatment adherence.	"It has affected my capacity to work." (Participant 2)
	Reduced earnings due to health	Reduced earnings because of illness or treatment can prevent patients from being able to afford medications.	"Earnings have been affected, I am trying my best to work because if I do not I will not get anything." (Participant 2)

The quantitative and qualitative results on sociodemographic factors influencing adherence to treatment show both convergence and divergence. The quantitative findings show that individuals in the 50-59 age group had significantly better adherence, while those with secondary and university education also had better adherence compared to those with primary education. These results align with the qualitative data, where older patients and those with more education expressed better knowledge and readiness to adhere to treatment. However, there was divergence concerning financial constraints. The quantitative analysis did not find a significant link between monthly income and adherence, yet the qualitative data consistently pointed to the financial burden, particularly in terms of medication and transportation costs, as a significant barrier to adherence. Additionally, while the quantitative results did not find a strong connection between family support and adherence, the qualitative data emphasized the pivotal role of family in maintaining adherence, with patients citing emotional and financial support as crucial for continuing treatment.

4.3.2 Clinical Factors as Determinants of Adherence

Bivariate analysis of clinical factors that determine adherence was done using Chi square. Participants with a longer duration with breast cancer showed a significant difference in adherence compared to shorter duration ($p = 0.007$) indicating that the duration since breast cancer diagnosis influenced adherence levels. Stage at Diagnosis also demonstrated a significant effect on adherence ($p = 0.026$) suggesting that patients diagnosed at later stages (Stage III) were more likely to adhere to treatment. Performance Status had a significant relationship with adherence ($p = 0.016$), showing that individuals with normal activity (PS 0) were more likely to adhere to their treatment. Anastrozole use revealed a significant association with adherence ($p = 0.016$), indicating better adherence among those using Anastrozole compared to

Tamoxifen. These findings underscore the importance of these clinical factors in predicting patient adherence and highlight areas for potential intervention to improve treatment outcomes.

Table 8: Bivariate Analysis of Clinical Factors as Determinants of Adherence

Variable	Category	Poor Adherence (Count & %)	Good Adherence (Count & %)	p-value
Duration since breast cancer diagnosis	0-4	22 (25.6%)	64 (74.4%)	0.007
	More than 10 years	8 (66.6%)	4 (33.3%)	
	5-9	6 (18.2%)	27 (81.8%)	
Stage at Diagnosis	Stage 0	2 (100.0%)	0 (0.0%)	0.026
	Stage I	2 (50.0%)	2 (50.0%)	
	Stage II	10 (18.2%)	45 (81.8%)	
	Stage III	22 (31.4%)	48 (68.6%)	
Histological Subtype	DCIS	4 (66.7%)	2 (33.3%)	0.102
	IDC	32 (26.4%)	89 (73.6%)	
	ILC	0 (0.0%)	2 (100.0%)	
	Other	0 (0.0%)	2 (100.0%)	
Current Stage	Stage 0	2 (33.3%)	4 (66.7%)	0.841
	Stage I	2 (33.3%)	4 (66.7%)	
	Stage II	10 (22.7%)	34 (77.3%)	
	Stage III	22 (29.3%)	53 (70.7%)	
Family History of Breast Cancer	No	28 (27.7%)	73 (72.3%)	0.909
	Yes	8 (26.7%)	22 (73.3%)	
Menopausal Status	No	10 (18.5%)	44 (81.5%)	0.054
	Yes	26 (33.8%)	51 (66.2%)	
Performance Status	PS 0: Normal Activity	18 (21.4%)	66 (78.6%)	0.016
	PS 1: Some Symptoms but still ambulatory	16 (35.6%)	29 (64.4%)	
	PS 2: Less than 50%	2 (100.0%)	0 (0.0%)	
Hospitalization in the Last Year	No	29 (26.6%)	80 (73.4%)	0.617
	Yes	7 (31.8%)	15 (68.2%)	
History of Heart Disease	No	32 (25.8%)	92 (74.2%)	0.071
	Yes	4 (57.1%)	3 (42.9%)	
History of Hypertension	No	28 (27.7%)	73 (72.3%)	0.909
	Yes	8 (26.7%)	22 (73.3%)	
History of Diabetes	No	34 (27.6%)	89 (72.4%)	0.871
	Yes	2 (25.0%)	6 (75.0%)	
Other Chronic Disease on Medication	No	36 (27.9%)	93 (72.1%)	0.380
	Yes	0 (0.0%)	2 (100.0%)	
Tamoxifen	No	22 (34.9%)	41 (65.1%)	0.066
	Yes	14 (20.6%)	54 (79.4%)	
Anastrozole	No	16 (20.0%)	64 (80.0%)	0.016
	Yes	20 (39.2%)	31 (60.8%)	
Letrozole	No	34 (28.1%)	87 (71.9%)	0.581
	Yes	2 (20.0%)	8 (80.0%)	

The multivariate analysis identified one significant predictor of medication adherence. Patients with more than 10 years of breast cancer duration had significantly reduced odds of good adherence compared to those with 0-4 years of breast cancer duration (OR = 0.084, p = 0.042). All other variables examined failed to reach statistical significance. These included 5-9 years duration of breast cancer (OR = 0.328, p = 0.086), stage II diagnosis compared to stage 0 (OR = 2.737, p = 0.224), family history of breast cancer (OR = 0.535, p = 0.365), menopausal status (OR = 1.182, p = 0.754), stage III current disease (OR = 0.516, p = 0.516), and hospitalization history (OR = 0.458, p = 0.290).

Table 9 Multivariate Analysis of Clinical Factors as Determinants of Adherence

Variable	Category	Poor Adherence (n & %)	Good Adherence (n & %)	Adjusted Odds Ratio	Sig.	95% CI for Exp(B)
Duration since breast cancer diagnosis	0-4 (Reference)	22 (25.6%)	64 (74.4%)	-	-	-
	5-9	6 (18.2%)	27 (81.8%)	0.328	0.086	0.092 -- 1.173
	More than 10 years	4 (50.0%)	4 (50.0%)	0.084	0.042	0.008 -- 0.914
Stage at Diagnosis	Stage 0 (Reference)	2 (100.0%)	0 (0.0%)	-	-	-
	Stage I	2 (50.0%)	2 (50.0%)	0.000	1.000	0.000 -- 0.000
	Stage II	10 (18.2%)	45 (81.8%)	2.737	0.224	0.539 -- 13.891
	Stage III	22 (31.4%)	48 (68.6%)	-	-	-
Current Stage	Stage 0 (Reference)	2 (33.3%)	4 (66.7%)	-	-	-
	Stage I	2 (33.3%)	4 (66.7%)	8248412417.0	0.999	0.000 -- .
	Stage II	10 (22.7%)	34 (77.3%)	2216854628.8	0.999	0.000 -- .
	Stage III	22 (29.3%)	53 (70.7%)	0.516	0.516	0.093 -- 2.877
Family History of Breast Cancer	No (Reference)	28 (27.7%)	73 (72.3%)	-	-	-
	Yes	8 (26.7%)	22 (73.3%)	0.535	0.365	0.139 -- 2.068
Menopausal Status	No (Reference)	10 (18.5%)	44 (81.5%)	-	-	-
	Yes	26 (33.8%)	51 (66.2%)	1.182	0.754	0.414 -- 3.379
Performance Status	PS 0: Normal Activity (Reference)	18 (21.4%)	66 (78.6%)	-	-	-
	PS 1: Some Symptoms	16 (35.6%)	29 (64.4%)	1.110E+10	0.999	0.000 -- .
	PS 2: Less than 50%	2 (100.0%)	0 (0.0%)	4828158499.9	0.999	0.000 -- .

Hospitalization in Last Year	No (Reference)	29 (26.6%)	80 (73.4%)	-	-	-
	Yes	7 (31.8%)	15 (68.2%)	0.458	0.290	0.108 -- 1.944
History of Heart Disease	No (Reference)	32 (25.8%)	92 (74.2%)	-	-	-
	Yes	4 (57.1%)	3 (42.9%)	7.423E+13	0.994	0.000 -- .
History of Hypertension	No (Reference)	28 (27.7%)	73 (72.3%)	-	-	-
	Yes	8 (26.7%)	22 (73.3%)	1866789.260	0.995	0.000 -- .
History of Diabetes	No (Reference)	34 (27.6%)	89 (72.4%)	-	-	-
	Yes	2 (25.0%)	6 (75.0%)	2295379.866	0.998	0.000 -- .
Other Chronic Disease on Medication	No (Reference)	36 (27.9%)	93 (72.1%)	-	-	-
	Yes	0 (0.0%)	2 (100.0%)	8.128E+31	0.998	0.000 -- .
Tamoxifen	No (Reference)	22 (34.9%)	41 (65.1%)	-	-	-
	Yes	14 (20.6%)	54 (79.4%)	1.769E+27	0.993	0.000 -- .
Anastrozole	No (Reference)	16 (20.0%)	64 (80.0%)	-	-	-
	Yes	20 (39.2%)	31 (60.8%)	26135049.65	0.995	0.000 -- .
Letrozole	No (Reference)	34 (28.1%)	87 (71.9%)	-	-	-
	Yes	2 (20.0%)	8 (80.0%)	0.640	0.584	0.129—3.117
Running out of Medication Awaiting Next Clinic	No (Reference)	2 (2.1%)	92 (97.9%)	-	-	-
	Yes	34 (91.9%)	3 (8.1%)	7.034E+34	0.992	0.000 -- .

The qualitative results revealed several themes and patterns. Emphasis on the importance of adherence was shared by Participant 9, who said *"The important thing is to take the medication as prescribed and as much as possible go on with your daily activities."* (Participant 9). However, side effects such as nausea were common, with Participant 2 reporting *"Sometimes you feel very nauseated after taking medications but it is not the case with this one."* (Participant 2). Availability of medication and its cost presented additional barriers, as highlighted by Participant 3: *"The drug is not available here, I usually suffer a lot because when I send for it in Nairobi it necessitates using cash."* (Participant 3). Support from healthcare professionals, like the nutritionist mentioned by Participant 8, was also important: *"My body was very weak. I had a nutritionist come in and talk to me."* (Participant 8).

Psychological and family-related factors played an important role in treatment adherence. Participant 2 expressed emotional readiness to begin treatment, saying *"I felt ready."* (Participant 2), while Participant 3 experienced initial shock, stating *"I*

knew I was dead. When I read Chandaria Cancer Center I knew I was dead." (Participant 3). Family involvement was crucial, with Participant 3 adding *"My family really follows up on me, they want to know after every visit what I was told and how I am doing."* (Participant 3). Financial support from family was vital for some patients, as evidenced by Participant 5's experience: *"During the surgery, my child, the one who used to work in Medihill is the one who helped me a lot."* (Participant 5). Intrinsic motivation was also a driving force, with Participant 1 stating *"I want it to go away completely makes me remember to take it."* (Participant 1).

Table 10: Main themes on Clinical Factors as Determinants of Adherence: Disease, Medication, and Treatment Impact

Category	Main Theme	Sub-Theme	Description	Sample Quote
Disease-Related Factors	Early-Stage Breast Cancer	Tumor Detection, Initial Concern	Initial detection of lumps or changes in the breast, leading to concern and subsequent medical consultation.	"I was doing my laundry and then I suddenly touched my breast. I hear they say if you feel you have a stone in your breast, you go to the hospital." (Participant 7)
		Diagnosis of Stage I Cancer	Early diagnosis of cancer, influencing the approach to treatment and adherence.	"I was diagnosed with Stage I breast cancer." (Participant 11)
	Disease Progression	Fast-growing Lump	Rapid tumor growth, leading to more intensive treatment and potential challenges to adherence.	"During the two weeks the lump grew very fast such that when I came, they did the tests hurriedly." (Participant 10)
		Tumor Size Growth	The significant increase in tumor size, leading to changes in treatment plans and adherence concerns.	"By the time I started treatment it was 5cm, it really went fast." (Participant 10)
	Comorbidities	Hypertension as a New Condition	The development of hypertension during cancer treatment, which may complicate treatment adherence.	"Yes, I did not have it before." (Participant 10)
	Symptom Impact on Adherence	Pain Management and Symptom Control	The pain caused by the cancer, impacting daily functioning and potentially hindering adherence to treatment.	"It reached a point the joints of my hands were painful; I was not able to grab something." (Participant 2)
		Physical Changes from Illness	Physical changes, like breast shape and size changes, affecting adherence to treatment.	"Even the breasts were losing shape, you can see one is bigger than the other." (Participant 7)
Medication Factors	Adherence & Trust in Treatment	Trust in Medical Treatment	Confidence in the medical system, encouraging adherence to prescribed treatments.	"I trust the system and there is no need to go traditional." (Participant 1)
		Emphasis on Adherence	The importance of taking medication as prescribed	"The important thing is to take the medication as

