ASSESSMENT OF INSTITUTIONAL SUPPORT ON HEALTHCARE WORKERS IN SAFE HANDLING OF CYTOTOXIC AGENTS AND RELATED WASTE AT KENYATTA NATIONAL HOSPITAL

HENRY KILEMI MITHEU

H56/6776/2017

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF SCIENCE IN NURSING (ONCOLOGY) OF THE UNIVERSITY OF NAIROBI.

SEPTEMBER, 2019

DECLARATION

I hereby declare that this thesis is my original work and has not been submitted anywhere else by any other person(s) for research purpose or award of any degree or otherwise.

Sign _____

Date…….

Henry Kilemi Mitheu

H56/6776/2017

University Nairobi

School of Nursing Sciences

SUPERVISORS CERTIFICATE OF APPROVAL

We the undersigned certify that this thesis has been submitted with our approval as internal supervisors.

James Mwaura, PHD

Senior Lecturer

School of Nursing Sciences

College of Health Sciences

University of Nairobi

Signature ……. Date……..

Lucy Kivuti Bitok, PHD

Senior Lecturer

School of Nursing Sciences

College of Health Sciences

University of Nairobi

Signature ……. Date……..

DEDICATION

To my wife Annah Syokau and my daughter Precious Mukiri for their continuous support during this period and to my parents, Mr.& Mrs. James Mitheu, for their support this far.

ACKNOWLEDGEMENT

First and foremost I would like to give thanks to the almighty God for His favors throughout my studies. This thesis could not have been complete without the inputs from a number of key players: my supervisors Dr. James Mwaura and Dr. Lucy Kivuti for their support and for working with me tirelessly through the whole process of carrying out this study. I also wish to extend my sincere appreciations to Dr. Kimani and Mrs. Kirui of School of nursing Sciences for their inputs and encouragement.

I also extend my sincere appreciation to the University of Nairobi, for offering me a scholarship and support towards my studies.

I would also want to truly thank my colleagues for their encouragement and my employer The County Government of Machakos for granting me a study leave so that I can pursue my studies.

Lastly I would also like to thank my parents and my wife for spiritual, financial and moral support throughout my studies and period of writing this thesis.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS AND ACRONYMS

ASHP	American Society of Health-Sytem Pharmacists
BSC	Biosafety Cabinets
CDSC	Cytotoxic Drug Safety Cabinet
CME	Continuous Medical Education
GFC	Ground Floor Ward C
GFD	Ground floor Ward D
HBM	Health Belief Model
HCW	Health Care workers
HD	Hazardous Drugs
HPM	Health Promotion Model
KNH	Kenyatta National Hospital
MOH	Ministry of Health
NIOSH	National Institute of Occupational and Safety Health
OSHA	Occupation Safety and Health Administration
PHDP	Predicting Use of HD Safe Handling Precautions
POGO	Pediatric Oncology Group of Ontario
PPE	Personal Protective Equipment
SPSS	Statistical Package for Social Sciences
TPB	Theory of Planned Behavior

UON University of Nairobi

WHO World Health Organization

OPERATIONAL DEFINITIONS

Cytotoxic agents: these are substances that are toxic/harmful to the body cells. They are synonymous to chemotherapy agents and anticancer drugs

Cytotoxic waste: refers to the materials, equipment and residues contaminated by cytotoxic drugs. It also included urine and stool of patients on chemotherapy drugs.

Handling: it encompasses receiving, storage, preparation, administration and disposal of the cytotoxic drugs and wastes

Hazardous Drugs: used synonymously as cytotoxic agents

Healthcare Workers: this includes all the personnel working in a hospital setting. In this study it includes the doctors, nurses, pharmacists, pharmaceutical technologists and cleaners.

Institutional support: refers to provision of the PPEs, policy and guidelines on handling of cytotoxic drugs and waste, and training and reevaluation of healthcare workers on handling the cytotoxic drugs and the waste.

Key informants: These are the officers in-charge of the various wards involved in the day to day supervision of the ward activities.

