PREVALENCE AND CLINICAL OUTCOMES OF RADIOTHERAPY-INDUCED SKIN BURNS AMONG CANCER PATIENTS AT THE KENYATTA NATIONAL HOSPITAL

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DECLARATION

I, Doris V. Wanja Machaki, hereby declare that this dissertation is my original work and has never been submitted for any academic award in any institution of higher learning.

Signature---------- Date ----------

Reg Number: H56/88632/2016

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DEDICATION

This work is dedicated to all the cancer patients who are undergoing radiotherapy treatment at KNH**.**

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LIST OF ABBREVIATIONS AND ACRONYMS

BMI	Body Mass Index
BP	Blood Pressure
BSN	Bachelor of Science in Nursing
CEO	Chief Executive Officer
CHS	College of Health Sciences
EBRT	External Beam Radiation Therapy
Gy	Gray
HIV	Human Immunodeficiency Virus
KNH	Kenyatta National Hospital
KRCHN	Kenya Registered Community Health Nurse
RT	Radiation Therapy
RTOG	Radiation Therapy Oncology Group
SON	School of Nursing
UON	University of Nairobi
UV	Ultraviolet

OPERATIONAL DEFINITIONS OF TERMS

Cancer:

It's a generic term for a large group of diseases characterized by the growth and spread.

Carcinoma:

A disease in which abnormal cells divide uncontrollably.

Chemotherapy:

A cancer treatment modality that uses one or more anticancer drugs.

Comorbid:

It's the simultaneous presence of two chronic diseases or conditions in a patient.

Desquamation:

It's the natural shedding and peeling of the outermost layer of the skin. In case of damage, this process is interrupted or changed and there may be additional shedding and peeling.

Erythema:

Redness of the skin caused by congestion of the capillaries in the lower layers of the skin. Mostly occurs due to skin injury, infection and inflammation

External beam radiation

It's a form of radiotherapy that involves directing radiation at the tumour from outside the body.

Gray (Gy):

International system unit of radiation dose

Internal radiotherapy:

It's a form of radiotherapy where the source of radiation is placed in your body or on an area of your body close to the tumour.

Necrosis:

Cell death.

Palliative:

Treatment that relieves pain or alleviating a problem without dealing with the underlying cause

Radiation:

Energy in the form of waves or stream of particles.

Radiodermatitis:

It's the integumentary system's response to exposure to ionizing radiation.

Sarcoma:

Malignant tumour of connective tissue.

Xerostomia:

A condition in which there is dryness of the mouth, reduction of saliva flow.

ABSTRACT

Background: Cancer is one of the leading causes of death globally. In Kenya, it's the third leading cause of death after cardiovascular and infectious diseases. Radiotherapy (RT) is one of the major treatment modalities of cancer, but it's associated with skin burns as one of the adverse effects. Locally the occurrence, predisposing factors are not clearly documented. This study determined the prevalence and clinical outcomes of RT-induced skin burns in cancer patients.

Methodology: This was a descriptive cross-sectional study, which employed both quantitative and qualitative methods of data collection. The study population consisted of patients diagnosed with cancer and undergoing RT at Kenyatta National Hospital (KNH). A systematic sampling method was used to recruit a proportion of study participants each day depending on patient turn out. 79 participants were enrolled. Data was collected using open and closed-ended questionnaires and a review of past patients' files**.** Statistics and data statistical software package version 14.0 (STATA) was used to analyze the data. Descriptive and inferential statistics were obtained, and findings presented in form of tables and graphs.

Results: The prevalence of RT-associated burns was 49.4%. Forty-four-point eight percent (44.8%) of the patients above 40 years had burns compared to 50% who were below 40 years. The number of cycles determined the risk of burns as demonstrated by 66.6% those who had above 10 cycles had burns compared to 36.8% who had less than 10 cycles. Patients who had radiation around the head and neck 16 (61%) had burns compared to 5 (41.7%) who had chest radiation. Out of the total 55 patients on RT who had received more than 41 Gy, 33 (60%) experienced burns. Of those receiving External Beam Radiation Therapy (EBRT), 30 had burns, compared to 5 cases for those receiving Brachytherapy. Further analysis was done and showed patients who underwent brachytherapy were likely ($p<0.017$) to get skin burns. Forty-two-point nine percent (42.9%) of the respondents with burns reported they appeared after the first week going upwards. The proportion of Grade 2 burns according to the Radiation Therapy Oncology Grading (RTOG) was 19.0%. From nurses feedback grade one was the most common 64.3% (9) while grade 2 had 28.6% (4). Most of the patients faced a lot of challenges emanating from RT burns as demonstrated by 76.5% reporting emotional distress, 17.6% reported health issues which included pain and mucositis.

Conclusion: The study observed that there is a relationship between predisposing factors and burns. The most significant ones been allergies, number of cycles and type of radiotherapy either EBRT or brachytherapy. Of these factors some can be mitigated like nutrition, use of low fraction of radiation in patients with skin allergies. It was observed that the clinical outcomes vary depending on the degree of burns sustained. Most of the patients reported emotional distress, pain, financial constrains has been among the leading challenges they experienced.

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CHAPTER ONE: INTRODUCTION

1.1 Background information

Cancer is a term used to describe a group of diseases characterized by abnormal cells which grow at a rapid speed and spread beyond their usual boundaries (Health, 2017). Globally, it's one of the leading cause of death, it's estimated that 14.4 million new cases and 8.2 cancer death occurred in 2012 (Torre *et al.*, 2015). In Kenya, it's the third leading cause of death after infectious and cardiovascular diseases with an estimate of 37,000 new cases and over 28,000 deaths annually (Health, 2017).

According to WHO (2012), the major treatment options for cancer include surgery, chemotherapy and radiotherapy. Each treatment modalities have its own adverse effects ranging from short-term to long-term for example but not limited to nausea, vomiting, diarrhoea, alopecia, low immunity, infertility. Combined treatment modalities have also proven to improve cancer treatment outcomes and survival rate (Yaeger and Brady, 2001).

Literature has shown that radiotherapy accounts for approximately 40% of curative in the treatment of cancer. It's the second most effective form of treatment modality (Trueman, 2013).

RT uses high-energy radiation to shrink tumours and kill cancer cells. Radiation can be done externally or placed in the body near cancer cells, external-beam radiation and internal radiation therapy or brachytherapy respectively. It can be used as neoadjuvant and adjuvant that is can be used before a tumour is removed and after removal of tumour respectively. Radiotherapy is also used in cancer as a palliative measure to reduce the symptoms in patients with locally or distant advanced cancer (Kamanzi *et al.*, 2016; Ducassou *et al.*, 2015; Juraskova and Lubotzky, 2015).

Combination of radiotherapy and chemotherapy in the management of cancer has a better outcome than the use of each alone (Sacco *et al.*, 2011; Yaromina, Krause and Baumann, 2012).

Effects of radiotherapy range from short term and long term and may range from haematological, immunological, cutaneous, and nutritional like weight loss. These effects usually depend on the site of radiation. For example, effects of radiation of tumours affecting the head and neck include but not limited to cellulitis, mucositis, weight loss, severe pain, xerostomia and osteoradionecrosis (Cancer Research UK, 2017).

Research has shown radiotherapy-induced burns account for 90.6% of burns worldwide (Portas, 2015). Studies have shown the skin is the most commonly affected organ due to the

high rate of cell turn over. Radiation skin reactions occur as a result of damage to the basal cell layer of the skin and result in an imbalance between the normal production of cells in this layer and the destruction of cells at the skin surface (Trueman, 2011; Ferreira *et al.*, 2017).

Up to half of the patients reportedly develop at least radiodermatitis and a small percentage may have more serious skin condition affecting a large surface area (Hernández Aragüés, Pulido Pérez and Suárez Fernández, 2017). The radiotherapy reactions occur approximately from a few days to 2–4 weeks following commencement of treatment (Palatty *et al.*, 2014; Ferreira *et al.*, 2017).

Studies have shown that the predisposing factors can be categorized into intrinsic factors which include but not limited to age, general health, and comorbid like diabetes, hypertensive, and hormonal status. Extrinsic factors include but not limited to dose, and number of fractions of radiation, concurrent chemotherapy and site of treatment. The cells are able to regenerate and repair themselves after the first session and cell death and apoptosis may occur in the subsequent sessions (Simonsson *et al.*, 2008; Trueman, 2011; Palatty *et al.*, 2014; Ferreira *et al.*, 2017).

Studies have shown that radiotherapy induces skin reactions may not be easily prevention hence KNH should design guidelines to manage radiotherapy induces skin burns and supportive care to aid in the reduction of side effect, prevention of further trauma and promote wound healing. The above can be achieved through the use of low dose of radiation, spreading out treatment schedules, aim at the precise area of the target (Trueman, 2011; National Cancer Institute - National Institutes of Health, 2012)

1.2 Statement of the problem

RT-induced skin burns are seen approximately a few days to 2–4 weeks after the first fraction of radiation (Trueman, 2011; Ferreira *et al.*, 2017).Depending on the site, the dose of the radiation, nutritional status, age, the comorbid effect of radiation on the skin may vary from mild to severe forms of burns (Hernández Aragüés, Pulido Pérez and Suárez Fernández, 2017). Among these factors which stands out at Kenyatta National Hospital. In Kenya there is no available data on prevalence, predisposing factors and clinical outcomes of skin burns in cancer patients post RT. Hence this study aims at finding out the prevalence predisposing factors and clinical outcomes of RT induced skin burns among patients at KNH

1.3 Study Questions

1. What is the prevalence of radiotherapy-induced skin burns?
2. What are the predisposing factors of skin burns post radiotherapy?
3. What are the clinical outcomes of radiotherapy burns among cancer patients?

1.4 Broad Objective

To determine the prevalence and clinical outcomes of radiotherapy-induced skin burns in cancer patients at Kenyatta National Hospital

1.5 Specific Objectives

1. To establish the prevalence of skin burns post radiotherapy in cancer patients.
2. To determine the predisposing factors of skin burns post radiotherapy.
3. To assess the clinical outcomes of radiotherapy burns among cancer patients.