			for better health outcomes.	prescribed and as much as possible go on with your daily activities." (Participant 9)
	Side Effects & Coping Strategies	Coping with Side Effects	Strategies used to manage or tolerate side effects, impacting overall treatment adherence.	"I decided not to read the side effects of the drug because every time I feel something I will say it is the side effects." (Participant 1)
		Nausea and Fatigue	Experiencing nausea or fatigue as a result of medication or chemotherapy side effects.	"Sometimes you feel very nauseated after taking medications but it is not the case with this one." (Participant 2)
	Medication Availability & Challenges	Medication Availability Issue	Difficulty obtaining medication due to supply issues or cost, impacting consistent adherence.	"The drug is not available here, I usually suffer a lot because when I send for it in Nairobi it necessitates using cash." (Participant 3)
	Treatment Progression & Support	Trust in Hospital Treatment	Faith in the medical team and ongoing support that encourages adherence to complex treatment plans.	"I chose the hospital treatment and that is why I am alive." (Participant 3)
Patient and Family Related Factors	Psychological Readiness	Readiness to Start Treatment	A patient's emotional state when first starting treatment influences their adherence to the medication regimen.	"I felt ready." (Participant 2)
		Shock and Stigma Surrounding Diagnosis	Initial shock and stigma may delay treatment initiation and affect long-term adherence.	"I knew I was dead. When I read Chandaria Cancer Center I knew I was dead." (Participant 3)
	Social and Family Support	Strong Family Support	Family members' active involvement in a patient's care can lead to better adherence by providing encouragement.	"My family really follows up on me, they want to know after every visit what I was told and how I am doing." (Participant 3)
		Dependence on Family for Financial Support	Dependence on family for financial resources can either facilitate or hinder access to medications.	"During the surgery, my child, the one who used to work in Medihill is the one who helped me a lot." (Participant 5)
	Coping with Treatment	Motivation for Adherence to Medication	Intrinsic motivation, such as wanting the illness to go away, drives adherence to prescribed regimens.	"I want it to go away completely makes me remember to take it." (Participant 1)
		Perseverance Through Treatment	Ongoing perseverance despite difficulties with the treatment helps ensure long-term adherence.	"I questioned whether I would really finish the radiotherapy but I pushed through till I was done." (Participant 8)
Cultural and Societal Factors		Stigma Surrounding Cancer Treatment	The societal stigma of cancer treatment can create barriers to adhering to prescribed medications.	"The stigma, knowing you have to take medicine daily, I take mine daily." (Participant 1)
		Resistance to Medical Treatment	Resistance to prescribed treatment due to personal beliefs or fear can reduce treatment adherence.	"I refused and I asked to go home because my children were at school." (Participant 3)
		Rejection of Traditional Treatment	Rejection of traditional treatments in favor of prescribed medical treatments enhances adherence.	"I told them no." (Participant 7)

The quantitative and qualitative data agreed on several key factors influencing adherence. Both highlighted that longer duration with breast cancer diagnosis was associated with better adherence, with the quantitative data showing improved adherence in patients with more than 10 years of experience, aligning with qualitative findings that longer management experience fosters adherence. Additionally, both datasets indicated that patients diagnosed at later stages, such as Stage III, were more likely to adhere to treatment, reflecting a shared understanding that disease progression encourages treatment commitment. However, there were differences between the two data types. Medication availability was an area of convergence: while the quantitative data linked running out of medication to non-adherence, the qualitative data highlighted coping strategies for managing side effects and medication access challenges.

4.3.3 Health System Factors as Determinants of Adherence

The bivariate analysis yielded the following p-values for the different factors. For monthly medical costs, the p-value of .084. This indicated that there no significant association between adherence status and monthly medical costs. In the case of travel time to the health facility, the p-value was .458. This result suggested no significant association between travel time and adherence, as the p-value was above the common threshold of .05 for statistical significance. Similarly, for transport cost to the health facility, with a p-value of .634, further confirming the lack of any significant relationship.

Table 11: Bivariate Analysis of Health System Factors as Determinants of Adherence

Variable	Category	Poor Adherence (n & %)	Good Adherence (n & %)	p-value
Monthly Medical Costs	Up to Ksh 100	6 (16.7%)	8 (8.4%)	.084
	Ksh 100 to 400	8 (22.2%)	11 (11.6%)	
	Above Ksh 400	22 (61.1%)	76 (80.0%)	
	Total	36 (27.5%)	95 (72.5%)	
Travel Time to Health Facility	Less than 30 Mins	0 (0.0%)	4 (4.2%)	.458
	30 to 60 Mins	4 (11.1%)	10 (10.5%)	
	Above 60 mins	32 (88.9%)	81 (85.3%)	
	Total	36 (27.5%)	95 (72.5%)	
Transport Cost to Health Facility	Ksh 0 to 100	4 (11.1%)	8 (8.4%)	.634
	Above Ksh 100	32 (88.9%)	87 (91.6%)	
	Total	36 (27.5%)	95 (72.5%)	

The multivariate analysis evaluated health system factors related to adherence status. For Monthly Medical Costs, the odds ratios (OR) for all categories were not significant, with the "Ksh 100 to 400" and "Above Ksh 400" categories having OR values of 0.000 (p = 0.836) and 0.764 (p = 0.836), respectively. Transport Cost to Health Facility also demonstrated no significant results for the "Ksh 0 to 100" category (OR = 18143624127.292, p = 0.996), while the "Above Ksh 100" category showed an OR of 4.193 (p = 1.000).

Table 12 :Multivariate Analysis of Health System Factors as Determinants of Adherence

Variable	Category	Poor Adherence (n & %)	Good Adherence (n & %)	Odds Ratio	Sig.	95% CI for Exp(B)
Monthly Medical Costs	Up to Ksh 100	6 (16.7%)	8 (8.4%)	.000	.996	.000 to .
	Ksh 100 to 400	8 (22.2%)	11 (11.6%)	.000	.836	.060 to 9.756
	Above Ksh 400	22 (61.1%)	76 (80.0%)	.764	.836	.060 to 9.756
	Total	36 (27.5%)	95 (72.5%)			
Travel Time to Health Facility	Less than 30 Mins	0 (0.0%)	4 (4.2%)	471110120.151	.999	.000 to .
	30 to 60 Mins	4 (11.1%)	10 (10.5%)	1.590	1.000	.000 to .
	Above 60 mins	32 (88.9%)	81 (85.3%)	4.193	1.000	.000 to .
	Total	36 (27.5%)	95 (72.5%)			
Transport Cost to Health Facility	Ksh 0 to 100	4 (11.1%)	8 (8.4%)	18143624127.292	.996	.000 to .
	Above Ksh 100	32 (88.9%)	87 (91.6%)	4.193	1.000	.000 to .
	Total	36 (27.5%)	95 (72.5%)			

Several factors directly influenced patients' adherence to treatment as per the qualitative data collected. Key elements such as trust in healthcare institutions and positive doctor-patient relationships played a significant role in ensuring patients followed their treatment regimens. As one patient shared, *"I trusted the institution... the procedures were so many"* (Participant 1), while another appreciated the respectful nature of their doctors, stating, *"The doctors are respectful people and they understand because I ask the doctor a lot of questions"* (Participant 4). However, delays in treatment and administrative challenges also hindered adherence. Long queues, waiting times, and delays in drug administration were frequently mentioned. One patient explained, *"The line was really long... I was helped by another and got a doctor for registration"* (Participant 5), while another expressed frustration with the delays, *"You can stay there till you come the following day"* (Participant 1). Access to treatment also impacted adherence, as patients voiced a desire for more accessible treatment closer to their homes: *"With the costs I incur while seeking treatment, it would be easier if I could get the treatment closer to home"* (Participant 2). Communication issues, such as being "brushed off" by staff, also created barriers to adherence, as one patient stated, *"Maybe what they can do is to improve how they talk to us"* (Participant 1). Finally, systemic support, such as difficulties with the NHIF system, medication availability, and costs significantly affected patients' ability to access and adhere to treatment. One patient noted, *"Once it approves you go to NHIF show them the message and they put a sticker on your card"* (Participant 6), while another expressed concern over medication costs, saying, *"Why not import it before it runs out here?"* (Participant 11). Despite these challenges, reassurance from healthcare providers and emotional support were critical for encouraging adherence, as evidenced by a patient who said, *"They really gave me hope, they told me that*

where I am coming from I should try my best to finish" (Participant 9). Overall, while trust and support fostered adherence, delays, communication issues, and financial constraints created significant barriers to treatment completion.

Table 13: Main Themes on Health System Factors and Their Impact on Adherence

Main Theme	Sub-Theme	Description	Sample Quote
Healthcare System Trust	Trust in the healthcare institution despite challenges	Despite challenges, patients trust the healthcare institution for their treatment.	"I trusted the institution the procedures were so many. We are so many waiting on the queue." (Participant 1)
	Positive doctor-patient relationship	Positive interactions with healthcare professionals foster trust and adherence.	"The doctors are respectful people and they understand because I ask the doctor a lot of questions." (Participant 4)
	Satisfaction with healthcare facility	General satisfaction with the healthcare facility supports adherence to treatment.	"No, I have loved MTRH, according to me the nurses here are good as they help you in case you are in need." (Participant 9)
	Supportive healthcare providers	Support from healthcare providers helps with the emotional and psychological aspects of treatment.	"They have really saved me, with advice and everything." (Participant 9)
Delays and Administrative Challenges	Delays in treatment scheduling	Delays in treatment appointments or procedures affect patient experience and treatment adherence.	"It took between late February and the operation was in May." (Participant 1)
	Long queues and waiting times	Prolonged waiting times due to long queues can cause frustration and impact adherence.	"The line was really long... I was helped by another and got a doctor for registration." (Participant 5)
	Delays in drug administration	Delays in administering medication or treatments can lead to gaps in care and adherence issues.	"You can stay there till you come the following day and already you have gone through the process and you are done, now you return for them to keep it in the refrigerator." (Participant 1)
	Systemic delays in treatment	Delays within the healthcare system (e.g., NHIF approval, medication delivery) can negatively impact treatment.	"The queue is long and they tell you to wait, the systems are down, which sometimes takes long." (Participant 8)
Access to Treatment	Desire for more accessible treatment	Patients desire more accessible treatment options closer to home, which could improve adherence.	"With the costs I incur while seeking treatment, it would be easier if I could get the treatment closer to home." (Participant 2)
	Suggestion for local access to medication	Access to medication closer to home, especially for rural patients, can improve medication adherence.	"If there was a way for the patients from the rural areas to get their medicines from their nearest hospitals." (Participant 8)
	Referral and treatment process	Referral processes can sometimes cause delays and confusion in receiving timely treatment.	"It is very visible I should go to Chandaria. I went to Memorial as it was the hospital then they sent me to Chandaria room 20 then eventually that booked me for biopsy." (Participant 1)
	Referral to specialized treatment centers	Referral to other hospitals for specialized treatment impacts adherence by requiring additional steps.	"They referred me to Chandaria." (Participant 9)
Communication & Coordination Issues	Communication issues with healthcare staff	Poor communication from healthcare professionals can hinder effective treatment and	"Maybe what they can do is to improve how they talk to us, because you may ask a question

		adherence.	and you are brushed off." (Participant 1)
	Delays in lab results and treatment	Delays in receiving results or feedback on tests or procedures can slow down treatment progress.	"So maybe that because now it is a must to go with the results when going to the doctor and then now you delay then the day goes by." (Participant 1)
	Frustration with hospital processes	Frustration with the hospital process, including running around different departments, can cause delays and reduce adherence.	"The process is hard, it does not need one person as I come. You go here, go there and go back." (Participant 5)
	Inconsistent patient interactions	Inconsistent or inappropriate interactions with healthcare providers can negatively impact patient experience and adherence.	"Not everyone is the same, for instance here in the pharmacy as they explain, one might think they are mad." (Participant 4)
Systemic Support and Resources	NHIF system process	Issues with NHIF processes, including errors and delays in approval, can delay treatment and medication access.	"Once it approves you go to NHIF show them the message and they put a sticker on your card then you now go to the pharmacy." (Participant 6)
	Medication availability and cost	Medication shortages or high costs negatively impact adherence to treatment regimens.	"They sent me home like three times." (Participant 9)
	Cost of doctor visit and treatment	High costs associated with treatment and consultations can discourage patients from continuing treatment.	"The problem is paying that 300 to save on time to get a doctor." (Participant 6)
	Availability of medication and cost	The cost and availability of medication directly affect patient adherence to their prescribed treatment plan.	"Why not import it before it runs out here?" (Participant 11)
Treatment Process and Experience	Surgical recommendation	The recommendation for surgery and its impact on patient adherence to the proposed treatment plan.	"After the results the doctor said I would undergo another surgery." (Participant 8)
	Post-surgery care and follow-up	Post-surgery care and follow-up is essential for ensuring adherence to the treatment plan.	"After the surgery a small tissue was taken for biopsy and told that these are the results." (Participant 4)
	Reassurance from healthcare provider	Emotional support and reassurance from healthcare providers during treatment increases adherence.	"He told me I was not going to die; I will live and take care of my children." (Participant 3)
	Suggestions for improving treatment efficiency	Improving treatment processes such as reducing waiting times can increase treatment adherence.	"Increasing the doctors and them coming in on time will help." (Participant 3)
	Support during treatment (e.g., emotional support)	Support during treatment, including encouragement and empathetic healthcare providers, fosters adherence.	"They really gave me hope, they told me that where I am coming from, I should try my best to finish." (Participant 9)

The quantitative and qualitative findings showed both convergence and divergence regarding health system factors influencing adherence. The analysis revealed a moderate association between monthly medical costs and adherence, but it was not statistically significant. Similarly, travel time and transport costs showed no

significant relationship. These findings contrast with the qualitative data, where patients highlighted the impact of financial and logistical challenges on adherence, such as struggles with transport costs. However, the quantitative results did show a significant association between missed refills due to cost and poor adherence, which aligned with qualitative accounts of financial difficulties. Overall, while the quantitative results were less significant in some areas, they confirmed the qualitative findings, particularly the role of financial strain in adherence.