Registrars: these are postgraduate medical students pursuing a master's degree specialization in either internal medicine, obstetrics and gynecology or pediatrics.

ABSTRACT

Healthcare workers are exposed to cytotoxic agents and waste in their day to day practice as they handle them. These agents are known to be carcinogenic, mutagenic and teratogenic hence posing a risk to those handling them. Institutions needs to protect their workers from exposure to cytotoxic agents by provision of the necessary personal protective equipment (PPEs) for use, providing frequent trainings on the need for protection and giving policies to guide the use and handling of cytotoxic agents and their wastes. Few studies have focused on safe handling of cytotoxic drugs by healthcare workers in KNH.

The main objective was to assess the institutional support of healthcare workers in safe handling of cytotoxic agents and related waste at Kenyatta National Hospital.

This was a descriptive cross-sectional study involving both qualitative and quantitative methods. A questionnaire, an observation check list and an interview guide were used to collect data. The study was carried out at KNH oncology wards/units. The study population included consultant doctors, registrars, nurses, pharmaceutical technologists, pharmacists and cleaners. The sample size was one hundred and sixty two respondents. The healthcare workers who consented to participate in the study were included while those who were on leave were excluded. Stratified simple random sampling was used to select the study participants. Pretesting of the study tool was done in KNH private wards to ascertain reliability and validity. Data analysis was done using SPSS and presented in graphs, charts and tables. Ethical approval was obtained from joint Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UON ERC) and permission to conduct the study from the heads of various departments at KNH. The study findings have been shared with the school of nursing sciences, UON libraries and the investigator intends to publish a manuscript in peer reviewed journals.

From the results, the response rate in this study was 92.5% with majority (77.3%, n=116) of the respondents being females. The mean age of the respondents was 35.9±9.98 years. Only 12% (n=20) of the healthcare workers in the oncology units had a specialized oncology training. Further analysis showed that healthcare workers with specialized oncology training were likely to practice safe handling compared to the ones who lacked specialized training (**P=0.000**). All the key informants were nursing officer in-charge of the oncology wards with mean age of 24.5±6.41. Most, 54% (n=81) of the respondents had no any form of training on handling of the cytotoxic drugs and wastes with majority being registrars at 71.4% (n=15). Further analysis showed that there was no association between safe handling of cytotoxic drugs/wastes and training on the same. Majority, 52% (n=78), of the respondents were not aware of existence of any policy document and this was corroborated by 50% (n=2) of the key informants. There was no association between accessibility of the institutional policy and safe handling of the cytotoxic drugs and wastes. Hospital did not provide the PPEs as required especially the shoe covers, eye and face shields and hair covering however there was statistical significance between provision of PPEs during waste disposal and safe handling of the cytotoxic drugs and the waste among nurses (**P=0.02**). Most, 82% (n=124) of the respondents reported that there are no spill kits available in various wards for cleaning of the chemotherapy drug spills. This was further confirmed by key informants.

In conclusion, there was shortage and lack of appropriate personal protective equipment and spill kits in the various KNH wards for handling cytotoxic drugs. Most of the healthcare workers in the various oncology wards lack specialized training in oncology and a basic training in the handling of the cytotoxics drugs and related wastes. The healthcare workers were not knowledgeable about the available policy regarding handling of the cytotoxic drugs and disposal of related wastes to minimize the exposure. This therefore, underscores the need to conduct training of HCW, equip the wards with supplies and policy/guidelines on safe handling of cytotoxic drugs/wastes.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

Cancer is estimated to account for 9.6 million deaths in 2018 making it the second leading cause of death globally (Bray *et al.*, 2018). In men; lung, prostate, colorectal, stomach and liver cancers are the most prevalent whereas; breast, colorectal, lung, cervix and thyroid cancer have high prevalence among women (Bray *et al.*, 2018). With the increasing number of cancer cases there is increased use of cytotoxics and other modalities in the treatment and this increases more likelihood of exposure of the healthcare workers to chemotherapy drugs.