1.6 Null Hypothesis

There is no relationship between radiotherapy induced skin burns and clinical outcomes

1.7 Problem Justification

The study will give us insight on how many patients have developed RT skin burns, how patients are affected once they develop the burns. Modifiable factors that predispose one to developing the RT burns and what the healthcare provider can do to minimize the occurrence.

1.8 Theoretical framework: Deliberative Nursing Process

Theoretical Framework of this research is going to be based on Ida Jean Orlando's (Pelletier) nursing process theory. Orlando's theory uses the term "need" while talking about individuals finding themselves in a position of requiring nursing care. Orlando's theory has been tested in various health care settings and the results support its' implementation to practice in various nursing fields (Schmieding, 2006, 443-444).

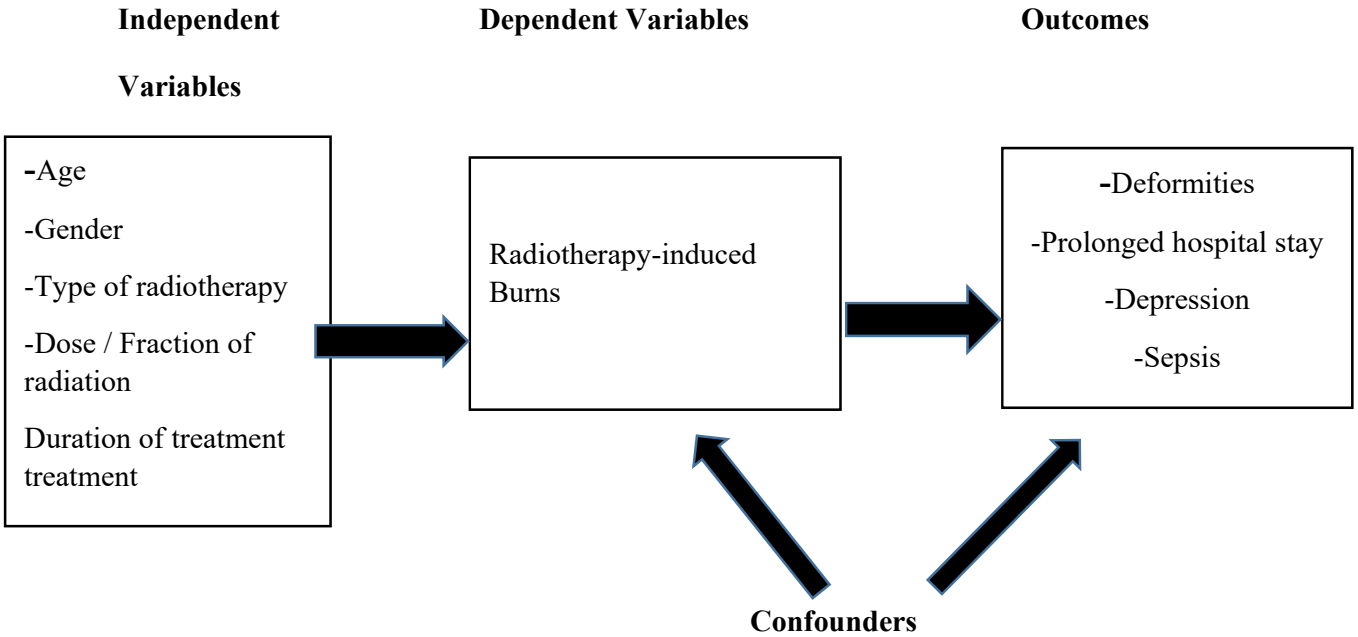
Orlando's nursing process focuses on improvement in the patient's behaviour by actions that are based on a patient's needs found through effective interaction with the patient (Parker & Smith, 2010, 79). According to Orlando when a person is not able to meet the needs that he has, he becomes distressed and is in need of nursing care. Accordingly, the persons that are able to meet their own needs are not distressed and do not need nursing care. If a patient has ineffective skills to express his/her needs and/or a nurse interprets the patient's behaviour incorrectly it can cause distress to the patient. That is why a nurse assesses the patient

(Schumacher et. al. 1998. 354, 359). Orlando highlights that it is crucial not only to meet the patient's needs but first of all find out what those needs are. If interventions are carried out before identifying if those interventions give benefits to the patient, nursing is not highly professional. Although all the nursing activities are planned for the patient's own good, what the patient himself thinks that he needs can be entirely opposite from what a nurse assumes (Orlando, 1990).

Anderson, Mertz & Leonard (1965) found that Orlando's theory promoted stress reduction during admission to surgery. Dumas & Johnson (1972) found a correlation with reduced postoperative complications. Pienschke (1973) with the suitability of care enhanced with an emphatic approach. Wolfer & Visintainer (1975) found deliberative nursing actions being as stress reductive with children and their parents. Thibaudeau & Reidy (1977) found out that using deliberative nursing process affected positively on mothers' treatment commitment. According to Reid (1992) with the use of the nursing process increased empathy occurred while taking care of cancer patients (Schmieding, 2006, 442-443).

In burn procedural pain, the presenting behaviour of the patient, regardless of the form in which it appears, may represent a plea for help. When a patient experiences a need that he cannot resolve, a sense of helplessness occurs. The patient's behaviour reflects this distress. The patient's pain stimulates a nurse reaction which marks the beginning of the nursing process and investigates to resolve the problem and later evaluates pain perception through a close dynamic nurse-patient relationship.

1.9 CONCEPTUAL FRAMEWORK



Intrinsic Factors	Extrinsic Factors
Obesity	Site of treatment
Comorbidities	Radiation Sensitivity
Nutrition	Dose / fraction
Lifestyle habits	Number of cycles

Figure 1. Conceptual Framework, Source (authors) 2014

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Cancer is a term used to denote a group of diseases which are characterized by the growth of abnormal cells which spread beyond their usual boundaries and can invade other tissues and organs. Normal cells tend to transform into tumour cells from a precancerous lesion to a malignant tumour. Globally, 5-10% all cancers are attributed to a genetic defect and 90–95% to environmental and lifestyle factors (Health, 2017).

In 2012, approximately 14 million new cases were diagnosed making cancer one of the leading causes of morbidity and mortality worldwide. Cancer is the second leading cause of death globally. In Kenya, it's the third leading cause of death after infectious and cardiovascular diseases respectively (Adedimeji *et al*, 2016; Health, 2017).

Not only does cancer affect the patient but the family and the society as a whole (Families and Underserved, 1900).

Breast cancer, cervical and prostate cancer are the most common cancers. In Kenya, the most common types of cancers are prostate cancer, cervical cancer, breast cancer, oesophageal cancer, and Kaposi's sarcoma (Adedimeji *et al.*, 2016; Health, 2017).

2.2 Cancer Management

Once a patient has been diagnosed with cancer, a multidisciplinary team assess the most appropriate treatment approach (Vincent, 2002). Treatment of cancer includes a combination of different treatment regime such as chemotherapy and radiotherapy or surgery and chemotherapy or all three surgery, chemotherapy then radiotherapy or single use of either form of treatment (National Institutes of Health, 2012; Trueman, 2013; Palatty *et al.*, 2014).

Factors influencing the treatment regime include but not limited to age, disease extent, and comorbidities (Sacco *et al.*, 2011).

2.2.1 Surgery

Approximately 90% of patients cured of solid malignant tumours have undergone surgical resection either alone or in combination. Surgeon's role is to remove a malignant tumour completely with an appropriate margin of normal tissue. Surgery can also be done palliatively when a tumour causes intestinal obstruction, pain or bleeding, to relieve these symptoms and

improve patients quality of life (Yaeger and Brady, 2001).

2.2.2 Chemotherapy

Edward and Allan (2015) reported that chemotherapy involves the administration of cytotoxic drugs either orally or intravenously. The oncologist usually chooses the mode of treatment depending on the type of cancer, the staging, and the disease extent. There is a different mode of chemotherapy administration which includes:

Primary Chemotherapy: chemotherapy is administered as the primary treatment for patients who present with advanced cancer for which no alternative treatment for instance patients with advanced metastatic disease in which the goal is to release tumour-related symptoms and improve the quality of life.

Neoadjuvant chemotherapy: its chemotherapy administered to a patient when a tumour is still present. The goal is to reduce the size of a primary tumour so that surgical resection can be made easier.

Adjuvant Chemotherapy: In this chemotherapy is administered after a tumour has been surgically resected. The goal is to reduce the incidence of both local and systemic recurrence and improve the overall survival of the patient.

2.3 Radiotherapy Treatment

Radiotherapy is one of the treatment options in the medical management of cancers. It is used as a neoadjuvant and an adjuvant utilizing high-energy radiation to destroy malignant cells and shrink tumours. It is also used as a palliative measure in patients with locally or metastasized cancer to reduce the symptoms (Kamanzi *et al.*, 2016, Ducassou *et al.*, 2015; Juraskova and Lubotzky, 2015). Approximately 16% of all cancer patients are on radiotherapy with a cure rate of 40% (Trueman, 2013).

Radiation modalities include: External-beam radiation where radiation is given externally, a machine is placed at a distance from the mapped site and radiation is aimed directly at a tumour and surrounding tumour.

Internal radiation therapy also is known as brachytherapy- In this radioactive material is given by; tubes inserted into the body and left to emit a low dose of radiation for up to 30 hours; or the tubes with high dose rate are inserted severally over a short period (Juraskova and Lubotzky, 2015). According to (Goutos and Ogawa, 2017) some of the advantages include: radiation deliver is focused on the target area; less exposure to the healthy skin; low doses of

radiation is used to achieve effective therapy compared to external beam radiotherapy.

2.4 Effects of radiotherapy

Not only does radiotherapy kills cancer or slows the growth but also it affects the healthy cell. These effects depend on the area of radiation, they can range from acute to late effects (National Cancer Institute–National Institutes of Health, 2012).

Effects affecting gastrointestinal tract usually occur 2–3 weeks of initiation of treatment (acute) and include nausea, abdominal pains and diarrhoea which resolve after 2–4 weeks of treatment completion. The late effects may include malabsorption, bowel dysmotility, intestinal fibrosis and fistula just to mention a few and these usually occur six months to three years after completion of treatment (Hauer-Jensen *et al.*, 2007; Juraskova and Lubotzky, 2015).