CHAPTER FIVE: DISCUSSION

5.1 Introduction

The purpose of this chapter is to interpret the findings from the study on adherence to endocrine therapy among HR+ breast cancer patients at MTRH. The discussion chapter delves into the key determinants that influenced patients' adherence to treatment, such as sociodemographic factors, clinical characteristics, and health system-related challenges. By critically analyzing the quantitative and qualitative data, this chapter aims to explore the implications of these findings, compare them with existing literature, and provide a comprehensive understanding of the factors that enhance or hinder adherence to endocrine therapy. Additionally, this chapter discusses the significance of the study results in relation to healthcare practices, patient care, and adherence strategies at MTRH.

5.2 Adherence to Endocrine Therapy Among HR+ Breast Cancer Patients at MTRH

This study at MTRH revealed that 72.5% of patients demonstrated good adherence to endocrine therapy, as indicated by the mean score of 1 on the Voils DOSE non-adherence scale. This finding mirrors the global pattern of adherence to endocrine therapy, which has been reported to vary significantly, with non-adherence rates ranging from 4.3% to 65.4% (Onwusah et al., 2023). In high-income countries, despite clinical trials showing promising adherence rates, only 50% of patients complete the full five-year course of treatment (Chlebowski et al., 2014). The adherence rates at MTRH, while higher than some global norms, still reflect the complexity of the challenge, particularly when compared to studies from African contexts. For instance, a study in Sudan reported a 93% adherence rate for both tamoxifen and aromatase (Mohamed & Elamin, 2020b). This difference suggests that,

while adherence is generally higher in Africa, disparities in patient access, education, and health infrastructure still affect compliance. The findings at MTRH underscore the importance of addressing both medical and social factors to optimize adherence, as high adherence rates in some African countries indicate the potential for improvement with the right interventions.

Globally, the factors influencing adherence to endocrine therapy are multifaceted, involving side effects, patient attitudes, psychological factors, healthcare provider communication, and socioeconomic influences (Toivonen et al., 2020). This is consistent with findings from MTRH, where despite a majority of patients adhering to their prescribed therapy, 27.5% still struggled with non-adherence. In Sub-Saharan Africa, where health systems often face underdevelopment and financial challenges, studies have revealed that lack of social support and insufficient patient education are key barriers (Macquart de Terline et al., 2019). Similar findings were observed in Ethiopia, where financial hardship and limited healthcare resources contributed to lower adherence rates (Reibold et al., 2021). Despite these barriers, the implementation of nurse-led interventions and improvements in patient-provider relationships has been shown to enhance adherence (Fadelu et al., 2022). The results at MTRH are consistent with these findings, indicating that while some patients were able to adhere, many were still hindered by a lack of information and support.

Globally, research has consistently shown that racial, ethnic, and socioeconomic factors influence adherence patterns. For example, African American women, particularly in rural settings, have shown lower adherence to endocrine therapy compared to their European American counterparts (Heiney et al., 2020). At MTRH, adherence was generally high, but like many studies globally, the remaining 27.5% of

non-adherent patients demonstrate the continuing struggle with long-term therapy. Factors such as psychological distress, side effects, and the perceived necessity of treatment often lead to non-adherence, particularly in populations with lower health literacy (Hwang et al., 2020). This aligns with the findings at MTRH, where some patients' reluctance to continue treatment could stem from a lack of understanding about the importance of adherence. Research has also highlighted that self-efficacy and a positive decisional balance are strongly associated with better adherence (Toivonen et al., 2020). Improving patients' confidence in managing their treatment, coupled with reinforcing the benefits of long-term adherence, could potentially enhance the adherence rates at MTRH. Additionally, studies from other regions, such as the implementation of patient education strategies in Ethiopia, demonstrate that improving patient knowledge about therapy significantly boosts adherence rates (Wako et al., 2021). The findings at MTRH align with this, suggesting that a concerted effort on education could mitigate barriers to adherence, resulting in better patient outcomes.

5.3 Sociodemographic Factors as Determinants of Adherence

The bivariate analysis at MTRH highlighted significant associations between adherence to endocrine therapy and sociodemographic factors, notably age and education level. Specifically, patients in the 50-59 age group had significantly higher adherence rates, in line with findings from global studies that show middle-aged patients often adhere more successfully to treatment due to a greater focus on health and improved management of chronic conditions (Lailler et al., 2021; Meneveau et al., 2020). This aligns with literature that indicates that older patients are more likely to adhere to endocrine therapy compared to younger and elderly patients, often because of better health literacy and health-related decision-making processes

(Schmidt et al., 2024). Fertility concerns are a significant consideration for younger women diagnosed with hormone receptor-positive breast cancer, as endocrine therapy often requires prolonged treatment that may delay or compromise future childbearing (Lambertini et al., 2017). Similarly, education level emerged as a significant determinant, where individuals with higher levels of education showed better adherence to their prescribed regimens. This finding supports existing research, which suggests that education plays a critical role in improving health literacy and adherence to complex treatment plans (Haji-Hersi et al., 2022).

The MTRH study's qualitative data revealed that financial barriers—such as high costs of medications and transportation—were significant barriers to adherence, particularly when patients lacked financial support from their families. This finding resonates with global studies that report how financial hardships and treatment-related costs hinder adherence to endocrine therapy (Haji-Hersi et al., 2022; Ingwu et al., 2019). For instance, some patients at MTRH voiced concerns about the financial strain of treatment, with one patient stating, "Ksh. 250 is a lot of money" (Participant 11). While the quantitative analysis did not reveal a statistically significant association between monthly income and adherence, the qualitative interviews strongly underscored financial burden as a critical barrier, suggesting that quantitative metrics may not fully capture the lived experience of financial strain. Similarly, family support, both emotional and financial, played a crucial role in improving adherence. Patients who received support from their families, either through reminders or financial help, were more likely to adhere to their prescribed treatment regimens. This is consistent with findings from studies that highlight the positive impact of family involvement in medication adherence (Yussof et al., 2022). Interestingly, the lack of

family support was also associated with poor adherence, emphasizing the critical role of emotional and social support in managing long-term therapy.

Psychosocial factors, including emotional stress, societal stigma, and patient-provider relationships, also emerged as significant factors influencing adherence at MTRH. While the quantitative results highlighted age and education as significant predictors, the qualitative data suggested that emotional distress related to the cost of treatment, societal stigma, and the lack of family support could contribute to non-adherence. Many patients expressed feelings of frustration and stress due to the high cost of their treatment, with one patient stating, "It has no side effects on me, it only just stresses me out when I do not have money" (Participant 9). These findings align with research indicating that emotional and psychological factors, such as depression and anxiety, can significantly affect adherence to medical treatments (Wako et al., 2021). Moreover, patient-provider communication was identified as a critical factor in improving adherence, with patients reporting that clear and empathetic communication from healthcare providers led to better understanding and greater willingness to adhere to the treatment regimen (Sutton et al., 2020). Despite the lack of significant associations between marital status or occupation and adherence in the quantitative data, the qualitative findings underscore that family involvement and work-related challenges, particularly in demanding jobs, can influence adherence. These insights suggest that healthcare interventions aimed at improving adherence should not only address the clinical aspects of treatment but also provide psychological and emotional support to patients, enhance communication with healthcare providers, and reduce financial barriers. This holistic approach could significantly improve medication adherence and overall patient outcomes.

5.4 Clinical Factors as Determinants of Adherence

The bivariate and multivariate regression analyses at MTRH revealed several key clinical factors influencing adherence to endocrine therapy, particularly the duration of breast cancer diagnosis, disease stage at diagnosis, performance status, and medication type. Patients diagnosed at later stages, particularly Stage III ($p = 0.026$), were more likely to adhere to treatment. This could be explained by the increased urgency and perceived necessity of treatment in advanced disease stages, which is consistent with the findings of Yang et al. (2023), who found that patients in advanced stages of cancer are generally more committed to adhering to prescribed treatments due to the severity of their condition. Furthermore, performance status (PS 0: normal activity) was associated with higher adherence ($p = 0.016$), in line with literature suggesting that a better functional status correlates with improved treatment adherence (Yussof et al., 2022).

Medication-related factors were also found to significantly affect adherence. The use of Anastrozole was associated with better adherence ($p = 0.016$), highlighting the impact of medication choice on treatment compliance. Anastrozole, an aromatase inhibitor, is known for having fewer and less severe side effects than other medications such as tamoxifen, which has been associated with significant adverse effects (Sawesi et al., 2014; Brett et al., 2018). This finding is supported by literature suggesting that medications with manageable side effects tend to result in better adherence, as patients are more likely to stay on treatment if side effects are minimal (Verma et al., 2011). On the other hand, the availability of medication and the issue of running out of medication were strongly linked to non-adherence ($p = 0.000$), emphasizing how disruptions in medication supply can lead to interruptions in treatment. This observation aligns with studies in developing countries, where

inconsistent access to medication due to shortages or high costs is a significant barrier to adherence (Haji-Hersi et al., 2021; Montagna et al., 2021). The qualitative findings further reinforced this, with patients reporting that delays in obtaining medication due to financial constraints or stock-outs often led to gaps in treatment, ultimately affecting adherence.

Both quantitative and qualitative data indicated that psychosocial and disease-related factors, such as emotional readiness and disease severity, significantly impacted adherence. The multivariate analysis identified that patients with longer breast cancer diagnosis histories (more than 10 years) were less likely to adhere ($p = 0.042$). This could be explained by patients with longer treatment histories having treatment fatigue, evolving life circumstances and changing risk perceptions (Brett et al., 2018). Additionally, patients diagnosed at later stages (Stage III) were more likely to adhere, reflecting a shared understanding that more advanced disease may increase the urgency to adhere to treatment (Yang et al., 2023). The emotional toll of the disease, including symptoms like pain and physical changes, was also a significant barrier. Qualitative data revealed that patients who experienced severe pain or physical changes due to the disease were less likely to adhere to treatment. These findings align with studies that indicate that physical symptoms and the burden of illness can significantly reduce adherence, as patients may prioritize symptom relief over continued treatment (Brett et al., 2018; Toivonen et al., 2020).

Furthermore, psychological and family-related factors played a key role in adherence. Patients who felt emotionally ready to start treatment or had strong family support were more likely to adhere, reinforcing the idea that emotional readiness and social support are critical for long-term adherence (Yussof et al., 2022). Conversely, patients who experienced initial shock or lacked family support were more likely to struggle

with treatment adherence, highlighting the significant role of psychosocial factors (Wako et al., 2021). This is consistent with existing literature, which suggests that emotional and social support, along with intrinsic motivation, plays a crucial role in enhancing adherence (Haji-Hersi et al., 2021; Yussof et al., 2022).

5.5 Health System Factors as Determinants of Adherence

The role of health system factors in determining adherence to endocrine therapy is pivotal, especially in resource-limited settings like Kenya. In this study, the quantitative analysis suggested an association between adherence and monthly medical costs ($p = 0.084$), though the relationship was not statistically significant. However, the qualitative data consistently pointed to financial barriers, with patients citing high medication costs as a significant factor in non-adherence. One patient explained, "The drug is not available here, I usually suffer a lot because when I send for it in Nairobi it necessitates using cash" (Participant 3). This finding aligns with existing literature that highlights how financial constraints, including treatment costs and lack of access to affordable medication, significantly hinder adherence, especially in low-income countries (Brett et al., 2018; Gbenonsi et al., 2021). The relationship between medical costs and adherence is complex, as some patients may not consider medication to be a priority when faced with competing financial demands (Yang et al., 2023).

While travel time and transport costs showed no significant association with adherence ($p = 0.458$ and $p = 0.634$, respectively), the qualitative data revealed that logistical barriers were a major concern for patients. One patient expressed, "With the costs I incur while seeking treatment, it would be easier if I could get the treatment closer to home" (Participant 2). This observation underscores the significant impact of travel time and transport costs on patients' ability to consistently attend appointments

and adhere to medication schedules. Literature consistently supports the notion that patients residing in rural areas or those without access to transportation face significant challenges in adhering to treatment regimens (Brett et al., 2018; Petricca et al., 2023). These logistical factors, while not statistically significant in this study, must be considered as potential barriers to adherence that could be addressed through improved access to healthcare facilities and transportation.