A study done in Iraq estimated that by the year 2020, the number of healthcare workers exposed to hazardous effects of antineoplastic agents will be more that 5.5 million (Mohsen and Fareed, 2013). This calls for an urgent action by the government and institutions where chemotherapy is used to take up measures to protect its workers by strictly enforcing the recommended guidelines.

Cytotoxics are used due to their ability to kill cancer cells by interfering with their cell division. When exposed to unintended cells, the cells end up being mutagenic, carcinogenic and/or teratogenic to the affected body tissues and organs. Occupational cytotoxic exposure occurs to healthcare workers through various methods namely: inhalation of the aerosolized drugs, skin absorption in case of spills and needle injuries during preparation and administration, handling of waste from the drugs and patients during their transport, disposal and cleaning of spills (Goodin *et al.*, 2011; Sheikh, 2016). Most of the healthcare workers do not follow already developed guidelines in their day to day practice of handling cytotoxics especially use of the personal protective equipment (PPEs) due to the shortage of supplies (Sheikh, 2016).

Chemotherapy safety protocols and standard operating procedures are important in managing, administration and patient care before, during and after treatment. The protocol should include

measures using good hygiene practices e.g. avoiding eating, smoking and drinking in areas where drugs are prepared, providing washing facilities and PPEs (Mohsen and Fareed, 2013). The PPEs provided should be of the right quality, suitable to the wearer and in good condition. The hospitals should strive to ensure that appropriate PPE are available for its staff.

According to South Australian Government, all the institutions dealing with cytotoxic agents and materials must seek to support and protect its workers handling the cytotoxic drugs. It recommends that institutions should: trains its workers on handling cytotoxics, provide PPEs, avail the guidelines for dealing with the cytotoxic drugs and waste and do continuous health surveillance monitoring of healthcare workers to ensure that they comply with the policy and the various legislations (South Australia Health, 2015).

In order to minimize exposure to chemotherapy, the drugs should be made available in a form that is ready to administer. All used supplies should be disposed in proper well labeled and coded bins (European Union, 2013). In KNH, most of the chemotherapy compounding takes place in the oncology pharmacy and very little is done at the ward level.

Occupation Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) recommends that employers should develop and avail policies and guidelines for handling chemotherapy safely. Employers should offer advance training in hazard communication; provide biological safety cabinet for drug preparation; provide suitable PPEs for those handling chemotherapy drugs and monitor all employees who are potentially-exposed in a medical surveillance program (NIOSH, 2004; OSHA, 2016). These measures once put in place they promote safety of the healthcare workers as they handle the antineoplastic drugs.

In Africa, there is a challenge in handling of the cytotoxic agents and wastes due to scarce infrastructure and supply chains and few trained personnel on cytotoxic use and disposal of the wastes (Vaz da Conceição, 2015). In Kenya, at Kenyatta National Hospital (KNH), unavailability

of the adequate personal protective equipment and too much workload have been shown to contribute to poor handling and increased risk of and exposure to cytotoxic materials (Sheikh, 2016).

This study sought to determine the availability of the personal protective equipment, training opportunities available for the HCW on safe handling of cytotoxic drugs and wastes and assess the disposal of cytotoxic wastes in oncology wards at Kenyatta National Hospital.

1.2 Problem Statement

Healthcare workers handling cytotoxic products are exposed during reconstitution, administration, handling of spills and the cytotoxic waste products. The exposed healthcare workers have been shown to be at risk of infertility, hair loss, fetal loss and possible malformations (New South Wales (NSW) SafeWork, 2017). Institutions handling cytotoxic agents and wastes should strive to ensure that its' healthcare workers are provided with the right PPEs and infrastructure for handling the cytotoxic agents and wastes.