Genitourinary symptoms include but not limited to slight bleeding or discharge from the vaginal, urinary retention or incontinence, burning sensation when passing urine. Fertility and sexual problems include erectile dysfunction, reduced vaginal dryness, painful coitus and early menopause just to mention a few (Juraskova and Lubotzky, 2015). Other effects include weight loss, severe pain, xerostomia and osteoradionecrosis (Cancer Research UK, 2017).

2.5 Effects of Radiotherapy on the skin

Studies have shown that skin is the most affected organ, can present with an acute skin reaction which can be mild erythema to moist desquamation. Approximately 85–87% of patients experience moderate to severe skin reactions and 10–15% of these progress to moist desquamation. Between 1997–2015 approximately 90.6% of total burns where due to RT-induced burns worldwide (Ryan *et al.*, 2013; Trueman, 2013; Portas, 2015).

The skin is composed of two major layers the epidermis and dermis. The dermis contains nerves, lymphatic and blood vessels, glands and hair follicles. The epidermis is composed of renewing cells in which production equals cell loss hence creating a continuous cycle. The new cells originate from the basal layer replacing the shedding cells. Hence, RT-induced skin burns occur as a result of damage of the basal cells which leads to an imbalance between new cell production at the basal layer and destruction of calls at the skin surface (Trueman, 2013; Palatty *et al.*, 2014).

Studies have shown that the most affected are areas in which rapidly proliferating cell and self-renewing organs are for example the epithelial surface of the skin and alimentary tract (Trueman, 2013).

Researches done have shown that RT-induced xerostomia is one of the most common complication among patients with head and neck cancer (Singh *et al.*, 2012). For patients with cancers involving the pelvis tend to get radiation proctopathy which is early inflammation in the pelvis occurring which occurs six weeks of radiation therapy (McCrone *et al.*, 2017).

Research done has shown RT-induced skin burns occur by affecting the regeneration of the skin through the process of repair, redistribution, repopulation and oxygenation. This includes damage to the skin occurs through the generation of free radicals as a result of radiolysis of water which causes damage to macromolecules (Trueman, 2013; Palatty *et al.*, 2014).

2.6 Predisposing factors of RT-induced skin burns

According to (Trueman, 2013; Palatty *et al.*, 2014; Portas, 2015; Ferreira *et al.*, 2017) studies have shown that different factors contribute to making the patient more susceptible to RT-induced skin burns. The factors can be classified as either intrinsic or extrinsic.

2.6.1 Intrinsic factors

These are patient-related factors and include:

Age: RT-induced skin burns are more common with the elderly as the repair process needed to combat the damaged caused by radiation is reduced compared to the young.

Comorbidities: Presences of other conditions like anaemia, diabetes, immunosuppression (HIV), genetic disorders, connective tissue disorders (like lupus, scleroderma) contribute to the severity of RT-induced skin burns.

Nutrition: Deficiencies like vitamin C deficiencies in patient make them more prone to radiation and alteration in wound healing process hence slowing down recovery.

Lifestyle habits: Smoking and tobacco use tend to reduce the haemoglobin oxygen carrying capacity increases the amount of carbon dioxide. This can cause a reduction in macrophages activity, induce platelet stickiness and reduce the ability of the skin cells and vasculature to grow and regenerate.

Obesity: Increases the surface area exposed to radiation hence increasing the risk by two folds compared to their lean counterparts. The skin folds also increase the risk of RT-induced skin burns due to the moisture.

2.6.2 Extrinsic Factors

These are more related to RT and they include:

Dose and fraction of radiation: RT-induced skin burns occur especially when fractionation dose exceeds 30–40 Gy. The more the doses the increase in the risk of skin burns due to an increase in the exposure to radiation.

The site of treatment: The neck, extremities, chest, abdomen, face hair scalp and breast tissue are the most sensitive areas of the body and are more prone to RT-induced skin burns.

Treatment combination: Concurrent use of radiation and chemotherapy especially with doxorubicin, bleomycin and 5-Fluorouracil which are associated with skin reactions after administration can increase the occurrence of RT-induced skin reactions (National Cancer Institute–National Institutes of Health, 2012; Trueman, 2013; Palatty *et al.*, 2014; Ferreira *et al.*, 2017).

Radiation sensitivity: Patients who are more sensitive to radiation are more prone to getting RT-induced skin burns

Duration of treatment: Treatment duration depends on the type of tumour a patient has and can be from two to even 10 weeks. The patient can be getting radiation once a day for five days. The longer the duration of treatment the higher the chances of getting RT-induced skin burns (Trueman, 2013; Palatty *et al.*, 2014; Ferreira *et al.*, 2017).

2.7 Clinical manifestation of RT-induced skin burns

RT-induced skin burns occur within days to weeks after initiation of RT treatment. The symptoms vary in severity from moderate to severe erythema, moist scaling. Early symptoms include erythema which may appear during the first 24-hours, skin dryness, itching, discomfort, pain and burning sensation this may persist up to four weeks after treatment. Pigmentation changes, hair loss, atrophy, fibrosis and ulceration are the late symptoms (Palatty *et al.*, 2014; Portas, 2015; Ferreira *et al.*, 2017).

The Radiation Therapy Oncology Group (RTOG) came up with a grading system which classifies the RT-induced skin burns into different grades as follows (Trueman, 2013; Portas, 2015).

Grade 0: No visible change to the skin

Grade 1: faint or dull erythema, itching, dry desquamation

Grade 2: bright erythema, sore, wet/moist desquamation, oedema, yellow/pale greenish exudate

Grade 3: Confluent moist desquamation, yellow/pale green exudate, severe soreness with oedema

Grade 4: Ulceration, bleeding, necrosis.

Management of the burns includes but not limited to:

Grade 1 cleaning the affected area with lukewarm water with mild soap, applying unscented lanolin-free moisturizer (Ryan *et al.*, 2013).

Grade 2 and 3: the affected area can either be open by use of collagenous ointment, silver sulfadiazine plus lidocaine. The wound care can be managed at home or in an outpatient setting. In grade 3 the wound is managed with an antibiotic to manage the infection and prevent further complications. Its paramount for the wound care to be done in a hospital set up (Portas, 2015).

Grade 4. Due to the severity of the RT-induced burns surgical treatment is used to include excision, skin autograft, and combination with local cellular therapy (Bey *et al.*, 2010).

Patient with xerostomia can be fitted with artificial dentures with a reservoir for artificial saliva (Singh *et al.*, 2012).

The ultimate goal is for management is to minimize treatment-induced symptoms; support the patient with self-care intervention; preventing further trauma and pain from inappropriate management; promoting wound healing environment (Trueman, 2013)

Protection of the healthy tissues can be through: use a low dose of radiation as possible that will kill the cancerous cells and limit damage to healthy cells; spreading out the treatment over time such as once a day; small doses twice a day for several weeks; ensuring the precise part of the body is radiated through mapping. Assessment of the target area during each session in order to identify and mitigate any signs before it progresses any further (National Cancer Institute–National Institutes of Health, 2012; Portas, 2015).

2.8 Complications of RT-induced burns on clinical outcomes on the cancer patient

RT-induced skin burns affect the patient in different ways which may include:

Deformities – RTOG grade 4 may lead to necrosis of the affected area predisposing the patient to undergo surgery, which can be amputation or lead to gross deformity.

Prolonged Hospital stays: Most of the RT sessions are done on outpatient basis. In cases of severe burns, there is need of inpatient management of the wound and continuation of RT. This brings about the unnecessary hospital stay.

Financial constraint: Additional management of skin burns due to radiotherapy adds more strain to the financial status of the family due to the prolonged hospital stay.

Psychological strains: Patients undergoing RT treatment are already under emotional, physical, psychological, social and financial stress due to the diagnosis. Burns induced by RT treatments makes this worse and may trigger the patient to go into depression.

Sepsis: The skin forms part of the primary immune defence system and once the skin integrity is compromised the patient is prone to infections. With an already compromised immune system due to the cancer state, the infection may progress to sepsis. This may lead to multiple organ failure.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study design

This was a descriptive cross sectional study aimed at assessing the prevalence and clinical outcome of radiotherapy-induced skin burns, among patients undergoing radiotherapy treatment at KNH.

3.2 Study site

The study was carried out at the Kenyatta National Hospital (KNH) one of the oldest hospitals in Kenya founded in 1901. It is located along Hospital Road, Upper Hill Nairobi and covers an area of 45.7 hectares. Kenyatta National Hospital is also the largest National Referral and Teaching Hospital in East Africa with a bed capacity of 2000 beds distributed in 50 wards. There are 24 theatres and over 6000 staff members. Over 10,000 people visit the hospital daily from all over Kenya and East African region. Kenyatta National Hospital is the largest referral hospital, it receives patients from all over the country which provides a greater diversity of radiotherapy treatments representative of the country generally. This, therefore, makes it a suitable study site. The study was conducted at the radiotherapy department of the KNH the only hospital that offers radiotherapy services. Services are offered by consultant radiation oncologists, nuclear medicine specialists, radiation technologists, nurses and other associated cadres. Therapy is delivered to both in-patients and out-patients. KNH offers both External Beam Radiotherapy (EBRT) and Brachytherapy.

3.3 Study Population

The study population consisted of patients diagnosed with cancer and undergoing radiotherapy at KNH. On average, a total of 120 patients are X-rayed every day.

3.3.1 Inclusion

The study included all the ages and participants must meet the following characteristics:

1. Consenting patients who are undergoing radiotherapy treatment for cancer in KNH radiotherapy unit.
2. Qualified nurses working in radiotherapy unit who consent to take part in the study.

3.3.2 Exclusion criteria

Participants were excluded from the study if they had any of the following characteristics.

1. Patients who declined to consent to participate as well as the mentally confused at the

time of collecting data.

2. Patients who want some immediate gain whether financial or material.
3. Qualified nurses who decline to consent to participate in the study.

3.4 Sampling frame and

The sampling frame included all patients on follow up at the KNH Therapy unit. All patients undergoing radiotherapy and consent to undertake the study were eligible to participate in this study. Enrollment of study participants was carried out at the beginning of each clinic day. This was done at the registration desk where all patients were reported for their appointments. A systematic random sampling method was used to recruit a specific number of study participants each day depending on patient turn out. Participants were informed about the need to participate in the study before being involved in the study.

Sampled participants were interviewed after being reviewed by the clinicians. This was done after assessing their eligibility and obtaining informed consent to participate in the study.