The analysis revealed a strong association between missed refills or appointments due to cost and non-adherence ($\chi^2 = 103.222$, $p = 0.000$). This finding was further reinforced by the multivariate analysis, where patients who missed appointments due to financial strain were significantly more likely to demonstrate poor adherence (OR = 0.082, $p = 0.001$). The qualitative data also highlighted the critical role of financial support in ensuring continuity of treatment. For instance, one patient shared, "During the surgery, my child, the one who used to work in Medihill is the one who helped me a lot" (Participant 5). Financial barriers like these directly impact treatment adherence, and this study's findings are consistent with literature that points to missed appointments and delayed refills as a significant contributor to poor adherence (Gbenonsi et al., 2021; Yang et al., 2023). Additionally, the availability of financial support, either from family or community resources, was crucial for some patients in overcoming these barriers, as shown in the qualitative data.

The qualitative data revealed that trust in healthcare institutions and strong patient-provider relationships positively impacted adherence. Patients who felt confident in the healthcare system were more likely to adhere to prescribed treatments. As one patient stated, "I trusted the institution... the procedures were so many" (Participant 1). This is consistent with literature that emphasizes the role of healthcare system trust in improving adherence, as patients who trust their healthcare providers are more

likely to follow treatment plans (Brett et al., 2018; Wako et al., 2021). Additionally, positive doctor-patient relationships, characterized by respect and clear communication, were seen as vital for encouraging adherence (Yang et al., 2023). One patient reported, "The doctors are respectful people and they understand because I ask the doctor a lot of questions" (Participant 4), indicating that good communication fosters adherence by reducing patient concerns and increasing confidence in treatment plans.

However, the study also revealed significant challenges within the healthcare system that affected adherence. Delays in treatment, long queues, and issues with the NHIF system were frequently mentioned by patients as barriers to timely treatment. As one patient explained, "The line was really long... I was helped by another and got a doctor for registration" (Participant 5). These delays and administrative inefficiencies align with literature highlighting that poor management, such as long wait times and system-related delays, can disrupt treatment adherence (Murphy et al., 2012; Petricca et al., 2023). Additionally, communication issues, such as being "brushed off" by staff, were cited as barriers to effective treatment (Participant 1). These findings reflect research that underscores the need for better patient-provider communication and more efficient healthcare system processes to improve adherence (Brett et al., 2018). Addressing these issues through policies that promote healthcare accessibility and affordability is essential for improving adherence and overall treatment outcomes.

5.6 Study Strengths and Limitations

This study possesses several strengths as well as notable limitations. Its cross-sectional design enabled the capture of a snapshot of current endocrine therapy use; however, a longitudinal follow-up would provide more comprehensive insights into therapy persistence and completion. Additionally, adherence was assessed through

patient self-report rather than more objective measures such as electronic medication monitoring, drug level assessments, or pharmacy refill data, introducing the potential for social desirability and recall bias. Nevertheless, the application of a robust sequential explanatory mixed-methods design facilitated an in-depth exploration of the complex factors influencing patient behavior and adherence. Moreover, while self-reported measures have inherent limitations, they remain a practical and comparatively reliable approach, offering a feasible means of integrating adherence assessment into routine clinical care (Gellad et al., 2017).

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusions

6.1.1 Adherence to Therapy

The findings from the study indicated that a significant proportion of HR+ breast cancer patients at MTRH demonstrated good adherence to endocrine therapy, with the majority consistently following their prescribed treatment. Trust in the healthcare system and positive doctor-patient relationships were central to improving adherence. While most patients adhered to their prescribed medication regimens, barriers such as financial constraints and lack of family support still posed challenges to some, highlighting the need for improved support systems and education to foster consistent adherence.

6.1.2 Determinants of Adherence to Therapy

6.1.2.1 Sociodemographic Factors as Determinants of Adherence

Sociodemographic factors, particularly age and education level, were found to influence adherence levels. Older patients and those with higher levels of education were more likely to adhere to their treatment regimens. However, socioeconomic factors, such as financial constraints and the availability of family support, were significant barriers for many patients. Financial strain, in particular, was a recurring theme, with many participants citing treatment costs as a barrier to adherence. This suggested that addressing financial barriers and enhancing family involvement in patient care could improve adherence outcomes.

6.1.2.2 Clinical Factors as Determinants of Adherence

Clinical factors, such as the duration of breast cancer diagnosis and the stage at diagnosis, played a critical role in influencing adherence. Patients diagnosed at later

stages, particularly Stage III, were more likely to adhere to treatment, possibly due to a heightened sense of the seriousness of their condition. The study also revealed that side effects from medications, although common, were managed in various ways by patients, with some avoiding information on side effects to better cope. These findings suggested that providing additional support for patients managing side effects and offering targeted interventions based on clinical characteristics might improve adherence.

6.1.2.3 Health System Factors Affecting Adherence

Health system factors, including treatment costs, healthcare access, and administrative delays, were determinants of adherence. The study found that high treatment costs, particularly for medications, were a substantial barrier to adherence, as patients struggled with affordability. Additionally, long travel times and healthcare system delays, such as long queues and poor communication, compounded these challenges. While the healthcare system was trusted by many patients, the logistical and financial challenges associated with accessing care suggested that improving system efficiencies and addressing financial barriers could lead to better treatment adherence.

6.2 Recommendations

To address the influence of sociodemographic factors such as age, education, and financial strain, it is recommended that healthcare systems implement tailored interventions for different age groups and education levels. For instance, elderly patients and those with lower education levels could benefit from additional counseling and educational resources to ensure better understanding and adherence to treatment regimens. Stakeholders, including policymakers and healthcare managers, should also address the financial barriers by introducing financial aid programs or partnerships with organizations that can help subsidize treatment costs for lower-

income patients. Furthermore, strengthening family involvement in patient care through education programs and support networks could enhance treatment adherence.

Healthcare providers should focus on providing personalized care based on clinical factors such as the duration and stage of breast cancer diagnosis. As patients diagnosed at later stages are more likely to adhere to treatment, interventions should be designed to increase awareness about the importance of adherence for early-stage patients.

Additionally, it is recommended that healthcare providers offer more robust support for managing medication side effects, including clearer communication about side effects and strategies for coping. Stakeholders in the healthcare sector should invest in training staff to support patients in managing side effects, and providing timely interventions, such as nutritional support or counseling, could help improve adherence.

REFERENCES

Adewale Adeoye, P. (2023). Epidemiology of Breast Cancer in Sub-Saharan Africa. In *Breast Cancer Updates*. IntechOpen.

Ahmad, A. (2019). Breast Cancer Statistics: Recent Trends. In *Advances in Experimental Medicine and Biology* (pp. 1–7). Springer International Publishing.

Alnaim, L. (2022). Health-Related Quality of Life in Women with Breast Cancer Undergoing Treatment with Hormonal Therapy – A Review Study. *European Journal of Breast Health*, *18*(4), 292–298.

Alsammak, M., & Khattabi, M. (2023). Breast cancer screening a literature review. *International Journal of Community Medicine and Public Health*, *10*(11), 4473–4479.

Barba, D., León-Sosa, A., Lugo, P., Suquillo, D., Torres, F., Surre, F., Trojman, L., & Caicedo, A. (2021). Breast cancer, screening and diagnostic tools: All you need to know. *Critical Reviews in Oncology/Hematology*, *157*, 103174.

Barroso-Sousa, R., Fonseca Reis Silva, D. DA, Machado Alessi, J. V., & Mano, M. S. (2016). Neoadjuvant endocrine therapy in breast cancer: current role and future perspectives. *Ecancermedicalscience*, *10*.

Bray, F., Laversanne, M., Sung, H., Ferlay, J., Siegel, R. L., Soerjomataram, I., & Jemal, A. (2024). Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA: A Cancer Journal for Clinicians*, *74*(3), 229–263.

Brett, J., Boulton, M., Fenlon, D., Hulbert-Williams, N. J., Walter, F. M., Donnelly, P., Lavery, B., Morgan, A., Morris, C., & Watson, E. (2018). Adjuvant endocrine therapy after breast cancer: a qualitative study of factors associated with adherence. *Patient Preference and Adherence*, *Volume 12*, 291–300.

Brett, J., Fenlon, D., Boulton, M., Hulbert-Williams, N. J., Walter, F. M., Donnelly, P., Lavery, B., Morgan, A., Morris, C., & Watson, E. (2018). Factors associated with intentional and unintentional non-adherence to adjuvant endocrine therapy following breast cancer. *European Journal of Cancer Care*, *27*(1), e12601.

Bujang, M. A., Sa'at, N., Tg Abu Bakar Sidik, T. M. I., & Chien Joo, L. (2018). Sample Size Guidelines for Logistic Regression from Observational Studies with Large Population: Emphasis on the Accuracy Between Statistics and Parameters Based on Real Life Clinical Data. *Malaysian Journal of Medical Sciences*, *25*(4), 122–130.

Cavazza, M., Banks, H., Ercolanoni, M., Cukaj, G., Bianchi, G., Capri, G., & Longo, F. (2020). Factors influencing adherence to adjuvant endocrine therapy in breast cancer-treated women: using real-world data to inform a switch from acute to chronic disease management. *Breast Cancer Research and Treatment*, *183*(1), 189–199.

Chlebowski, R. T., Kim, J., & Haque, R. (2014). Adherence to Endocrine Therapy in Breast Cancer Adjuvant and Prevention Settings. *Cancer Prevention Research*, *7*(4), 378–387.

Collin, L. J., Cronin-Fenton, D. P., Ahern, T. P., Goodman, M., McCullough, L. E., Waller, L. A., Kjærsgaard, A., Damkier, P., Christiansen, P. M., Ejlertsen, B., Jensen, M.-B., Sørensen, H. T., & Lash, T. L. (2021). Early Discontinuation of Endocrine Therapy and Recurrence of Breast Cancer among Premenopausal Women. *Clinical Cancer Research*, *27*(5), 1421–1428.

Concato, J., Peduzzi, P., Holford, T. R., & Feinstein, A. R. (1995). Importance of events per independent variable in proportional hazards analysis I. Background, goals, and general strategy. *Journal of Clinical Epidemiology*, *48*(12), 1495–1501.

Coughlin, S. S. (2019). *Epidemiology of Breast Cancer in Women* (pp. 9–29).

Davies, S., & Voutsadakis, I. A. (2022). Adherence to adjuvant hormonal therapy in localised breast cancer. *European Journal of Cancer Care*, *31*(6).

Destounis, S., & Santacroce, A. (2018). Age to Begin and Intervals for Breast Cancer Screening: Balancing Benefits and Harms. *American Journal of Roentgenology*, *210*(2), 279–284.

Fadelu, T. A., Buswell, L., & Anderson, B. O. (2022). Improving Adherence to Adjuvant Endocrine Therapy in Sub-Saharan Africa: Challenges and Innovative Nurse-Driven Solutions. *The Oncologist*, *27*(8), 607–609.

FENGA, C. (2016). Occupational exposure and risk of breast cancer. *Biomedical Reports*, *4*(3), 282–292.

Fetensa, G., Yadecha, B., Tolossa, T., & Bekuma, T. T. (2019). Medication Adherence and Associated Factors among Chronic Heart Failure Clients on Follow Up Oromia Region, West Ethiopia. *Cardiovascular & Hematological Agents in Medicinal Chemistry*, *17*(2), 104–114.

Gakunga, R., Ali, Z., Korir, A., Kinyanjui, A. W., Ochieng', E., Gikaara, N., Maluni, F., & Subramanian, S. (2019). Social determinants and individual health-seeking behaviour among women in Kenya: protocol for a breast cancer cohort feasibility study. *BMJ Open*, *9*(1), e023171. H

Gao, J. J., Cheng, J., Prowell, T. M., Bloomquist, E., Tang, S., Wedam, S. B., Royce, M., Krol, D., Osgood, C., Ison, G., Sridhara, R., Pazdur, R., Beaver, J. A., & Amiri-Kordestani, L. (2021). Overall survival in patients with hormone receptor-positive, HER2-negative, advanced or metastatic breast cancer treated with a cyclin-dependent kinase 4/6 inhibitor plus fulvestrant: a US Food and Drug Administration pooled analysis. *The Lancet Oncology*, *22*(11), 1573–1581.

García-Sancha, N., Corchado-Cobos, R., & Pérez-Losada, J. (2025). Understanding Susceptibility to Breast Cancer: From Risk Factors to Prevention Strategies. *International Journal of Molecular Sciences*, *26*(7), 2993.

Gbenonsi, G., Boucham, M., Belrhiti, Z., Nejjari, C., Huybrechts, I., & Khalis, M. (2021). Health system factors that influence diagnostic and treatment intervals in women with breast cancer in sub-Saharan Africa: a systematic review. *BMC Public Health*, *21*(1), 1325.

Gellad, W. F., Thorpe, C. T., Steiner, J. F., & Voils, C. I. (2017). The myths of medication adherence. *Pharmacoepidemiology and Drug Safety*, *26*(12), 1437–1441.

Genberg, B. L., Wachira, J., Steingrimsson, J. A., Pastakia, S., Tran, D. N. T., Said, J. A., Braitstein, P., Hogan, J. W., Vedanthan, R., Goodrich, S., Kafu, C., Wilson-Barthes, M., & Galárraga, O. (2021). Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomised trial. *BMJ Open*, *11*(5), e042662.