KNH receives highest number of the cancer patients being diagnosed in the country and many are on the chemotherapy as part of the treatment. As the number of the patients increase, there is increased works load to healthcare workers hence putting them at a greater risk handling the cytotoxics (Jamah, 2014). As the institution provides the required equipment and infrastructure for the staffs handling chemotherapy and its waste, the knowledge of the healthcare workers on how to use them is important to ensure they use them well. A study conducted at KNH in 2016 on knowledge and practice of handling cytotoxic products recommended that the hospital provides continuous training through CMEs, seminars and workshops. It further recommended continuous reevaluation of the trained workers to ensure good grasp of knowledge and skill for safe chemotherapy handling (Sheikh, 2016).

1.3 Justification

Due to increasing number of cancer patients diagnosed every year in Kenya, KNH receives a big percentage of the same for treatment and management. This has led to increased use of the cytotoxic agents in various wards and department. Healthcare workers handling these agents and wastes need to handle them with a lot of care to avoid contamination.

To be able to handle the cytotoxic agents appropriately, healthcare workers handling the agents and waste needs support from the hospital management. The support can be by providing PPEs, training and offering CMEs to staff on handling chemotherapy, use of PPEs and also providing other necessary materials and equipment required for handling and disposal.

Few studies have been carried out to assess the healthcare workers knowledge on handling of the cytotoxic agents and wastes but none has focused on the in institutional support towards achieving safe disposal and handling of the same. This study was designed to evaluate institutional support by KNH management in regards to handling of cytotoxic wastes. The findings would be used to design appropriate interventions to support effective handling of cytotoxic wastes.

The findings of this study can be used as the basis for developing a policy by the government and specific institutions on how to protect its workers/employees handling antineoplastic drugs through the necessary support.

1.4 Study Objectives

1.4.1 Broad Objective

To assess institutional support on safe handling of cytotoxic agents and related waste by healthcare workers at Kenyatta National Hospital.

1.4.2 Specific Objectives

i. To assess availability and accessibility of the policy/guidelines on cytotoxic drugs and waste handling at Kenyatta National Hospital.

ii. To assess the training opportunities available for the HCW on safe handling of cytotoxic drugs and wastes at Kenyatta National Hospital.

iii. To determine the availability of personal protective equipment in various wards handling chemotherapy at Kenyatta National Hospital.

iv. To assess the disposal of cytotoxic wastes in oncology wards at Kenyatta National Hospital.

1.5 Research Questions

i. How available and accessible are the policy/guidelines on cytotoxic drugs and waste handling various wards/units handling chemotherapy at Kenyatta National Hospital?

ii. What training opportunities are there for staff on safe handling and disposal of cytotoxic wastes at KNH?

iii. Are the PPEs available for use by HCW handling chemotherapeutic agents in oncology wards at KNH?

iv. What is the practice of disposal of cytotoxic wastes in oncology wards at KNH?

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter comprises a survey of the various scholarly articles, reports and books read by the author in the process of the study. Literature search was done through Pubmed, Hinari and Google scholar. The key words used were: cytotoxic wastes, safe handling of cytotoxic wastes and institutional support on handling cytotoxic wastes.

2.1 Exposure to Cytotoxic Drugs

Cytotoxic drugs are medicines used as chemotherapy due to their ability to kill cells with cancer. They prevent growth and replication of the cancer cells. Their action is non-selective hence interfering with both cancerous and normal cells and various side effects (Fauzia Barket Ali, Shireen Arif, 2015). The prolonged occupational exposure to cytotoxic drugs and waste products has been associated with carcinogenic, mutagenic and teratogenic effects (Fauzia Barket Ali, Shireen Arif, 2015; Sheikh, 2016). Continuous exposure and handling cytotoxic drugs and wastes has also been associated with skin local reactions, hair loss contact dermatitis, abdominal pain, headaches, and liver damage (Fauzia Barket Ali, Shireen Arif, 2015).

Healthcare organizations should have the following indicator for a good/positive safety climate: safety policies and procedures which should be adhered to; providing education and training on sound practices; availing of equipment and supplies necessary for safety; provision of feedback and bolstering of safety and provision of support for safety programs (Polovich, 2016). These recommendations from Callahan and colleagues sets the basis for the hospitals and other institutions to adopt those recommendations to protect its workers.