A survey of the files of was done to assess the patient's radiotherapy skin burns clinical outcomes of the patients for the past one year.

3.5 Sample size:

The sample size was calculated based on Fisher's formula for estimating the minimum sample size that is the best representative of the population.

The sample size of nurses was 50 percent of the total nurses working the oncology units.

$\frac{50 \times 28}{100} = 14$ nurses.

A sample size of nurses will be 13 nurses.

The Fisher's et al. 1998 formula

$$n = \frac{Z2pq}{d2}$$

n= the desired sample size (if the target population is greater than 10,000).

z= the standard normal deviate at the required confidence level.

p= the proportion in the target population estimated to have the characteristic being measured.

q=1-p

d= the level of statistical significance set.

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

=384.16

=384

If the target population is less than 10,000, the required sample size will be smaller. In this case, the sample estimate is calculated using the formula:

$$nf = \frac{n}{1 + (n/N)}$$

Where:

nf= the desired sample size (when the population is less than 10,000).

n= the desired sample size (when the population is more than 10,000).

N=the estimate of the population size.

nf= n/1+ (n/N)

nf= 384 / 1+ (384/100)

nf= 384 / 1+3.84

nf=384/4.84

nf=79.33

Sample size was 79 patients

3.6 Data Collection

Two research assistants were recruited and trained on the objectives of the study and also on the data collection instruments. These research assistants were the clinicians working in the Radiotherapy clinics and who were available for the entire period of data collection. Pretesting of questionnaires was carried out at KNH on 10 patients undergoing radiotherapy and who were not included in the final sample.

Necessary adjustments to the questionnaires were made as informed by the findings of the pilot study to improve on the reliability of the data to be collected in the main study. Following

recruitment of study participants and obtaining informed consent to participate in the study, data was collected by administering structured questionnaires, to the participants.

Consent forms were given to the respondents to read understand what the research is all about and then those who signed the formed were allowed to participate in the study.

3.6.1 Patients questionnaires

The study consisted of open and closed-ended questionnaires. The questionnaires were administered physical on the day of collection of data. The questionnaires were self-administered to the patients.

These questionnaires captured socio-demographic data and key variables of the study which include; intrinsic factors which include age, allergies, number of cycles and comorbid like diabetes, hypertensive, and clinical outcomes RT burns.

3.6.2 Nurses questionnaires

The nurse's questionnaires were administered through the drop and pick method. The nurse's questionnaires captured information of management of burns and clinical related outcomes.

3.6.3 Checklist

Survey of the file records was done to access the patient records for the past one year. The medical records for sample patients were obtained from the records department. The data that was extracted was patient demographics, clinical characteristics, clinical outcomes, and the current clinical condition of the patients of patients attending radiotherapy treatments.

3.7 Data analysis and presentation

STATA version 14 was used for statistical analysis. Descriptive and inferential statistics were obtained for example frequencies and percentages for numerical outcomes while means and the standard deviation were used for continuous data like age. Logistic regression was done to identify independent predictors of the clinical outcome variable and the various factors as the predictor variables.

Dummy table showing analysis for the number of patients who underwent RT in 2017

	XBRT	**BRACHYTHERAPY**
FEMALE	646	446
MALE	557	346
TOTAL	1203	792

3.8 Dissemination Plan

The ethics and review committee received a copy of the research. The research outcome was given to the school of nursing sciences and students and in the school website. The final research copy was made available at the University of Nairobi libraries for future references. The research study will be published in one of the international journals.

3.9 Ethical consideration

Ethical approval was sought from Kenyatta National Hospital/University of Nairobi Ethical and Research Committee to carry out the study in the hospital. Explanation to the study subjects on the purpose and the benefits of the study, confidentiality of their information and volunteerism was carried out in addition to obtaining an informed consent from the study subjects. Data obtained was treated with confidentiality at all times.

Voluntary participation: Participants were informed that participation in the study was voluntary and that they had the right to withdraw at any time which would not result in any penalties.

Informed consent: The participants were given an information sheet which briefed them about the study (see appendix) and a consent form (see appendix) which they will be requested to read and sign.

Confidentiality: Participants was assured that all information shared will be held in confidence.

Anonymity: Participants were assured that they will not be named in the research report and any possible publication arising from the study. Participation will not be aimed at jeopardizing the participant's employment.

Potential benefits and risks: Qualitative interviews on sensitive topics may provoke powerful emotional responses from a participant (Gonzalez-Perez, 2007). Participants were informed that there may be some risks associated with participating in this research study since all human interactions and talking about self or others carry some amount of risk. They were, however, assured that such risks will be minimized and that the researcher would act promptly to assist if any discomfort was experienced during the interview. Participants were also informed that there would not be any financial or other benefits to them but that the research would be used to improve the knowledge on male practitioner's experiences and challenges.

Permission to conduct the study was sought from the RT unit and research department at KNH.

CHAPTER FOUR: RESULTS

4.1 Introduction

This study was conducted to assess the prevalence, risk factors and clinical outcome of radiotherapy-induced skin burns in patients undergoing cancer treatment at KNH. The results represented in this chapter are derived from data obtained from three tools: structured questionnaires completed by 79 patients, abstracted patient files were reviewed. The results have been presented in three sections as per the study objectives. Section one deals with the feedback from the patients, section two covers data collected from patient's files and section three data from nurses. Each section will have three sub-sections in which prevalence, predisposing factors and clinical outcomes of radiotherapy-induced skin burns will be discussed.

PART A: Data from patients' Questionnaires

4.1 Patients Demographic Data

Of the respondents below 19 years were 12.7% (n=79) patients, and 5.1% (n=79) were above 70 years. A majority were female 69.6% (n=79), and 56.4% (n=78) of primary education.

Table 4.1 Demographic data of the patients' respondents

		Frequency	Percent
Age (n=79)	0–19	10	12.7
	20–39	16	20.3
	40–59	37	46.8
	60–79	12	15.2
	> 80	4	5.1
Gender (n=79)	Female	55	69.6
	Male	24	30.4
	Total	79	100
Education (n=78)	No formal	7	9.0
	Primary	44	56.4
	Secondary	23	29.5
	University/College	4	5.1

4.2 Common cancers among the respondents

The common types of cancers among the study respondent were cervical cancers with 41.56% (n=77), while head and neck cancer accounted for 29.87% (n=77), breast cancer had 14.29% (n=77), Wilm's tumour and abdomen cancer counted for 9.09% (n=77) and Muscles and blood had 5.19% (Table 4.2)

Table 4.2 Types of cancers

Cancer type	Frequency (N)	Percent (%)
Wilms' tumour and Abdomen	7	9.09
Breast Cancer	11	14.29
Cervical Cancer	32	41.56
Head and Neck	23	29.87
Muscle and Blood cancer	4	5.19
Total	77	100

4.3 Staging of the cancer

In cancer staging, the participants who participated in the study were at different cancer stages, with 1.6% at stage 0, 10.9% stage 1, and stage 1B 4.7%, stage 2B 20%, stage 3A 37.5%, stage 3B 3.1%, stage 4 6.3%. This is reflected in table 4.3 below.

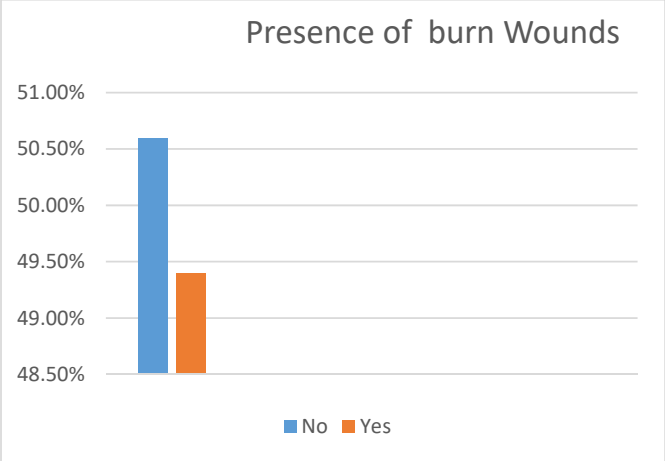
Table 4.3 Cancer stage at diagnosis

	Frequency (N)	Percent (%)
Stage 0	1	1.6
Stage I	7	10.9
Stage IB	3	4.7
Stage IIA	10	15.6
Stage IIB	13	20.3
Stage IIIA	24	37.5
Stage IIIB	2	3.1
Stage IV	4	6.3
Total	64	100.0

4.4 Prevalence of skin burns on patients undergoing radiotherapy

Of the respondents, 49.4% (n=38) had radiotherapy-induced skin burns (graph 4.3).

Graph 4.1 Presence of burn



4.4.3 Predisposing factors

This section presents results of predisposing factors. This will include intrinsic factors: age, comorbidities, nutritional status, lifestyle habits, and obesity. Extrinsic factors; dose and fraction of radiation, site of treatment, radiation sensitivity, and duration of treatment (Table 4.4).

Table 4.4 Relationship between various predisposing factors and RT-induced skin burns

		Presence of Wound			P-Value
		No	Yes	Total	
Age (n=79)	0-19	5	5	10	0.636
	20-39	8	8	16	
	40-59	22	15	37	
	60-79	5	7	12	
	Above 80	1	3	4	
Comorbidities (n=21)	Diabetes	2	2	4	0.352
	Hypertension	4	1	5	
	HIV AID's	5	7	12	
	Total	11	10	21	
Nutritional	Poor	1	1	2	0.638
	Fair	16	21	37	

(n=77)	Good	17	13	30	
	Excellent	5	3	8	
Number of Cycles (n=71)	1 - 10	24	14	38	0.001
	11 - 20	11	9	20	
	21-30	0	10	10	
	Above 31	0	3	3	
Combined Treatment (Chemotherapy) (n=79)	No	21	19	40	0.914
	Yes	20	19	39	
Radiation Type (n=72)	EBRT	37	30	67	0.017
	Brachytherapy	0	5	5	
Site of radiation (n=78)	Head and Neck	10	16	26	0.418
	Chest	7	5	12	
	Abdomen	13	11	24	
	Pelvis	10	6	16	
Skin Allergies (n=78)	No	40	33	73	0.018
	Yes	0	5	5	

4.5 Clinical Outcomes of RT-induced skin burns

In this section, we are going to discuss how it took for the burns to appear, common RTOG grade among the respondents, and challenges faced by the patients.