Glassman, D., H., S., R., R., L., & M., S. (2017). Adjuvant Endocrine Therapy for Hormone-positive Breast Cancer, Focusing on Ovarian Suppression and Extended Treatment: An Update. *Anticancer Research*, *37*(10).

Haji-Hersi, M. F., Tilley, S., Shelton, C. A., Lamb, N., & Kamdem, L. K. (2022). Drug- and patient-related factors are the strongest predictors of endocrine therapy adherence in breast cancer patients. *Journal of Oncology Pharmacy Practice*, *28*(5), 1070–1076.

Haque, Md. M., & Desai, K. V. (2019). Pathways to Endocrine Therapy Resistance in Breast Cancer. *Frontiers in Endocrinology*, *10*.

Heiney, S. P., Truman, S., Babatunde, O. A., Felder, T. M., Eberth, J. M., Crouch, E., Wickersham, K. E., & Adams, S. A. (2020). Racial and Geographic Disparities in Endocrine Therapy Adherence Among Younger Breast Cancer Survivors. *American Journal of Clinical Oncology*, *43*(7), 504–509.

https://www.health.go.ke/kenya-officially-launch-social-health-authority-october-1-2024. (n.d.).

Hwang, G. S., Paranjpe, R., Opsomer, C., Lu, K., Abajue, U., Abughosh, S., Zaghloul, H., & Trivedi, M. V. (2020). Oral Endocrine Therapy Agent, Race/Ethnicity, and Time on Therapy Predict Adherence in Breast Cancer Patients in a Large Academic Institution. *Clinical Breast Cancer*, *20*(6), 520–526.

Jelínek, L., Václavík, J., Ramík, Z., Pavlů, L., Benešová, K., Jarkovský, J., Lazárová, M., Janečková, H., Spurná, J., & Táborský, M. (2021). Directly Measured Adherence to Treatment in Chronic Heart Failure: LEVEL-CHF Registry. *The American Journal of the Medical Sciences*, *361*(4), 491–498.

Khan, R., Kaul, P., Islam, S., Savu, A., Bagai, A., van Diepen, S., Bainey, K. R., Welsh, R. C., & Goodman, S. G. (2021). Drug Adherence and Long-Term Outcomes in Non-Revascularized Patients Following Acute Myocardial Infarction. *The American Journal of Cardiology*, *152*, 49–56.

Korde, L. A., Somerfield, M. R., Carey, L. A., Crews, J. R., Denduluri, N., Hwang, E. S., Khan, S. A., Loibl, S., Morris, E. A., Perez, A., Regan, M. M., Spears, P. A., Sudheendra, P. K., Symmans, W. F., Yung, R. L., Harvey, B. E., & Hershman, D. L. (2021). Neoadjuvant Chemotherapy, Endocrine Therapy, and Targeted Therapy for Breast Cancer: ASCO Guideline. *Journal of Clinical Oncology*, *39*(13), 1485–1505.

Krauss, K., & Stickeler, E. (2020). Endocrine Therapy in Early Breast Cancer. *Breast Care*, *15*(4), 337–346.

Lailler, G., Memoli, V., Le Bihan Benjamin, C., Ben Diane, M.-K., Lauzier, S., Mancini, J., Bousquet, P. J., & Bouhnik, A.-D. (2021). Five-Year Adjuvant Endocrine Therapy Adherence Trajectories Among Women with Breast Cancer: A Nationwide French Study Using Administrative Data. *Clinical Breast Cancer*, *21*(4), e415–e426.

Lambertini, M., Goldrat, O., Clatot, F., Demeestere, I., & Awada, A. (2017). Controversies about fertility and pregnancy issues in young breast cancer patients: current state of the art. *Current Opinion in Oncology*, *29*(4), 243–252.

Ling, R. Z. Q., Jiao, N., Hassan, N. B., He, H., & Wang, W. (2020). Adherence to diet and medication and the associated factors among patient with chronic heart failure in a multi-ethnic society. *Heart & Lung*, *49*(2), 144–150.

Liu, H., Shi, S., Gao, J., Guo, J., Li, M., & Wang, L. (2022). Analysis of risk factors associated with breast cancer in women: a systematic review and meta-analysis. *Translational Cancer Research*, *11*(5), 1344–1353.

Łukasiewicz, S., Czeczelewski, M., Forma, A., Baj, J., Sitarz, R., & Stanisławek, A. (2021). Breast Cancer—Epidemiology, Risk Factors, Classification, Prognostic Markers, and Current Treatment Strategies—An Updated Review. *Cancers*, *13*(17), 4287.

Lund, L. W., Ammitzbøll, G., Hansen, D. G., Andersen, E. A. W., & Dalton, S. O. (2019). Adherence to a long-term progressive resistance training program, combining supervised and home-based exercise for breast cancer patients during adjuvant treatment. *Acta Oncologica*, *58*(5), 650–657.

Macharia, L. W., Mureithi, M. W., & Anzala, O. (2019). Cancer in Kenya: types and infection-attributable. Data from the adult population of two National referral hospitals (2008-2012). *AAS Open Research*, *1*, 25.

Macquart de Terline, D., Kane, A., Kramoh, K. E., Ali Toure, I., Mipinda, J. B., Diop, I. B., Nhavoto, C., Balde, D. M., Ferreira, B., Dèdonougbo Houenassi, M., Ikama, M. S., Kingue, S., Kouam Kouam, C., Takombe, J. L., Limbole, E., Mfeukeu Kuate, L., N'guetta, R., Damorou, J. M., Sesso, Z., … Antignac, M. (2019). Factors associated with poor adherence to medication among hypertensive patients in twelve low and middle income Sub-Saharan countries. *PLOS ONE*, *14*(7), e0219266.

Mann, R. M., Hooley, R., Barr, R. G., & Moy, L. (2020). Novel Approaches to Screening for Breast Cancer. *Radiology*, *297*(2), 266–285.

Mao, X., Omeogu, C., Karanth, S., Joshi, A., Meernik, C., Wilson, L., Clark, A., Deveaux, A., He, C., Johnson, T., Barton, K., Kaplan, S., & Akinyemiju, T. (2023). Association of reproductive risk factors and breast cancer molecular subtypes: a systematic review and meta-analysis. *BMC Cancer*, *23*(1), 644.

Meneveau, M. O., Keim-Malpass, J., Camacho, T. F., Anderson, R. T., & Showalter, S. L. (2020). Predicting adjuvant endocrine therapy initiation and adherence among older women with early-stage breast cancer. *Breast Cancer Research and Treatment*, *184*(3), 805–816.

Mercer, T., Njuguna, B., Bloomfield, G. S., Dick, J., Finkelstein, E., Kamano, J., Mwangi, A., Naanyu, V., Pastakia, S. D., Valente, T. W., Vedanthan, R., & Akwanalo, C. (2019). Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS) in western Kenya: a study protocol of a cluster randomized trial. *Trials*, *20*(1), 554.

Miaskowski, C., Shockney, L., & Chlebowski, R. T. (2008). Adherence to Oral Endocrine Therapy for Breast Cancer: A Nursing Perspective. *Clinical Journal of Oncology Nursing*, *12*(2), 213–221.

Milosevic, M., Jankovic, D., Milenkovic, A., & Stojanov, D. (2018). Early diagnosis and detection of breast cancer. *Technology and Health Care*, *26*(4), 729–759.

Mohamed, K. E. H., & Elamin, A. (2020a). Adherence to endocrine therapy and its relation to disease-free survival among breast cancer patients visiting an out-patient clinic at Khartoum Oncology Hospital, Sudan. *Journal of Evaluation in Clinical Practice*, *26*(6), 1731–1743.

Mohamed, K. E. H., & Elamin, A. (2020b). Adherence to endocrine therapy and its relation to disease-free survival among breast cancer patients visiting an out-patient clinic at Khartoum Oncology Hospital, Sudan. *Journal of Evaluation in Clinical Practice*, *26*(6), 1731–1743.

Montagna, E., Zagami, P., Masiero, M., Mazzocco, K., Pravettoni, G., & Munzone, E. (2021). Assessing Predictors of Tamoxifen Nonadherence in Patients with Early Breast Cancer. *Patient Preference and Adherence*, *Volume 15*, 2051–2061.

Murphy, C. C., Bartholomew, L. K., Carpentier, M. Y., Bluethmann, S. M., & Vernon, S. W. (2012). Adherence to adjuvant hormonal therapy among breast cancer survivors in clinical practice: a systematic review. *Breast Cancer Research and Treatment*, *134*(2), 459–478.

Nabieva, N., & Fasching, P. (2021). Endocrine Treatment for Breast Cancer Patients Revisited—History, Standard of Care, and Possibilities of Improvement. *Cancers*, *13*(22), 5643.

O'Neil, D. S., Chen, W. C., Ayeni, O., Nietz, S., Buccimazza, I., Singh, U., Čačala, S., Stopforth, L., Joffe, M., Crew, K. D., Jacobson, J. S., Neugut, A. I., Ruff, P., & Cubasch, H. (2019). Breast Cancer Care Quality in South Africa's Public Health System: An Evaluation Using American Society of Clinical Oncology/National Quality Forum Measures. *Journal of Global Oncology*, *5*, 1–16.

Paranjpe, R., John, G., Trivedi, M., & Abughosh, S. (2019). Identifying adherence barriers to oral endocrine therapy among breast cancer survivors. *Breast Cancer Research and Treatment*, *174*(2), 297–305.

Peduzzi, P., Concato, J., Feinstein, A. R., & Holford, T. R. (1995). Importance of events per independent variable in proportional hazards regression analysis II. Accuracy and precision of regression estimates. *Journal of Clinical Epidemiology*, *48*(12), 1503–1510.

Petricca, K., Kambugu, J., Githang'a, J., Macharia, W. M., Njuguna, F., McLigeyo, A., Nyangasi, M., Orem, J., Kanyamuhunga, A., Laiti, R., Katabalo, D., Schroeder, K., Rogo, K., Maguire, B., Wambui, L., Nkurunziza, J. N., Wong, B., Neposlan, J., Kilawe, L., … Denburg, A. E. (2023). Access to essential cancer medicines for children: a comparative mixed-methods analysis of availability, price, and health-system determinants in east Africa. *The Lancet Oncology*, *24*(5), 563–576.

Ramashia, P. N., Nkosi, P. B., & Mbonane, T. P. (2024). Barriers to Radiotherapy Access in Sub-Saharan Africa for Patients with Cancer: A Systematic Review. *International Journal of Environmental Research and Public Health*, *21*(12), 1597.

Reibold, C. F., Tariku, W., Eber-Schulz, P., Getachew, S., Addisie, A., Unverzagt, S., Wienke, A., Hauptmann, S., Wickenhauser, C., Vetter, M., Jemal, A., Thomssen, C., & Kantelhardt, E. J. (2021). Adherence to Newly Implemented Tamoxifen Therapy for Breast Cancer Patients in Rural Western Ethiopia. *Breast Care*, *16*(5), 484–490.

Roheel, A., Khan, A., Anwar, F., Akbar, Z., Akhtar, M. F., Imran Khan, M., Sohail, M. F., & Ahmad, R. (2023). Global epidemiology of breast cancer based on risk factors: a systematic review. *Frontiers in Oncology*, *13*.

Rugo, H. S., Li, H., & Gui, X. (2017). Strategies and Progress of Endocrine Therapy for Patients with Metastatic Breast Cancer. In *Advances in Experimental Medicine and Biology* (pp. 403–418). Springer Singapore.

Sawesi, S., Carpenter, J. S., & Jones, J. (2014). Reasons for Nonadherence to Tamoxifen and Aromatase Inhibitors for the Treatment of Breast Cancer: A Literature Review. *Clinical Journal of Oncology Nursing*, *18*(3), E50–E57.

Sayed, S., Fan, S., Moloo, Z., Wasike, R., Bird, P., Saleh, M., Shaikh, A. J., Figueroa, J. D., Naidoo, R., Makokha, F. W., Gardner, K., Oigara, R., Njoroge, F. W., Magangane, P., Mutebi, M., Chauhan, R., Mwanzi, S., Govender, D., & Yang,

X. R. (2021). Breast cancer risk factors in relation to molecular subtypes in breast cancer patients from Kenya. *Breast Cancer Research*, *23*(1), 68.

Sayed, S., Moloo, Z., Wasike, R., Bird, P., Oigara, R., Govender, D., Kibera, J., Carrara, H., & Saleh, M. (2014). Is breast cancer from Sub Saharan Africa truly receptor poor? Prevalence of ER/PR/HER2 in breast cancer from Kenya. *The Breast*, *23*(5), 591–596.

Sayed, S., Ngugi, A. K., Mahoney, M. R., Kurji, J., Talib, Z. M., Macfarlane, S. B., Wynn, T. A., Saleh, M., Lakhani, A., Nderitu, E., Agoi, F., Premji, Z., Zujewski, J. A., & Moloo, Z. (2019). Breast Cancer knowledge, perceptions and practices in a rural Community in Coastal Kenya. *BMC Public Health*, *19*(1), 180.