2.2 Availability and accessibility of policy/guidelines on Handling of Cytotoxic

All wastes should be segregated and disposed of according to hospital policy and state and country regulations that apply (Connor and McDiarmid, 2006). Failure to use the laid down policies and guidelines leads to the exposure of the healthcare workers to acquiring infections.

Studies have revealed that failure to use the recommended guidelines in the healthcare is mostly contributed by lack of awareness of existence a guideline and lack of familiarization with the guidelines by the healthcare workers (Fürthauer, Flamm and Sönnichsen, 2013). If the guidelines are not followed each and every care workers ends up doing things differently hence lack of consistency.

Occupation Safety Health Administration (OSHA) recommends that the Standard operating procedures (SOPs) or policy and procedures providing for a comprehensive safety program to deal with all aspects of the safe handling of HDs should be made available at the operational level (OSHA, 2016). This includes the wards and pharmacies handling the chemotherapy drugs. The policy acts as a point of reference and guides healthcare workers in their day to day practice.

A study carried out in Iran on management of cytotoxic drugs and wastes showed that in Low- and middle-income countries there was an increase in the incidence of cancers and the usage of cytotoxic drugs (Askarian, Momeni and Danaei, 2013). It further showed that despite availability of the various guidelines on how to manage the cytotoxic waste, there was low compliance on the same and it cut across the government and private facilities (Askarian, Momeni and Danaei, 2013). Askarian *et al* showed that despite the policies being available they were not accessible to the most of the staff. From this study, it is evident that apart from developing a policy the institution should sensitize its workers on the same and avail it at their point of use for reference purposes.

2.3 Training Opportunities for Healthcare Workers on Handling of Cytotoxic Agents and Waste Products

According to Goodin et al., (2011), employees who handle cytotoxic drugs and related waste must be provided with appropriate and adequate information and instruction that is appropriate to their day to day work. These training helps create awareness on the various ways of exposure and the precautions to protect themselves, other staff and patients handling cytotoxic wastes and drugs (Easty *et al.*, 2015). Nurses must be competent in oncology practice and aware of the risks in their working environment for them to quality care and maintain the required (Crannell, 2012). Therefore nurses working in oncology unit must be well educated and regularly retrained on the chemotherapy use and administration. This is not an exception to the doctors and the other healthcare workers working in these units.

According to the South Australian Government policy on handling of cytotoxic drugs and related wastes, it is the duty of the various institutions to provide information, instruction, training and supervision of all healthcare workers handling cytotoxic drugs and related waste. The SA government recommends that only healthcare workers who have received suitable training and have achieved the appropriate level of competency and proficiency should be allowed to handle cytotoxic drugs and related waste (South Australia Health, 2015). The Royal Children's Hospital Melbourne policy indicates that all HCW must familiarize themselves with the hospital guidelines prior to handling of chemotherapy drugs and related wastes. The policy states that "No person must be involved in the handling, transport, preparation, administration or disposal of waste of any cytotoxic substance, without appropriate training to ensure the protection of the operator, the environment and the patient" (The Royal Children's Hospital Melbourne, 2018).

In Karachi, Pakistan, a study on association of knowledge on the attitude and practice of registered nurses regarding handling of cytotoxic drugs showed that limited knowledge on handling of

cytotoxic drugs contributed errors harming the patients and exposing themselves to the drugs. This study showed that 20% of the nurses were not trained on how to handle cytotoxic drugs and 43.33% believed that there was no need of using PPEs when handling the drugs (Fauzia Barket Ali, Shireen Arif, 2015). For successful handling of the chemotherapy drugs, hospitals must strive to provide the right policies and guidelines. This was revealed in Pakistan study where nurses said that sufficient education, training and hospital policy are effective to improve cytotoxic drug handling (Fauzia Barket Ali, Shireen Arif, 2015).