4.5.1 How long did it take for the skin burn to appear?

From the study, the participants that reported RT-induced skin burn 14.3 % (n=5) reported the burn appeared within a week, 42.9% (n=15) within 2 weeks after commencing treatment, 37.1% (n=13) above 2 weeks and 5.7% (n=2) after one month of treatment commencement.

Table 4.5 Time taken for the RT burns to appear

Time taken	Frequency (n)	Percent (%)
Less than a week	5	14.3
1-2 weeks	15	42.9
Above 2 weeks	13	37.1
Any other (1 month)	2	5.7
Total	35	100.0

4.5.2 Common RTOG grade

Majority of the participants, 75% (n=15) had grade 2, 15% (n=3) had grade 1.

Table 4.6 RTOG grades

Grade	Frequency (n)	Percent (%)
Grade 0	1	5
Grade 1	3	15
Grade 2	15	75
Grade 4	1	5
Total	20	100

4.5.3 Challenges faced by the patient on clinical outcome

Most of the participants 76.5% (n=13) experienced emotional distress, 17.6% (n=3) had health issues, while 5.9% (n=1) had financial constraints **(Table 4.7)**

Table 4.7 Challenges faced by patients who had RT-induced skin burns

	Frequency (n)	Percent (%)
Emotional	13	76.5
Financial	1	5.9
Health issues	3	17.6
Total	17	100

Part B: Retrospective data from Patients records

4.2.1 Demographic Data from patients file review

Of the files reviewed, a majority 79.7% (n=63) were between the ages of 50–79 years Majority were female 59.5% (n=47), 78.6% (n=55) were married. Of the participants 45.2% (n=14) had primary education, while 40.7% (n=22) were unemployed, as shown in Table 4.1.

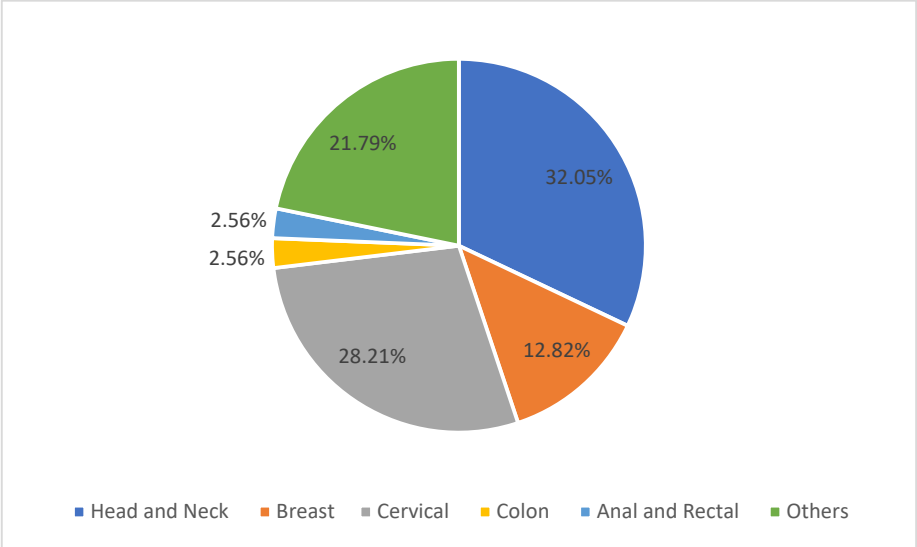
Table 4.1 Demographic data from reviewed files

		Frequency (n)	Percentage (%)
Age (n=79)	0-19	3	3.8
	20-49	12	15.2
	50-79	63	79.7
	Above 80	1	1.3
	Total	79	100
Gender (n=79)	Female	47	59.5
	Male	32	40.5
	Total	79	100
Marital status (n=79)	Single	8	11.4
	Married	55	78.6
	Divorced	1	1.4
	Widowed	5	7.2
	Separated	1	1.4
	Total	70	100
Education level (n=79)	No formal	1	3.2
	Primary	14	45.2
	Secondary	8	25.8
	College	8	25.8
	Total	31	100
Occupation (n=79)	Student	3	5.6
	Unemployed	22	40.7
	Self-Employed	17	31.5
	Employed	12	22.2
	Total	54	100

4.2.2 Cancer Types

From the files reviewed, patients with head and neck cancers were 25(32.5%), those with cervical cancer were 22(28.21%), breast cancer 10(12.82%), colon 2(2.56%), and anal rectal 2(2.56%).

Chart 4.1 Cancer types



4.2.3 Cancer Stages

From the files reviewed at the time of diagnosis 22.2% (n=6) patients had stage III, 22.2% (n=6) had stage IIIB, 18.5% (n=5) had stage IIB, rest had different stages.

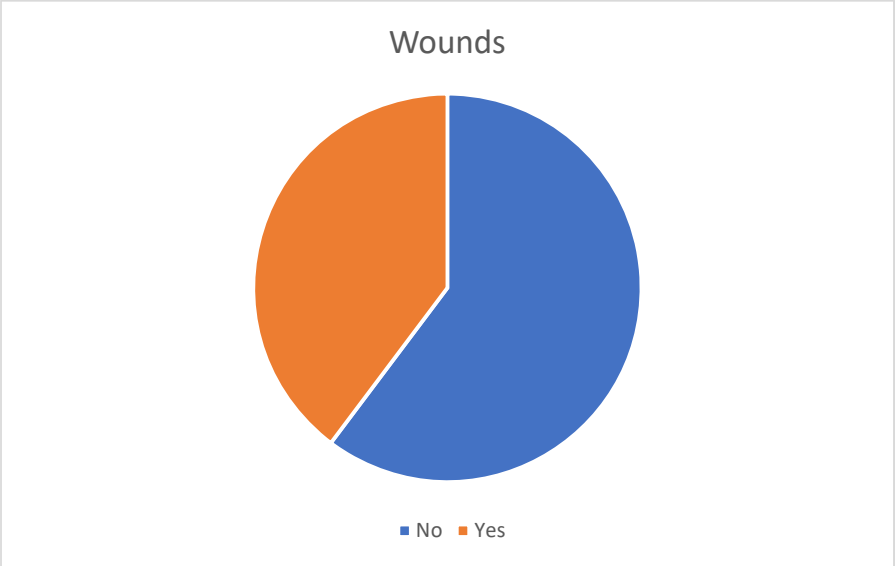
Table 4.2 Cancer staging at time of diagnosis

Cancer Stage	Freq.	Percent
1	1	3.7
1B	1	3.7
II	2	7.4
IIB	5	18.5
III	6	22.2
IIIA	3	11.1
IIIB	6	22.2
IV	2	7.4
IVB	1	3.7
Total	27	100

4.2.4 Prevalence of RT-induced Skin burns

A total of 39.74% (n=31) of the files reviewed patients had RT-induced skin burns, while 60.26% (n=47) didn't.

Chart 4.2 Presence of wounds



4.2.5 Predisposing factors of RT-induced skin burns

This section presents results of predisposing factors and their relationship with RT-induced burns as shown in Table 4.3. This will include: intrinsic factors: age, comorbidities, nutritional status, lifestyle habits, obesity. Extrinsic factors; dose and fraction of radiation, site of treatment, radiation sensitivity, and duration of treatment.

Table 4.3 Relationship between predisposing factors and RT-induced skin burns

		Presence of Wound			P-Value
		No	Yes	Total	
Age (n=79)	0-19	2	1	3	0.737
	20-49	6	6	12	
	50-79	38	24	62	
	Above 80	1	0	1	
	Total	47	31	78	
BMI (n=66)	Underweight	7	10	17	0.207
	Normal	18	14	32	
	Overweight	8	3	11	
	Obese	5	1	6	
	Total	38	28	66	
Dose (n=72)	1 - 10	0	1	1	0.314
	11 - 20	4	0	4	
	21-30	7	5	12	
	31-40	0	1	1	
	41-50	26	19	45	

	51-60	6	3	9	
Number of cycles (n=49)	1 - 10	8	3	11	0.310
	11 - 20	1	4	5	
	21-30	17	11	28	
	31-40	1	2	3	
	41-50	1	1	2	
Treatment combination (Chemotherapy) (n=54)	NO	14	6	20	0411
	YES	20	14	34	
Radiotherapy type (n=74)	Both	0	3	3	0.024
	Brachytherapy	0	2	2	
	External	43	26	69	
Comorbidities (n=30)	Diabetes	3	2	5	0.451
	Hypertension	5	3	8	
	HIV / AIDs	9	8	17	
Smoking (n=69)	No	31	21	52	0.709
	Yes	11	6	17	
Alcohol (n=70)	No	29	18	47	0.946
	Yes	14	9	23	
Treatment Site (n=71)	Head and Neck	12	11	23	0.705
	Brain	1	1	2	
	Chest	6	2	8	
	Pelvic	20	12	32	
	Lower limbs	2	2	4	
	Skin	0	1	1	
	Bone	1	0	1	

4.2.6 Clinical Outcomes of RT-induced skin burns

4.2.6.1 Common RTOG grades

From the files reviewed 61% (n=14) patients had grade 2 burns, 26% (n=6) patients had grade 1 burns, 9% (n=2) patients had grade 0 burns and 4% (n=1) patient had grade 4 burns.

Table 4.9 Common RTOG grades

RTOG Grade	Frequency	Percentage
Grade 0	2	9%
Grade 1	6	26%
Grade 2	14	61%
Grade 4	1	4%
Total	23	100%

4.2.6.2 Management of RT-induced skin burns

From the files reviewed patients with RT-induced skin burns had different management as presented below.

RT-induced burns brings about the morbidity and different management approaches are used. From the review of files, the commonest treatment approaches were: Use of betadine mouth wash; saline gargles; hydrocortisone cream; keeping the radiated site clean and dry; sitz bath; surgical repair.