Schmidt, J. A., Woolpert, K. M., Hjorth, C. F., Farkas, D. K., Ejlertsen, B., & Cronin-Fenton, D. (2024). Social Characteristics and Adherence to Adjuvant Endocrine Therapy in Premenopausal Women with Breast Cancer. *Journal of Clinical Oncology*, *42*(28), 3300–3307.

Seely, J. M., & Alhassan, T. (2018). Screening for Breast Cancer in 2018—What Should We be Doing Today? *Current Oncology*, *25*(11), 115–124.

Shah, T., & Guraya, S. (2017). Breast cancer screening programs: Review of merits, demerits, and recent recommendations practiced across the world. *Journal of Microscopy and Ultrastructure*, *5*(2), 59.

Smith, S. G., Green, S. M. C., Ellison, R., Foy, R., Graham, C. D., Mason, E., French, D. P., Hall, L. H., Wilkes, H., McNaught, E., Raine, E., Walwyn, R., Howdon, D., Clark, J., Rousseau, N., Buxton, J., Moore, S. J. L., Parbutt, C., Velikova, G., … Collinson, M. (2023). Refining and optimising a behavioural intervention to support endocrine therapy adherence (ROSETA) in UK women with breast cancer: protocol for a pilot fractional factorial trial. *BMJ Open*, *13*(2), e069971.

Sutton, A. L., Salgado, T. M., He, J., Hurtado-de-Mendoza, A., & Sheppard, V. B. (2020). Sociodemographic, clinical, psychosocial, and healthcare-related factors associated with beliefs about adjuvant endocrine therapy among breast cancer survivors. *Supportive Care in Cancer*, *28*(9), 4147–4154.

Terry, M. B., & Colditz, G. A. (2023). Epidemiology and Risk Factors for Breast Cancer: 21st Century Advances, Gaps to Address through Interdisciplinary Science. *Cold Spring Harbor Perspectives in Medicine*, *13*(9), a041317.

Thomas, R., Rowell, R., Crichton, S., & Cain, H. (2018). Patients electing to have PET rather than surgery for operable breast cancer are a high risk of treatment failure. *Breast Cancer Research and Treatment*, *172*(3), 597–601.

Toivonen, K., Williamson, T., Carlson, L., Walker, L., & Campbell, T. (2020). Potentially Modifiable Factors Associated with Adherence to Adjuvant Endocrine Therapy among Breast Cancer Survivors: A Systematic Review. *Cancers*, *13*(1), 107.

Tonorezos, E., Devasia, T., Mariotto, A. B., Mollica, M. A., Gallicchio, L., Green, P., Doose, M., Brick, R., Streck, B., Reed, C., & de Moor, J. S. (2024). Prevalence of cancer survivors in the United States. *JNCI: Journal of the National Cancer Institute*, *116*(11), 1784–1790.

Verma, S., Madarnas, Y., Sehdev, S., Martin, G., & Bajcar, J. (2011). Patient Adherence to Aromatase Inhibitor Treatment in the Adjuvant Setting. *Current Oncology*, *18*(10), 3–9.

Voils, C. I., King, H. A., Thorpe, C. T., Blalock, D. V., Kronish, I. M., Reeve, B. B., Boatright, C., & Gellad, Z. F. (2019). Content Validity and Reliability of a Self-Report Measure of Medication Nonadherence in Hepatitis C Treatment. *Digestive Diseases and Sciences*, *64*(10), 2784–2797.

Voutsadakis, I., & Davies, S. (2022). 224P Adherence to adjuvant hormonal therapy in patients with localized breast cancer. *Annals of Oncology*, *33*, S228.

Wako, Z., Mengistu, D., Dinegde, N. G., Asefa, T., & Wassie, M. (2021). Adherence to Adjuvant Hormonal Therapy and Associated Factors Among Women with Breast Cancer Attending the Tikur Anbessa Specialized Hospital, Addis Ababa Ethiopia, 2019: A Cross-sectional Study. *Breast Cancer: Targets and Therapy*, *Volume 13*, 383–392.

Yang, S., Park, S. W., Bae, S. J., Ahn, S. G., Jeong, J., & Park, K. (2023). Investigation of Factors Affecting Adherence to Adjuvant Hormone Therapy in Early-Stage Breast Cancer Patients: A Comprehensive Systematic Review. *Journal of Breast Cancer*, *26*(4), 309.

Yazdani, A., & Haghighat, S. (2022). Determining Prognostic Factors of Disease-Free Survival in Breast Cancer Using Censored Quantile Regression. *Breast Cancer: Basic and Clinical Research*, *16*, 117822342211080.

Yussof, I., Mohd Tahir, N. A., Hatah, E., & Mohamed Shah, N. (2022). Factors influencing five-year adherence to adjuvant endocrine therapy in breast cancer patients: A systematic review. *The Breast*, *62*, 22–35.

APPENDIX

Appendix 1: STUDY DATA COLLECTION FORM

Code Number:

Adherence to Endocrine Therapy in Hormone Receptor Positive Breast Cancer

1. Date of enrollment: __ __/ __ __/ __ __ __ __ (example: 26/OCT/2024)
   d d/ m m /y y y y

Demographics

1. Date of Birth: __ __/ __ __ /__ ___ __
2. Gender:

□ Male □ Female

3. Highest Education Level:

□ Primary □ Secondary □ University □ College

4. Monthly Income Level (Ksh):

□ No job □ <1000 □ >1000-4999 □ >5000

5. Active Health Insurance:
□ None □ NHIF □ Private □ Other
6. Marital Status:

□ Single □ Married □ Separated □ Other…………………

7. Occupation:
□ Employed □ Self-Employed □ Other
8. Monthly Medication Cost:
□ 0-100KSH □ 101-400KSH □ >400KSH
9. Time to travel to health facility (one way):
□ 0-30Mins □ 31-60mins □ >60mins
10. Cost of transportation to health facility (one way):
□ 0 KSH □ 1-99KSH □ >100KSH

Breast Cancer Diagnosis

1. a) Year of Breast Cancer Diagnosis……… b) Stage at diagnosis □ 0 □ I □ II □ III □ IV

c) Histologic Subtype □ DCIS □ LCIS □ IDC □ ILC □ Other

2. Current Breast Cancer Stage: □ 0 □ I □ II □ III □ IV

3. Immunohistochemistry staining □ER □ PR □ HER-2

Medical History & Clinical Information

1. Family history of Breast Cancer: □ Yes □ No

2. Menopausal status: □ Yes □ No

3. Performance status:

□ PS 0: Normal activity

□ PS 1: Some symptoms, but still near fully ambulatory

 PS 2: Less than 50%

 PS 3: More than 50% of daytime in bed

 PS 4: Completely bedridden

4. Hospitalization in the last year: Yes No Unknown

5. Comorbidities on Medication

i. History of Heart Disease	Yes No Unknown
ii. History of Hypertension	Yes No Unknown
iii. History of Diabetes	Yes No Unknown
iv. Other Chronic Disease on Medication	Yes No

6. Endocrine therapy prescription data

 Tamoxifen Anastrozole Letrozole Other

7. Running out of medication before next appointment. Yes No

8. Medication Adherence (Voils DOSE-Nonadherence)

Part 1: Extent of Nonadherence

In order for endocrine therapy medication for breast cancer to work, people have to take it as prescribed. For one reason or another, many people can't or don't always take all of their medication as prescribed. We want to know how often you have missed your endocrine therapy medication.

Over the past 7 days…	**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**Every time**
I missed my medicine.	○	○	○	○	○
I skipped a dose of my medicine.	○	○	○	○	○
I did not take a dose of my medicine.	○	○	○	○	○

Part 2: Reasons for Nonadherence

(Administer only to patients who did not take all their endocrine therapy medicines as prescribed in the last 7 days)

People miss doses for various reasons. Please tell us which reasons contributed to you missing a dose of your endocrine therapy medication.

Over the past 7 days…

Item	Not at all					Very much
I missed my dose because… I forgot	○	○	○	○	○	
I missed my dose because… the medication caused side effects	○	○	○	○	○	
I missed my dose because… I did not have my medicines with me	○	○	○	○	○	
I missed my dose because… I could not afford the medication	○	○	○	○	○	
I missed my dose because… the medication was unavailable where I get medicines	○	○	○	○	○	
I missed my dose because… the medication was not working	○	○	○	○	○	
I missed my dose because… I did not want others to see my medications	○	○	○	○	○	
I missed my dose because… I was too late with my dose	○	○	○	○	○	
I missed my dose because… I was asleep	○	○	○	○	○	
I missed my dose because… there was no one to help me	○	○	○	○	○	
I missed my dose because… I have too many medications to take	○	○	○	○	○	
I missed my dose because… I ran out of medication	○	○	○	○	○	
I missed my dose because… I was afraid the medication would interact with other medication I take	○	○	○	○	○	
I missed my dose because… I was feeling too sick to take it	○	○	○	○	○	
I missed my dose because… I could not get answers to my questions about the medication	○	○	○	○	○	
I missed my dose because… the medication affected my sex life	○	○	○	○	○	

Appendix 2: IN-DEPTH INTERVIEW GUIDE

Name of the interviewer: …………………………………………….

Name of the interviewee: …………………………………………….

Place of the interview: …………………………………………………

Date of the interview: ………………………………………………….

Thank you for agreeing to participate in this study. I am going to ask you a few questions regarding your experience with breast cancer. Feel free to skip any questions you may not feel comfortable answering. We will keep your data in a confidential manner. While we carry on with our discussion, I would like to ask your permission to audio record this interview so that we may retain what we discuss. We will however not record your name or any identifying information. Welcome.

[*Start recording*]

The date today is …… and this is participant number …… We will straight away begin our discussion.

<u>Questions</u>

1. Please tell me about your experience with breast cancer.
    a. When was the breast cancer diagnosis made?
    b. How did you come to be diagnosed with breast cancer?
        - What symptoms did you have?
        - What led to your decision to screen for breast cancer?
    c. How did you feel about the news of breast cancer?
    d. What did you do after your diagnosis?
        - How soon were you enrolled into any treatment or therapy?
        - How ready did you feel to start treatment?
        -
2. Now tell me about your experience with breast cancer treatment.
    a. What kind(s) of treatments/therapies have you been undertaking?
    b. How do you feel about this treatment?
        - What do you like about your medications/treatment?
        - What do you not like about your medications/treatment?
    c. Do you feel breast cancer treatment has brought any significant improvement in your health?
        - Improved health status
    d. Have you had to consider other alternative treatment options?
        - Herbal medicines
        - Spiritual healing
3. What challenges if any do you face with your endocrine treatment
    a. Tell me about any challenges related to the pills?
        - Side effects
        - Dosage
        - Number of pills to take

- Other concurrent treatment
- Treatment/medication related cost and economic impact of the treatment.
- Impact of treatment on general quality of life
-

b. Tell me about any challenges related to health facility where you seek care?
    - Provider related factors (e.g. provider-patient relationship, expertise, etc. - *do not read out to the participant*)
    - Hospital setting challenges (e.g. Queues, waiting time, etc. – *do not read out to the participant*)

c. Are there other ways in which these medications or treatment have affected you?

d. How often do you discuss the medications you are taking with your doctor?

4. How would you describe support you receive from your family, community and the society?
    a. In what ways do you feel or not feel supported in your breast cancer journey?
        - Psychosocial support
        - Financial support (health insurance, financial support from family, etc.)
    b. [*If supported*]Who provides such support? [*If not supported*]Who would be best placed to provide such support?
    c. Does your family have any history of breast cancer?
        - If yes, did this make any difference on how you feel about the disease?

5. In what ways do you think the barriers we have discussed could be addressed?
    a. How could barriers related to the healthcare system be addressed?
    b. How could barriers related to your medication be addressed?
    c. How could barriers related to progression of the disease be addressed?
    d. How could barriers related to the healthcare system be addressed?

6. Is there anything else that you would like to add about the challenges in taking your medications?

Thank you very much for participating in this interview.

[*End recording*]

Appendix 3: Informed Consent

Study Title: Adherence to Endocrine Therapy and Its Determinants in Hormone Positive Patients Living with Breast Cancer in MTRH

Name of Principal Investigator(s): Dr. Nathan Anjichi

Co-investigator(s): Dr. Jenny Morgan, Dr Evangeline Njiru

Name of Organization: Moi University School of Medicine

Address: P.O Box 4606 030100 Telephone Number: +254 53 2033235

Name of Sponsor/Funding Agency: None

Informed Consent Form for: Adherence to Endocrine Therapy Study Participants

This Informed Consent Form has two parts:

- **Part I**: Information Sheet [to share information about the study with you]
- **Part II**: Certificate of Consent [for signatures if you choose to participate]

PART I: INFORMATION SHEET

Introduction: You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions.

Taking part in this research study is voluntary. Saying no will not affect your rights to health care or any other services. Your treatment/payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that information provided by you be destroyed under supervision. This would be before data is de-identified and aggregated. You will be notified if new information becomes available about the risks or benefits of this research. You will receive a copy of this form after it is signed

Purpose of the study: The purpose of this study is to find out about the drugs which you've been prescribed for treatment of your breast cancer. Specifically, we would like to find out which drugs your doctor has prescribed to you, and how you've been taking those drugs over the last one week. We will use the information you provide us, combined with that from other patients in this clinic, to understand how the doctors at this facility treat patients like you, how patients take the medicines they've been prescribed, and the reasons why they may not always be able to take those medicines. The results of this study will not only improve breast cancer care at this hospital, but may also be applicable to other similar settings in Kenya and other developing countries.

Study site: This study is being conducted at the MTRH Oncology Clinic.

Study population: You are eligible to take part in this research study because you are greater than 18 years old, and are enrolled in the MTRH oncology clinic for management of breast cancer.

Study procedures: This will be a cross-sectional study which means we will complete all study procedures on your day of enrolment in the shortest time possible. We aim to recruit between 131 participants.

If you agree to participate in the study, you will do the following:

The research staff will ask to see the medication prescription that you've been issued today by your doctor. In addition, the research staff will conduct a structured interview with you, as well as review your clinic file to obtain additional information.

Benefits: You may not experience any direct benefit from the study. However, a better understanding of how patients with breast cancer are managed at MTRH, how they take their medicines and any barriers they experience to using medicines as

prescribed will help the hospital improve the oncology clinic services. You, your family, and your community may therefore benefit from this research.

Risks/Discomforts: We will only be collecting health and socio-demographic information that is a routine part of care. Any information shared by you will be anonymous, safely stored, and will be kept private and confidential.

Payments and Reimbursements:

No payments or reimbursements will be provided to you for your participation in this study.

Confidentiality: All reasonable efforts will be made to keep your protected information private and confidential. Using or sharing ("disclosure") of such information will follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the use and disclosure of your study information. We may need to share your protected information with the community advisory board, MTRH//MU-IREC, NACOSTI or the healthcare team. We will retain your research records for at least six years after the study is completed. At that time, the research information is destroyed by shredding any paper documents, and deleting any computer records. If you decide to withdraw your permission for use of your personal data, contact Dr. Nathan Anjichi in writing and let them know your decision. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality. You have the right to see and copy your personal information related to the research study for as long as the study team holds this information

Compensation for injury: We do not anticipate that any injury may occur to you resulting from participating in this study.

PART II: CONSENT OF PATICIPANT

I have read or have had someone read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks, discomfort, and possible benefits (if any) of the study. I freely volunteer to take part in this study.

[If the participant is illiterate, or for some reason is unable to write, they should provide a thumbprint and a competent witness must be engaged during the consent process]

______________________ _____________________ __________

Name of Participant Signature of participant/Thumbprint
Date & Time

_______________________ ________________________ __________

Name of Witness [Optional] Signature of Witness
Date & Time

______________________ ____________________ __________

Name of the person obtaining consent Signature of person obtaining consent
Date & Time

Dr. Nathan Anjichi _________________________ __________

Printed name of the Principal Investigator Signature of Investigator
Date

Contacts for questions about the study

Questions about the study: Dr. Nathan Anjichi |Phone: 0729305522 |
Email: nathan.anjichi@mu.ac.ke

Questions about your rights as a participant: You may contact the Institutional Ethics and Research Committee (MTRH//MU-IREC) 0787723677 or email irec@mtrh.go.ke or irecoffice@gmail.com. The MTRH//MU-IREC is a group of people that review studies for safety and to protect the rights of participants.

FOMU YA KIBALI ILIYOARIFIWA

Kichwa cha Utafiti: Kuzingatia Tiba ya Endocrine na Viamuzi Vyake kwa Wagonjwa wa Kipokezi cha Homoni Wanaoishi na Saratani ya Matiti MTRH

(Ma)Jina la Mchunguzi Mkuu: Dkt. Nathan Anjichi

Wachunguzi wenza: Dkt. Jenny Morgan, Dkt. Evangeline Njiru

Jina la Shirika: Chuo Kikuu cha Moi-Shule ya Matibabu

Anwani: Sanduku la Posta 4606 030100 Nambari ya Simu: +254 53 2033235

Jina la Mfadhili/Wakala wa Ufadhili: Hakuna

Fomu ya Kibali ya: Kuzingatia Tiba ya Endocrine kwa wagonjwa wa Kipokezi cha Homoni wanaoishi na Saratani ya Matiti MTRH

Hii Fomu ya Kibali ina sehemu mbili:

- **Sehemu ya I**: Karatasi ya Habari [kushiriki habari na wewe kuhusu utafiti]
- **Sehemu ya II**: Cheti cha Kibali [ya saini ikiwa utachagua kushiriki]

SEHEMU YA I: KARATASI YA HABARI

Utangulizi:Unaulizwa kushirika katika somo la utafiti. Taarifa hii inapeanwa kukuambia kuhusu utafiti. Tafadhali soma fomu hii kwa makini. Utapewa nafasi kuuliza maswali.

Kushiriki katika huu utafiti ni kwa hiari. Kusema hapana haitaathiri haki zako kwa huduma ya afya au huduma zingines. Matibabu yako/malipo au kujiandikisha kwa mpango yoyote ya afya au kustahiki kwa manufaa haitaathiriwa ikiwa utaamua kutoshiriki. Pia uko huru kujiondoa kutoka kwa utafiti huu wakati wowote. Ikiwa baada ya ukusanyaji wa data utaamua kujiondoa, unaweza omba kwamba taarifa

uliyopeana yaharibiwe chini ya usimamizi. Hii itafanyika kabla ya data kutotambuliwa na kujumlishwa. Utajulishwa ikiwa habari mpya inapatikana kuhusu hatari au manufaa ya utafitu huu. Utapokea nakala ya fomu hii baada ya kutiwa saini

Madhumuni ya utafiti: Madhumuni ya utafiti huu ni kujua kubaini kuhusu dawa ambazo umeandikiwa kwa ajili ya matibabu ya ugonjwa wako wa saratani. Hasa, tungependa kujua ni dawa gani daktari wako amekuandikia, na jinsi umekuwa ukitumia dawa hizo katika wiki moja iliyopita. Tutatumia maelezo unayotupatia, pamoja na maelezo kutoka kwa wagonjwa wengine katika kliniki hii, kuelewa jinsi madaktari katika kituo hii wanatibu wagonjwa kama wewe, jinsi wagonjwa wanavyotumia dawa walizoandikiwa, na sababu zinazowafanya wasiweze kutumia dawa hizo kila wakati. Matokeo ya utafiti huu sio tu ya kuboresha huduma za magonjwa ya saratani ya matiti katika hospitali hii, lakini pia yanaweza kutumika kwa mazingira mengine kama hayo nchini Kenya na nchi zingine zinazoendelea.

Eneo la Utafiti: Utafiti huu unafanyika katika kliniki ya saratani ya MTRH.

Idadi ya Watu kwa Utafiti: Unastahili kushiriki katika somo hili la utafiti kwa sababu wewe ni mkubwa zaidi ya miaka 18, na umejiandikisha katika kliniki ya saratani ya MTRH kwa ajili ya usimamizi wa matatizo ya saratani.

Utaratibu wa Utafiti:Hii itakuwa utafiti wa sehemu mbali mbali ambayo inamaanisha tutakamilisha taratibu zote za masomo katika siku yako ya usajili kwa muda mfupi iwezekanavyo. Tunalenga kuandikisha hadi washiriki 131.

Ikiwa utakubali kushiriki katika utafiti huu, utafanya yafuatayo:

Wafanyakazi wa utafiti wataomba kuona dawa ambayo umepewa leo na daktari wako. Kwa kuongezea wafanyikazi wa utafiti watafanya mahojiano yaliyopangwa na wewe, pamoja na kuhakiki faili yako ya kliniki ili kupata maelezo ya ziada.

Manufaa:Hautaweza kupata manufaa yoyote ya moja kwa moja kutoka kwa utafiti. Hata hivyo, uelewaji mzuri wa namna wagonjwa wenye matatizo ya saratani wanavyosimamiwa katika chuo cha MTRH, namna wanavyotumia dawa zao na vikwazo vyovyote wanavyopata katika kutumia dawa kama ilivyoagizwa vitasaidia hospitali kuboresha huduma za kliniki za saratani. Wewe, familia yako, na jamii yako mnaweza kufaidika na utafiti huu.

Hatari/Usumbufu:Tutakuwa tunakusanya habari ya afya na demografia ya jamii ambayo ni sehemu ya mambo ya kila siku ya huduma. Taarifa yoyote utakayoshiriki itakua ya kutotambulika, kuhifadhiwa salama, na kuwekwa faragha na.

Malipo na Marejesho:Hakuna malipo au marejesho yatakayotolewa kwako kwa ushiriki wako katika utafiti huu.

Usiri:Jitihada zinazowezekana zitafanywa ili kuweka habari yako iliyolindwa ya kibinafsi na ya siri. Kutumia au kushiriki ("ufichuzi") ya habari hiyo itafuata miongozo ya kibinafsi ya Kitaifa. Kwa kusaini hati ya idhini ya utafiti huu, unatoa ruhusa ("idhini") kwa matumizi na ufichuzi wa maelezo yako ya utafiti. Tunaweza kuhitaji kushiriki maelezo yako yaliyolindwa na bodi ya ushauri wa jamii, MTRH / / MU-IREC, NACOSTI au timu ya huduma ya afya. Tutahifadhi rekodi zako za utafiti kwa angalau miaka sita baada ya utafiti kukamilika. Kwa wakati huo, habari za utafiti huharibiwa kwa kukatakata karatasi yoyote, na kufuta rekodi zozote za kompyuta. Ukiamua kuondoa ruhusa yako ya matumizi ya data yako ya kibinafsi, wasiliana na Dkt. Nathan Anjichi kwa maandishi na uwajulishe uamuzi wako. Wakati huo, tutaacha ukusanyaji zaidi wa habari yoyote kukuhusu. Hata hivyo, taarifa za afya zilizokusanywa kabla ya kujiondoa huu zinaweza kuendelea kutumika kwa madhumuni ya kutoa taarifa na ubora wa utafiti. Una haki ya kuona na kunakili

maelezo yako ya kibinafsi kuhusiana na somo la utafiti kwa muda mrefu kama timu ya utafiti inashikilia habari hii

Fidia kwa majeraha:Hatutarajii jeraha lolote litatokea kwako kutokana na kushiriki katika utafiti huu.

SEHEMU YA II: IDHINI YA MSHIRIKI:

Nimesoma au mtu amenisomea maelezo ya somo la utafiti. Mchunguzi au mwakilishi wake amenielezea utafiti kwangu na amejibu maswali yangu yote niliyonayo kwa wakati huu. Nimeambiwa hatari zinazowezekana, usumbufu na faida zinazowezekana (ikiwa kunayo) ya utafiti. Najitolea kwa hiari kushiriki katika utafiti huu.

[Ikiwa mshiriki hajasoma, au kwa sababu fulani hawezi kuandika, wanafaa kupeana kidole gumba na shahidi mwenye uwezo lazima wahusishwe kwa mchakato wa kibali]

__________________________ ______________________ __________

Jina la Mshiriki Saini ya mshiriki/Kidole Gumba

Tarehe na Saa

_____________________ _________________________ __________

Jina la Shahidi [Hiari] Saini ya Shahidi

Tarehe na Saa

___________________ _____________________ __________

Jina la mtu anayetafuta idhini Saini ya mtu anayetafuta idhini

Tarehe na Saa

Daktari Nathan Anjichi _________________________ __________

Jina lililochapishwa la mchunguzi Saini ya Mchunguzi

Tarehe

Maelezo ya mawasiliano kwa maswali kuhusu utafiti

Maswali kuhusu utafiti: Daktari Nathan Anjichi |Simu: 0729305522 |

Barua pepe: nathan.anjichi@mu.ac.ke

Maswali kuhusu haki zako kama mshiriki: Unaweza kuwasiliana na Kamati ya Kitaasi ya Maadili na Utafiti (MTRH//MU-IREC) 0787723677 au barua pepe irec@mtrh.go.ke au irecoffice@gmail.com. The MTRH//MU-IREC ni kikundi cha watu wanaohakiki utafiti kwa usalama na kulinda haki za washiriki.

Appendix 4: Ethical Approvals

MTRH/MU-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/612/2023
Approval Number: 0004588

26th October, 2023

Dr. Nathan J. Anjichi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Anjichi,

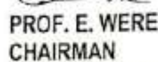
ADHERENCE TO ENDOCRINE THERAPY AND ITS DETERMINANTS IN HORMONE RECEPTOR POSITIVE PATIENTS LIVING WITH BREAST CANCER AT MOI TEACHING AND REFERRAL HOSPITAL

This is to inform you that ***MTRH/MU-IREC*** has reviewed and approved the above referenced research proposal. Your application approval number is ***FAN: 0004588.*** The approval period is **26th October, 2023- 25th October, 2024.** This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MTRH/MU-IREC.***
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MTRH/MU-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MTRH/MU-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from ***MOH at the recommendation of NACOSTI*** for each batch of shipment.
vi. 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.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MTRH/ MU-IREC.***

Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH) and its satellites sites.