Part C: Results from clinical Nurse's interviews on occurrence of post RT burns

Of the respondents 50% (n=7) were between the ages of 20–39, and 50% (n=7) between 40–59 years. Majorities were female 57.1% (n=8). Most of the respondents had a diploma in KRCHN. Only 14.3% (n=2) of the respondents had any form of training on RT as shown in **(Table 4.1)**

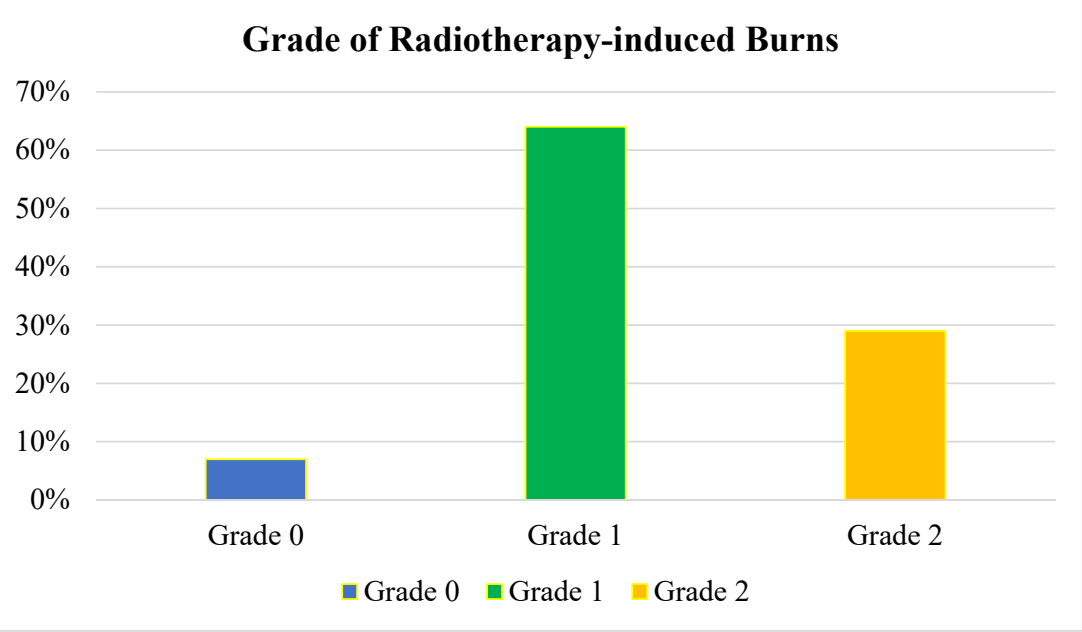
Table 4.1 Demography description of the respondents

		Frequency (n)	Percentage (%)
Age in years (n=14)	20 - 39	7	50
	40 - 59	7	50
Gender (n=14)	Female	8	57.1
	Male	6	42.9
Qualifications (n=14)	KRCHN	11	78.6
	BSN	3	21.4
Specialization	NO	12	85.7
	YES	2	14.3

4.3.2 RTOG as reported by the nurses

From the nursing report RTOG grade 1 was the most commonly reported 64.3% (n=9) followed by grade 2 28.6% (n=4) then grade 0 7.1% (n=1). **(Graph 4.2)**

Graph 4.2 RTOG commonly reported



4.3.3 Clinical outcome of RT induce skin burns as reported by the nurses

From the participants 35.48% (n=11) of the cases have mucositis, (16.12% (n=5) reports pain, 12.94% (n=4) reports cellulitis, xerostomia, depression and bowel dysmotility had 9.67% (n=3) each.

Table 4.4 Clinical outcomes of RT-induced skin burns

	Frequency	Valid Percent
Mucositis	11	35.48%
Weight loss	2	6.45%
Severe pain	5	16.12%
Xerostomia	3	9.67%
Bowel dysmotility	3	9.67%
Depression	3	9.67%
Cellulitis	4	12.94%
Total	31	100%

4.3.4 Management of RT-induced skin burns

Qualitative results from the nurses' interview showed that there was different treatment approached used which included: Application of dermazine; use of antibiotics and analgesics; use of betadine mouth wash; instruct patients not to clean the area been radiated; use of hydrogen peroxide; exposing the radiated area and application of soothing creams; psychological support about the outcome of radiation.

4.3.5 Challenges faced by the nurses in managing RT-induced skin burns

The respondent's responses when asked to identify challenges they face in managing skin burns: availability of creams; Consistent management regime; Affordability of the creams available; Most of the patients don't report the burns hence are missed out; Lack of guidelines for management of the RT-induced burns; Patients are unable to buy creams; the RT burns are painful and heal slowly.

4.3.6 Recommendations of managing RT-induced skin burns as reported by the nurses

The respondents involved in the study had the following recommendations on managing RT-induced skin burns: Avail creams in the hospital for easier access by the patients; development of management guidelines; Hydrogel cream to be procured into KNH pharmacy; Sensitive patients to be changed to 3D line; Patients to keep skin clean and moist, avoid contact with UV light; Clear instruction should be communicated on the management of the patients prior to RT

and reduction of risk factors; Psychotherapy for patients; Radiotherapy to avail creams to patients and give them psychological support about the outcome of radiation.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 Cancers Type and Staging and Prevalence of RT-induced Skin Burn

The common types of cancers among the study participants were cervical cancers, head and neck cancer, breast cancer. As from the patients' records at the time of diagnosis, stages III, IIIB and IIB had high number of patients. The remaining were in different other stages. The study did not explore the relationship between the stages of cancer and radiotherapy-induced skin burns. However, it extensively looked into the area of treatment which is strongly attributed to the type of cancer and the induced skin burn. From the data obtained, patients with head and neck tumours had RT-induced skin burns, 11 patients with cancers affecting the abdomen and 6 patients with cancers affecting the pelvic region had RT-induced skin burns. The side effects of radiotherapy depend on the size and nature of the treatment area. As it has been evident from the data obtained in the study, radiation around the head and neck areas is likely to have more effects than in the pelvic and the abdomen areas. Stereotactic radiosurgery (radiation given in one large dose) is usually given to people with tremors in the head. The large dose given, therefore, is the primary reason for higher risk of side effects including the skin burn. This, therefore, explains the high prevalence of RT-induced skin burns among patients with head and neck tremors. Patients receiving treatment in the abdomen area also had relatively high cases of burns. This case is attributed to the larger area receiving the radiations. The findings are in line with Kuipers, and Velders (2009)'s study where it was stated that RT-induced skin burn is exacerbated by radiations on a larger surface area. This justification similarly applies to treatment in the pelvic area where radiations are directed within a smaller area hence less cases of radiotherapy-induced burns.

5.2 Radiation Dose and RT-induced Skin Burn

It was found in our study that the acute adverse effects increased with an increase in the radiotherapy dose which was in keeping with Padraig Warde et.al. (2012) observation on RT for dose effect on adverse events. He noted that the severity of the reaction varies according to the total radiation dose given and the time it is given among other important factors. Patients in our study were exposed to radiation at a maximal dose level of 64 Gy and the lowest was 10 Gy. Most of the patients receiving 40 Gy and above experienced burns. Therefore, it is undisputable that the prevalence if RT-induced skin burns increase with increase in the radiation dose. According to Weerakkody et al. (2008), the risk of suffering RT-induced burns

increases with the dose received by the patient or a radiotherapy staff. The dose is determined by various factors that include the time of exposure, equipment used and mode of operation.

5.3 Type of Radiation and RT-induced Skin Burns

Radiotherapy-induced skin burn is also highly influenced by the type of radiation used for treatment. Patients receiving brachytherapy had a higher risk of developing RT burns compared with patients receiving EBRT.

5.4 Number of cycles and RT-induced Skin Burns

The period of exposure to the radiation has significant impact on the occurrence of RT-induced skin burns. From the research, statistic difference was noted among the subjects who had burns and those without burns across the number of cycles of therapy they received. Higher risk of getting burns was noted in patients with 21 or more cycles. Lower number of burns were observed in patients with less cycles. Lengthy exposure to radiations escalates the risk for developing skin burns (Weerakkody et al., 2008). However, this may vary depending on the radiation dosage being received at each cycle.

5.5 Age and RT-induced Skin Burns

It is clear that age has an impact on the likelihood of a patient undergoing radiotherapy to develop skin burns. The highest rate of RT-induced skin burn was observed among the older patients above 40 years. These statistics indicates that older people are more likely to develop skin burns as a result of radiotherapy. According to Shortt et al. (2007), the natural ageing process affects the epidermal cell cycle which can result in extended healing times. It is the slow healing process that is responsible for the high cases of skin burn among the older patients.

5.6 Comorbidity and RT-induced Skin Burns

Comorbidity is another critical factor that may influence the development of induced skin burns. As stated by Wayam and Lekesa (2010), other illnesses and some medications can increase the risk and intensity of skin reactions and impact upon the healing process. Some of these ailments and medications include diabetes, HIV/AIDs and steroids among others. In this research, patients with comorbid had increased risk of developing RT burns. High rate of burns is witnessed among patients with HIV/AIDs because it impacts the patient's immune hence the healing process. The lowest rate was witnessed with the patients with hypertension since the condition has no effect on the healing process. These findings correlate with Otisno (2010)'s study where 86% of HIV/AIDs victims suffered from RT indicated skin burn.

5.7 Nutritional Status and RT-induced Skin Burns

Adequate nutritional intake is necessary for optimum repair of tissue damage. The skin of undernourished patients may be at increased risk of damage (International Commission on Radiological Protection, 2007). From the study, nutritional status of 77 participants was obtained where most of them reported good and fair nutritional status with 36 and 35 patients respectively. Four reported excellent while two reported a poor nutritional status. Highest numbers of skin burns were observed among patients with fair condition (21 patients), followed by good nutritional status with 13 patients. Only 3 patients with excellent nutritional status had skin burn.

5.8 Relationship between Smoking and Alcohol Intake with RT-induced Skin Burn

From the data obtained in the study, a high percentage of those who used alcohol and tobacco suffered induced skin burn. In their study, Kimoto et al. (2013) concludes that substance abuse and alcohol consumption can decrease capillary blood flow and oxygen levels thus increasing the severity of the skin reaction and impairing the body's ability to heal damaged tissues and fight infection.

5.9 Obesity and RT-induced Skin Burn

The BMI also impact the chances of developing RT-induced skin burns. According to Bryk (2006), extra adipose tissue can compromise healing and exacerbate skin toxicity due to the extra skin folds or areas where there is a natural skin fold such as natal cleft and inframammary fold. Similar results were obtained in this research where a high percentage of the overweight individuals in the study suffered from induced skin burns.