Sincerely,



PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: (+254)-0532033471/2/3/4
Fax: 0532061749
Email: ceo@mtrh.go.ke/ceosoffice@mtrh.go.ke

NANDI ROAD
P.O. BOX 3-30100
ELDORET,KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

26th October, 2023

Dr. Nathan John Anjichi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

ADHERENCE TO ENDOCRINE THERAPY AND ITS DETERMINANTS IN HORMONE RECEPTOR POSITIVE PATIENTS LIVING WITH BREAST CANCER AT MOI TEACHING AND REFERRAL HOSPITAL

You have been authorised to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) and its satellites sites. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff, patients and study participants seen at MTRH.

1. The study shall be under Moi Teaching and Referral Hospital regulation.
2. A copy of MTRH/MU-IREC approval shall be a prerequisite to conducting the study.
3. Studies intending to export human bio-specimens must provide a permit from MOH at the recommendation of NACOSTI for each shipment.
4. No data collection will be allowed without an approved consent form(s) to participants unless waiver of written consent has been granted by MTRH/MU-IREC.
5. Take note that **data** collected must be treated with due confidentiality and anonymity.

The continued permission to conduct research shall only be sustained subject to fulfilling all the requirements stated above.

The approval period is 26th October, 2023 – 25th October, 2024.

For

DR. WILSON K. ARUASA, *MBS, EBS*
CHIEF EXECUTIVE OFFICER

c.c.
- Senior Director, Clinical Services
- Director, Nursing Services
- HOD, HRISM

All correspondences should be addressed to the Chief Executive Officer
Visit our Website: www.mtrh.go.ke
TO BE A GLOBAL LEADER IN THE PROVISION OF EXCEPTIONAL MULTI-SPECIALTY HEALTH CARE, TRAINING AND RESEARCH

MTRH/MU-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/612/2023
Approval Number: 0004588

26th October, 2024

Dr. Nathan John Anjichi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Anjichi,

RE: CONTINUING APPROVAL

The Moi Teaching and Referral Hospital/Moi University College of Health Sciences- Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Adherence to Endocrine Therapy and Its Determinants in Hormone Receptor Positive Patients Living with Breast Cancer at Moi Teaching and Referral Hospital".

Your proposal has been granted a Continuing Approval with effect from 26th October, 2024. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 25th October, 2025. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: (+254)-0532033471/2/3/4
Fax: 0532061749
Email: ceo@mtrh.go.ke/ceosoffice@mtrh.go.ke

NANDI ROAD
P.O. BOX 3-30100
ELDORET,KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

25th October, 2024

Dr. Nathan John Anjichi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

ADHERENCE TO ENDOCRINE THERAPY AND ITS DETERMINANTS IN HORMONE RECEPTOR POSITIVE PATIENTS LIVING WITH BREAST CANCER AT MOI TEACHING AND REFERRAL HOSPITAL

You have been authorised to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) and its satellites sites. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff, patients and study participants seen at MTRH.

1 The study shall be under Moi Teaching and Referral Hospital regulation.
2 A copy of MTRH/MU-IREC approval shall be a prerequisite to conducting the study.
3 Studies intending to export human bio-specimens must provide a permit from MOH at the recommendation of NACOSTI for each shipment.
4 No data collection will be allowed without an approved consent form(s) to participants unless waiver of written consent has been granted by MTRH/MU-IREC.
5 Take note that data collected must be treated with due confidentiality and anonymity.

The continued permission to conduct research shall only be sustained subject to fulfilling all the requirements stated above.

The approval period is 25th **October, 2024 – 24**th **October, 2025.**

DR. PHILIP K. KIRWA
CHIEF EXECUTIVE OFFICER

c.c. - Ag. Senior Director, Clinical Services
- Director, Nursing Services
- HOD, HRISM

All correspondences should be addressed to the Chief Executive Officer
Visit our Website: www.mtrh.go.ke
TO BE A GLOBAL LEADER IN THE PROVISION OF EXCEPTIONAL MULTI-SPECIALTY HEALTH CARE, TRAINING AND RESEARCH

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 613979

Date of Issue: 12/December/2023

RESEARCH LICENSE

This is to Certify that Dr.. Nathan John Anjichi of Moi University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Uasin-Gishu on the topic: ADHERENCE TO ENDOCRINE THERAPY AND ITS DETERMINANTS IN HORMONE RECEPTOR POSITIVE PATIENTS LIVING WITH BREAST CANCER AT MOI TEACHING AND REFERRAL HOSPITAL for the period ending : 12/December/2024.

License No: NACOSTI/P/23/31730

613979

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

LICENSE AGREEMENT

This Agreement is entered into effective this **January 1, 2024** (the "Effective Date") by and between **Duke University** ("Duke"), a nonprofit educational, health care, and research institution located in Durham North Carolina, and **Moi Teaching and Referral Hospital** ("Licensee") which is located in **Kenya**.

WHEREAS, Duke University, the University of Pittsburgh, The Trustees of Columbia University in the City of New York, The University of North Carolina at Chapel Hill and the US Department of Veterans Affairs (henceforth referred to individually as "Party" and together as "Parties") have developed and hold joint copyright in the following health measures ("INSTRUMENT"):

Domains of Subjective Extent of Nonadherence (DOSE-Nonadherence), a two-domain self-report measure of medication non-adherence, published in Voils, C. I., King, H., Thorpe, C. T., Blalock, D. V., Kronish, I., Reeve, B. B., Boatright, C., & Gellad, Z. F. (2019). Content validity and reliability of a self-report measure of medication nonadherence in hepatitis C treatment. *Digestive Diseases and Sciences*. E-pub ahead of print Apr 29, 2019.

WHEREAS, Licensee would like to use the above mentioned INSTRUMENT to assess **"Adherence to Endocrine Therapy and its Determinants in Hormone Receptor Positive Patients Living with Breast Cancer at Moi Teaching and Referral Hospital."**, in a total of **One** (1) clinic and an estimated **One hundred and thirty one (131)** uses of the INSTRUMENTS on the aforementioned subjects (such uses herein referred to as the "PROJECT");

NOW, THEREFORE, in consideration of these premises, the mutual covenants made herein, and other good and valuable consideration, the parties hereby agree as follows:

1. License. Duke hereby grants to Licensee, and Licensee hereby accepts from Duke under the terms of this Agreement, a limited, non-exclusive license to Duke's copyrights in the INSTRUMENT only, to distribute and copy the INSTRUMENTS and available translations thereof (and to have INSTRUMENTS copied and distributed on Licensee's behalf), for the sole purpose of the PROJECT. The INSTRUMENTS shall be distributed by Licensee at no charge to the recipients.

   The INSTRUMENT contains two main sections: "Extent of Nonadherence" ("Part 1) and "Reasons for Nonadherence" ("Part 2"). Licensee shall have no rights to modify the content or title of the INSTRUMENT in any way without the written approval of the primary developer of the INSTRUMENT Dr. Corrine Voils, Ph.D., except that Licensee has permission to modify Part 2 under derivative rights according to the specific needs of the PROJECT. The copyright for all such modified versions shall reside with the Parties, and the Parties will be free to use the modified versions and to provide it to others without obligation to Licensee. All uses of the INSTRUMENT as well as instructions provided to recipients must be consistent with the terms contained in this Agreement as well as in the user's guide provided to Licensee with the copy of the INSTRUMENT.

2. Ownership. Title to the INSTRUMENTS, and all copyrights therein including derivative rights, shall remain with the Parties, and this agreement shall not be taken in any way to restrict the Parties' ability to use, copy, modify, or license INSTRUMENTS to third parties. Licensee shall have no rights in INSTRUMENTS except those expressly granted by this Agreement.

3. Royalties. The rights granted herein shall be granted royalty-free for the term of the Agreement.

revised July 8, 2021

4. Payments & Notices. All notices related to this Agreement shall reference Duke file 6673 and shall be delivered to :

For delivery via the U.S. Postal Service:
DUKE UNIVERSITY
BOX 90083
Durham, NC 27708
Attn: Agreements Manager

Licensee's contact information:

Name: NATHAN JOHN ANJICHI
Institution: MOI TEACHING AND REFERRAL HOSPITAL
Address: P. O BOX 3-30100, ELDORET, KENYA

Phone number: + 254 729 305522
Email: johnanjichi@gmail.com

5. Translations. The INSTRUMENTS are all available in English and some select foreign languages, a list of which will be provided by Duke upon request. Translations of the INSTRUMENTS into other languages are encouraged; however, to coordinate with existing translations and other ongoing efforts, Licensee shall contact Duke prior to initiating any translation effort, and shall not proceed without first obtaining Duke's approval. All new translations shall be subject to Duke's approval, which approval shall not be unreasonably withheld. All translations shall be carried out in collaboration with Dr. Voils. and will be translated in accordance with a standard process, an outline of which is available from Duke upon request. The copyright for each new translation will reside with the Parties, and they will be free to use the translated version and to provide it to others without obligation to Licensee.

6. Use of Name. Licensee will not use the name, logo or service marks or the name of any Party's employees or subsidiaries in advertising or publicity without the Parties' prior written consent; except that Licensee shall include a standard notice indicating that the copyright on INSTRUMENTS is held by the Parties, the year of creation, and that all rights in the INSTRUMENTS are reserved.

7. Results of Use. Licensee agrees to provide Dr. Voils, with a summary of the psychometric analysis of all the subjects in the PROJECT, including reliability and validity information. Dr. Voils shall be free to use such information in research and continued development of the INSTRUMENT, and to provide such information to collaborators in such research. Duke will maintain the confidentiality of such data, and will not disclose such data other than to Dr. Voils for use in the further development and validation of the INSTRUMENTS.

8. Right of Approval. If Licensee makes any alterations to the form of the INSTRUMENTS provided by Duke except for Part 2 as discussed in Article 1, then Licensee will provide Duke with a copy of the form of the INSTRUMENTS which Licensee intends to distribute for approval by Dr. Voils, or her designee. Such approval not to be unreasonably withheld and for the sole purpose of confirming that the INSTRUMENTS have been accurately reproduced and are not printed in a manner implying product or program endorsement by any of the Parties or Dr. Voils. Duke's approval shall not be taken in any way as an endorsement by any Party or Dr. Voils of Licensee's research program, clinical practice or

of educational products or other materials to be distributed by Licensee. Neither Licensee nor its agents shall represent that any Parity or Dr. Voils has made any such endorsement. Licensee may not publish any of the INSTRUMENTS (in whole or in part) without the prior written authorization of Duke except as provided herein.

9. **Warranty. The Parties makes no representations that any copyrights in the INSTRUMENTS and its derivatives will be held valid, or enforceable, or that the use or distribution of INSTRUMENTS and derivatives, will not infringe upon any copyrights or other intellectual property rights of third parties. INSTRUMENTS are provided "as is", without any warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Licensee agrees to defend, indemnify, and hold harmless all the Parties from any loss, claim, damage, or liability which may arise from Licensee's use or distribution of INSTRUMENTS; provided, however, that Licensee shall not be responsible for gross negligence or willful misconduct on the part of the Parties. The Parties shall have no obligation, express or implied, to supervise, monitor, review or otherwise assume responsibility for Licensee's clinical practice or for medical or treatment decisions made by Licensee or its patients.**

10. Term and Termination. This Agreement shall be effective on the date first written above, and shall terminate ***June 30, 2024***. In the event Licensee materially breaches any of the terms of this Agreement, Duke may, at any time thereafter, give written notice of the breach to Licensee, and demand that the same be cured. In the event that such breach is not cured within thirty (30) days after such notice, this Agreement shall terminate. Upon termination, Licensee shall immediately cease all use and distribution of the INSTRUMENTS. Termination of this Agreement shall not relieve either party of the obligations arising hereunder before termination, including the responsibility for paying previously accrued royalties if any.

11. Assignment. Neither party may assign its rights and obligations under this agreement to a third party without the written permission from the other party which will not be unreasonably withheld; except that, either party may assign its rights to its subsidiaries or other entities controlled by that party.

12. Entire Understanding. This Agreement represents the entire understanding between the parties, and supersedes all other agreements, express or implied, between the parties concerning its subject matter. No additional rights are provided to Licensee under any patent applications, trade secrets, copyrights, or other proprietary rights of Duke University. Any modification or addition to any provision of this Agreement must be agreed to in writing by a duly authorized representative of each party.

13. Governing Law. The law of the State of North Carolina shall govern this Agreement.

WHEREFORE, the parties hereto place their hands and seals:

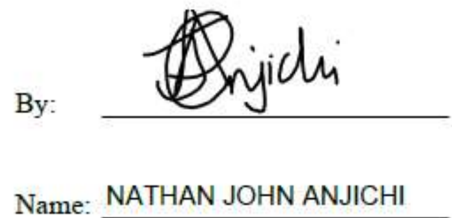
DUKE UNIVERSITY

By: ____________________

Nadine Wong, Ph.D.
Managing Director,
Licensing & Strategic Initiatives,
Office for Translation &
Commercialization

Date: November 15, 2023

LICENSEE



By: ____________________

Name: NATHAN JOHN ANJICHI

Title: INTERNAL MEDICINE REGISTRAR

Date: NOVEMBER 15th, 2023