5.10 Clinical outcomes of RT-induced skin burns

Occurrence of burns increases morbidity, disease burden among patients. RTOG grade 1 and 2; pain; emotional distress common among the patients. This is in keeping with a study done by Cancer Research UK, (2017)

5.11 Conclusion

The study observed that there is a relationship between predisposing factors and burns. The most significant ones been allergies, number of cycles and type of radiotherapy either EBRT or brachytherapy. Of these factors some can be mitigated like nutrition, use of low fraction of radiation in patients with skin allergies. It was observed that the clinical outcomes vary depending on the degree of burns sustained. Most of the patients reported emotional distress, pain, financial constrains has been among the leading challenges they experienced.

5.12 Recommendations

1. Lack of clear policies and guidelines to support management of RT burns reduces effectiveness in management hence the RT department needs to develop clear policies
2. The study was done in KNH radiotherapy unit only hence results cannot be generalized. Other researchers can do comparative studies in other institutions
3. Researchers can do longitudinal studies to find out the long term effect of RT

5.13 Study Limitations:

Most of the participants didn't have knowledge on what dose of radiation they were receiving. This made it hard to find a relationship between radiation dose and skin burns. The participants had knowledge deficit on what skin allergies were all about. This was challenging as the researcher had to explain what exactly it meant.

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APPENDICES

Appendix I: Work Plan

Activity	**Dec 2017**	**Jan 2018**	**Feb 2018**	**Mar 2018**	**April 2018**	**May 2018**	**June 2018**	**July 2018**	**Aug 2018**	**Sept 2018**
Proposal development										
Approval by Nursing School										
Approval by Ethic research committee										
Study Pre-test										
Data Collection										
Data analysis										
Report writing and result presentation										
Dissemination: submission and Publication										

Appendix II: Budget

DESCRIPTION / ITEM	UNIT	QUANTITY	COST PER UNIT	TOTAL COST
Proposal Writing				
Typing and printing	Reams	2	500	1000
Note book	Pieces	2	500	600
Writing material	Pieces	10	20	200
Photocopy	Ream	2	500	1000
KNH ethical committee			2000	2000
Questionnaire's				
Typing and Printing	Reams	2	500	1000
Photocopy	Reams	2	500	1000
Data collection cost				
Research Assistance	Individual	2	10,000	20,000
Researcher	Individual	1	40,000	40,000
Transport	Trip	30 days	300	9,000
Subtotal				75,800
Contingency cost In case the prices fractions			10% Total cost	7,580
Grand Total				**83,380**

Appendix III: Letter to KNH/UON Ethics and Research Committee

Doris V Wanja Machaki

University of Nairobi

School of Nursing Sciences

1st March 2018

To

The Chairperson

KNH/UON Ethics and Research Committee

P. O. Box 20723-00202

Nairobi.

Dear Sir / Madam

RE: Ethical review and Approval of proposal Entitled **PREVALENCE AND CLINICAL OUTCOMES OF RADIOTHERAPY-INDUCED SKIN BURNS IN CANCER PATIENTS AT KENYATTA NATIONAL HOSPITAL.**

I am a second year post graduate nursing student, pursuing Master of Science in Nursing (Oncology). I am writing to request permission to carry out research on Occurrence and clinical outcomes of Radiotherapy-induced skin burns in patients undergoing radiotherapy treatment at KNH, oncology unit. The study will be carried out in the radiotherapy unit, KHN.

Your kind consideration to allow me carry out this research in KNH will be highly appreciated; It will go a long way in facilitating completion of my study. The research findings will be utilized both locally and internationally in improving provision of quality patient care.

Thank you

Yours sincerely,

Doris V. Wanja Machaki. **Reg No: H56/88632/2016**

Appendix IV: Letter to KNH Chief Executive Officer (CEO)

Doris V Wanja Machaki

University of Nairobi

School of Nursing Sciences

1st March 2018

To

The CEO

Kenyatta National Hospital

Nairobi.

Through

Assistant Chief Nurse,

Radiotherapy Department KHN

Dear Sir / Madam

RE: Permission to undertake study entitled: PREVALENCE AND CLINICAL OUTCOMES OF RADIOTHERAPY-INDUCED SKIN BURNS IN CANCER PATIENTS AT KENYATTA NATIONAL HOSPITAL

I am a second year post graduate nursing student, pursuing Master of Science in Nursing (Oncology). I am writing to request permission to carry out research on Occurrence and clinical outcomes of Radiotherapy-induced skin burns in patients undergoing radiotherapy treatment at KNH, oncology unit. The study will be carried out in the radiotherapy unit, KHN.

Your kind consideration to allow me carry out this research in KNH will be highly appreciated; It will go a long way in facilitating completion of my study. The research findings will be utilized both locally and internationally in improving provision of quality patient care.

Thanks for your continuous support

Yours sincerely,

Doris V. Wanja Machaki. **Reg No: H56/88632/2016**

CC. Chief Nurse, KNH

Deputy Chief Nurse Medicine, KNH

Appendix V: Informed consent information for patients

Title of the study

PREVALENCE AND CLINICAL OUTCOMES OF RADIOTHERAPY-INDUCED SKIN BURNS IN CANCER PATIENTS AT KENYATTA NATIONAL HOSPITAL

Doris V. Wanja Machaki

University of Nairobi

P.O Box 30197-00400

Nairobi.

Supervisors

Supervisor

Prof. Ann Karani

Mobile number: 0721850910

Introduction

Introduction: I am a student at the School of Nursing Sciences, University of Nairobi pursuing a Master of Science Degree in Nursing. I am conducting a study titled: occurrence and clinical outcomes of post radiotherapy skin burns in cancer patients at Kenyatta National Hospital.

This study will be conducted at Kenyatta national hospital medical oncology units.

This study will be looking to determine the clinical outcomes of skin burns due radiations during radiotherapy. To achieve this, the study will look at the, intrinsic factors and extrinsic factors and how they determine clinical outcome conditions of skin burns in cancer patients. This research will ultimately help in improving management post radiotherapy skin burns.

The purpose of this information is to give you details pertaining to the study that will enable you make an informed decision regarding participation. You are free to ask questions to clarify any of the aspects we will discuss in this information and consent form. I will also ask you questions regarding the study before you sign the consent form to ascertain your comprehension of the information provided.

Purpose of the study

This study will determine the factors leading to clinical outcomes of skin burns of patients undergoing therapy. Identifying trends in clinical outcomes is very important for patients receiving care for chronic conditions such as cancer.

Risks

There will be no economic or physical risks to participating in the study. However, you will take some time off your schedule to respond to questions from the researcher administered questionnaire. Also, during the interview, some questions will require you to disclose some personal information that might trigger some negative feelings and possibly anxiety. If this happens, the researcher will refer you to the hospital counselor.

Benefits: There is no direct monetary benefit in participating in this study. However, the results of the study will be useful in facilitating the understanding of the various factors that determine the occurrence of burn wounds and how they can be controlled. The findings will be availed to the hospital, other relevant decision makers and stakeholders to aid in putting in place measures that will improve the care given in management of skin burns for patients undergoing radiotherapy in order to avoid those suffering complications.

Confidentiality: Confidentiality will be maintained and the information you provide will only be used for the intended purpose of the study. In addition, your name will not be required on any forms or used during publication of the final report thus ensuring your anonymity. All materials used during the study will be under lock and key and only the personnel involved in this study will have access to them. Electronic files will be saved on password and fire-wall protected computers.

Voluntary participation: Participation in this study is voluntary. Refusal to take part will not attract any penalty. You retain the right to withdraw from the study without any consequences. You are free not to answer any question during the interview.

Compensation: There is no compensation for participating in the study

Appendix VI: Consent form

If you Consent to Participate in the study please sign below:

I hereby consent to participate in this study. I have been informed of the nature of the study being undertaken and potential risks explained to me. I also understand that my participation in the study is voluntary and the decision to participate or not to participate will not affect my employment status at this facility in any way whatsoever. I may also choose to discontinue my involvement in the study at any stage without any explanation or consequences. I have also been reassured that my personal details and the information I will relay will be kept confidential. I confirm that all my concerns about my participation in the study have been adequately addressed by the investigator and the investigator have asked me questions to ascertain my comprehension of the information provided.

Participants Signature (or thumbprint) ……Date…… I confirm that I have clearly explained to the participant the nature of the study and the contents of this consent form in detail and the participant has decided to participate voluntarily without any coercion or undue pressure.

Investigator

Signature…….Date……...

For any Clarification, please contact

Doris V. Wanja Machaki

Researcher

Mobile Number: 0723508945

Email: doris.machaki@gmail.com

Or

Supervisor

Prof. Ann Karani

Mobile number: 0721850910

Appendix VII: Questionnaire for patients

Please tick appropriately

SECTION A: DEMOGRAPHIC DATA.

1. What is your age?

a) Less than 20 years ( )
b) 20-39 years ( )
c) 40-59 years ( )
d) over 60 years

2. What is your gender?

a) male ( )
b) female ( )

3. What is your highest level of education?

a) Never been to school ( )
b) Primary ( )
c) Secondary ( )
d) University/college ( )

4. Do you suffer from the following disease(s)?

Diabetes ( ) Epilepsy ( ) Hypertension ( ) any other specify ……

5. Lifestyle:
Smoking: Yes ( ) No ( )
Alcohol : Yes ( ) No ( )

6. a)What is your current weight ___ Kg
b) Lowest weight during in this Illness _____ Kg

c) Height (m)_____

7. Nutritional intake, please tick appropriately.

a) Excellent ( )
b) Eats most of every meal.
c) Usually eats a total of or more servings of proteins.
d) Good ( )
e) Eats over half of most meals.

OR

a) Is on adequate tube feeding or TPN regimen
b) Fair ( )
c) Rarely eats a complete meal and generally eats a little of any food offered.

OR

a) Receives less than optimum amount of liquid diet or tube feeding

b) Poor: ( )
c) Never eats a complete meal.

8. Do you have skin allergic conditions? Yes ( ) No ( )

9. How does your skin react to allergic conditions?

a) Moderate reaction ( )
b) Severe reaction ( )

10. a) Is your skin allergic to radiations Yes ( ) or No ( )

b) If yes, does it react severely with increase in number of radiations yes ( ) No ( )

11. Which type of cancer do you have?

a) Lung cancer ( )
b) Breast cancer ( )
c) Prostate cancer ( )
d) Cervical cancer ( )
e) Any other please specify.……

12. Which type of radiation therapy are you receiving?

a) External Beam Radiation Therapy ( )
b) Brachytherapy ( )

13. Which part of your body was radiotherapy done?

a) Head ( )
b) Neck ( )
c) Chest ( )
d) Abdomen ( )
e) Legs ( )
f) Any other specify……

14. Which Stage of cancer diagnosis are you in?

a) Stage 0 ( )
b) Stage I ( )
c) Stage IIA ( )
d) Stage IIB ( )
e) Stage IIIA ( )
f) Stage IV ( )

15. Do you have Chemotherapy and radiotherapy (Combined Treatment)?

a) Yes ( )
b) No ( )

16. What dose of radiation did you receive?

a) 0-10 ( )
b) 10-20 ( )

c) 20-30 ( )
d) 30-40 ( )
e) Above 40 ( )

17. How many cycles have you received? ……

18. How often do you receive radiation per week?

a) Twice a week ( )
b) Thrice a week ( )
c) More than thrice a week ( )
d) Any other please specify ( )……

19. Have you seen any changes on your skin?

Yes ( ) No ( )

20. How long did it take for the wound to appear?

a) Less than a week ( )
b) 1-2 weeks ( )
c) Above 2 weeks ( )
d) Any other……

21. What is the current condition of the wound?

a) Pus discharge ( )
b) Healing ( )
c) Scar fading away ( )
d) Worsening ( )
e) Any condition please specify ……

22. Do you take or apply drugs to heal the wounds?

a) No ( )
b) Yes ( )

23. What are the challenges you face since the developing the skin burn?

a. Emotional ( )
b. Financial ( )
c. Health issues
    i. Pain
    ii. Surgery
    iii. Deformities
    iv. Infections

Appendix VIII: Informed consent information for Nurses

Title of the study

PREVALENCE AND CLINICAL OUTCOMES OF RADIOTHERAPY-INDUCED SKIN BURNS IN CANCER PATIENTS AT KENYATTA NATIONAL HOSPITAL.

Doris V. Wanja Machaki

University of Nairobi

P. O. Box 30197-00400

Nairobi.

Supervisors

Supervisor

Prof. Ann Karani

Mobile Number: 0721850910

Introduction

Introduction: I am a student at the School of Nursing Sciences, University of Nairobi pursuing a Master of Science Degree in Nursing. I am conducting a study titled: occurrence and clinical outcomes of post radiotherapy skin burns in cancer patients at Kenyatta National Hospital.

This study will be conducted at Kenyatta national hospital medical oncology units.

This study will be looking to determine the clinical outcomes of skin burns due radiations during radiotherapy. To achieve this, the study will look at the, intrinsic factors and extrinsic factors and how they determine clinical outcome conditions of skin burns in cancer patients. This research will ultimately help in improving management post radiotherapy skin burns.

The purpose of this information is to give you details pertaining to the study that will enable you make an informed decision regarding participation. You are free to ask questions to clarify any of the aspects we will discuss in this information and consent form. I will also ask you questions regarding the study before you sign the consent form to ascertain your comprehension of the information provided.

Purpose of the study

This study will determine the factors leading to clinical outcomes of skin burns of patients undergoing therapy. Identifying trends in clinical outcomes is very important for patients receiving care for chronic conditions such as cancer.

Risks

There will be no economic or physical risks to participating in the study. However, you will take some time off your schedule to respond to questions from the researcher administered questionnaire. Also, during the interview, some questions will require you to disclose some personal information that might trigger some negative feelings and possibly anxiety. If this happens, the researcher will refer you to the hospital counselor.

Benefits: There is no direct monetary benefit in participating in this study. However, the results of the study will be useful in facilitating the understanding of the various factors that determine the occurrence of burn wounds and how they can be controlled. The findings will be availed to the hospital, other relevant decision makers and stakeholders to aid in putting in place measures that will improve the care given in management of skin burns for patients undergoing radiotherapy in order to avoid those suffering complications.

Confidentiality: Confidentiality will be maintained and the information you provide will only be used for the intended purpose of the study. In addition, your name will not be required on any forms or used during publication of the final report thus ensuring your anonymity. All materials used during the study will be under lock and key and only the personnel involved in this study will have access to them. Electronic files will be saved on password and fire-wall protected computers.

Voluntary participation: Participation in this study is voluntary. Refusal to take part will not attract any penalty. You retain the right to withdraw from the study without any consequences. You are free not to answer any question during the interview.

Compensation: There is no compensation for participating in the study

Appendix IX: Consent form

If you Consent to Participate in the study, please sign below:

I hereby consent to participate in this study. I have been informed of the nature of the study being undertaken and potential risks explained to me. I also understand that my participation in the study is voluntary and the decision to participate or not to participate will not affect my employment status at this facility in any way whatsoever. I may also choose to discontinue my involvement in the study at any stage without any explanation or consequences. I have also been reassured that my personal details and the information I will relay will be kept confidential. I confirm that all my concerns about my participation in the study have been adequately addressed by the investigator and the investigator have asked me questions to ascertain my comprehension of the information provided.

Participants Signature (or thumbprint) ……Date……

I confirm that I have clearly explained to the participant the nature of the study and the contents of this consent form in detail and the participant has decided to participate voluntarily without any coercion or undue pressure.

Investigator Signature……. Date ……...

For any Clarification, please contact

Doris V. Wanja Machaki

Researcher

Mobile Number: 0723508945

Email: doris.machaki@gmail.com

Or

Supervisor

Prof. Ann Karani

Mobile number: 0721850910

Appendix X: Questionnaires for Nurses

SECTION A: DEMOGRAPHIC DATA.

1. What is your age?

A. 20-39 years ( )
B. 40-59 years ( )
C. over 60 years

2. What is your gender?

D. male ( )
E. female ( )

3. What is your qualification?

F. ENROLLED ( )
G. KRCHN ( )
H. BSN ( )
I. MSc. N ( )

4. Do you have any specialized training in oncology/radiotherapy nursing?

YES ( ) NO ( )

5. What is the most common grade of radiotherapy-induced skin burns do you see?

i) Grade 0: No visible change to the skin ( )
ii) Grade 1: faint or dull erythema, itching, dry desquamation ( )
iii) Grade 2: bright erythema, sore, wet/moist desquamation ( )
iv) Grade 3: Confluent moist desquamation, yellow/pale green exude ( )
v) Grade 4: Ulceration, bleeding, necrosis ( )

6. How do you manage the skin burns?

……

……

7. What are the clinical outcomes of the radiotherapy? You can tick more than once

A. Cellulitis ( )
B. Mucositis ( )
C. Weight loss ( )
D. Severe pain ( )
E. Depression ( )
F. Xerostomia ( )
G. Osteoradionecrosis ( )

H. Bowel dysmotility ( )

I. Intestinal fibrosis ( )

J. Any other please specify

……

……

8. What challenges do you face in managing the skin burns?

……

……

……

……

9. What are your recommendations on the skin burn management procedures?

……

……

……

Appendix XI: Data collection form

Serial Number …….

Instructions

Fill out all the questions in the data collection tool.

Patient Demographics

1. Age**……**
2. Gender: Male ( ) Female ( )
3. Education Level

Primary ( ) Secondary ( ) College ( ) University ( )

4. Occupation

Student ( ) Unemployed ( ) Self-employed ( ) Employed ( )

4. Weight in Kg……
5. Height in Meters……..
6. BMI……..
7. Marital status

Single	
Married	
Divorced	
Widowed	
Separated	

9. Smoking Yes ( ) No ( )

10. Alcohol user Yes ( ) No ( )

Clinical characteristics

1. Report on the outcomes associated from the skin burn on the patient.

……

……

2. Report on the wound management practices performed on the skin burn.

……

……

……

CHECK LIST

TYPE OF CANCER	TYPE OF RADIOTHERAPY EXTR / Brachytherapy	RADIOTHERAPY FRACTION	TOTAL DOSES RECEIVED			RTOG Stage
			To the skin	Tumour dose	Total dose	

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

KENYATTA NATIONAL HOSPITAL APPROVED 21 MAY 2018 KNH/UoN-ERC P.O. Box 20723-00202 NRB.

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

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

Ref: KNH-ERC/A/185

May 21, 2018

Doris Val Wanja Machaki
Reg. No.H56/88632/ 2016
School of Nursing Sciences
College of Health Sciences
University of Nairobi

Dear Doris

RESEARCH PROPOSAL – PREVALENCE AND CLINICAL OUTCOMES OF RADIOTHERAPY INDUCED SKIN BURNS IN CANCER PATIENTS AT THE KENYATTA NATIONAL HOSPITAL (P140/03/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is from 21st May 2018 – 20th May 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) 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*).
f) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Director, School of Nursing Sciences, UoN
Supervisors: Prof.Anna Karani, Mrs. Angeline C. Kirui

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

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

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   DORIS VAL WANJA MACHAKI
2. Email address: doris.machaki@gmail.com Tel No. 0723508945
3. Contact person (if different from PI) N/A
4. Email address: ..... Tel No. .....
5. Study Title
   PREVALENCE AND CLINICAL OUTCOMES OF RADIOTHERAPY INDUCED SKIN BURNS IN CANCER PATIENTS AT THE KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted CANCER TREATMENT CENTRE
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the Department where the study will be conducted.
   Name: ..... Signature ..... Date .....
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: Dr Catherine Mpanjoka Signature ..... Date 8/6/2018
9. KNH UoN Ethics Research Committee approved study number P140/03/2018
   (Please attach copy of ERC approval)
10. I DORIS VAL WANJA MACHAKI commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
    Signature ..... Date 8th JUNE 2018
11. Study Registration number (Dept/Number/Year) CTC / 40 / 2018
    (To be completed by Research and Programs Department)
12. Research and Program Stamp

KENYATTA NATIONAL HOSPITAL * Research Resource Centre * P.O. Box 20723 - 00202 NAIROBI 11 JUN 2018

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