The practice of safe handling of cytotoxic drugs and waste is low even in the healthcare workers who have knowledge. A study in Jordan hospital assessing compliance on safe handling of antineoplastic drugs revealed that despite adequate knowledge on risks associated with exposure to drugs most nurses did not observe the protocols and the laid down policies (Al-Azzam *et al.*, 2015). According to King Edward Memorial Hospital, only personnel who have successfully completed a course of instruction and training on cytotoxic drugs and wastes are allowed to deal with cytotoxic drugs, wastes contaminated with cytotoxics and spills (King Edward Memorial Hospital, 2017)

Lack of knowledge on preventive measures against exposure to cytotoxic drugs among health care workers increases their unsafe behavior during their day to day practice. A study carried out in Nepal showed that most nurses in oncology units reported that their source of information on handling of cytotoxic drugs was mostly from the hospitals administration though training organized by the hospitals (Chaudhary and Karn, 2012). The Nepal study compares with the one carried out in Kenya which revealed that most of the healthcare workers who worked at oncology units in KNH had gotten their knowledge on cytotoxic drugs during their practice through conference (Sheikh, 2016).

2.4 Personal Protective Equipment

Personal protective equipment (PPE) provide protection to workers against exposure to aerosols and residues that are cytotoxic and hazardous in nature. Correct and consistent use of the PPEs when handling the cytotoxic drugs and waste reduces exposure and the risk of getting cancer due to the exposure (American Society of Health-Sytem Pharmacists (ASHP), 2006).

PPEs used to mix/prepare, to dispose and to clean spill should be considered contaminated with cytotoxic residues and should be disposed well like any other cytotoxic drug or waste. PPEs used to administer cytotoxic, perform patients care or discard patients waste should be considered contaminated with hazardous drug residue and potentially contaminated with infectious material (ASHP 2006). According to Easty *et al.*, (2015) it is the employers responsibility to provide the necessary PPEs and the training on how to use the equipment.

To reduce exposure to chemotherapy agents; National Institute for Occupational Safety and Health (NIOSH) recommends use of: "biosafety cabinets to reduce exposure against fumes emitted during reconstitution of drugs; two pairs of powderless and disposable gloves; single-use long sleeved chemo-protective gown with a closure at the back; respirator to protect from fumes and droplets; face protectors; administrative controls and mindful work cultures to reduce risks for exposure. When the above measures are used carefully and consistently, they minimize occupational exposure to cytotoxic agents (NIOSH, 2004).

2.4.1 Gloves

Gloves should be used at all times when handling cytotoxic waste. According to NIOSH double gloving is important in controlling spills and cleaning and disposing of hazardous waste. The recommendation is that the gloves used to handle cytotoxics should be nitrile, vinyl powder free latex gloves (American Society of Health-Sytem Pharmacists, 2006; Ministry of Health Kenya, 2013).

2.4.2 Gowns

Gowns should be always be worn during preparation of chemotherapy drugs to protect the healthcare workers from the preparation and protecting the preparation from being contaminated by healthcare provider (NIOSH, 2004). Health care providers should always gown before chemotherapy administration for protection against spill or splash. Most health care workers wear gown during preparation of the cytotoxics than during their administration (Polovich, 2016).

The gowns should be long sleeved with knit cuffs to fit over gloves and closing at the back. This reduces the powders and liquid exposure (NIOSH, 2004; Ministry of Health Kenya, 2013).

2.4.3 Eyes and Face Shields

The eye and face shields prevents the cytotoxic agents from spilling to the mucous membranes where they cause serious effect. The recommended eye and face shields includes the goggles and face masks which protects against splash and spills when cytotoxic material is being handles outside the biological safety cabinets. Surgical masks do not protect against exposure to cytotoxic drugs hence the need for N95 respirator mask which provides a barrier from splashes, droplets, and sprays (NIOSH, 2004).

2.4.4 Shoes and Hair Covering

The floors where cytotoxic products are being compounded/prepared for administration are at a high risk of spills. Wearing of closed shoe wears prevents exposure of the healthcare workers feet. Several studies recommends that shoe covers should not be worn outside the compounding or designated rooms for preparation (NIOSH, 2004; ASHP, 2006; MoH Kenya, 2013).

In Angola, scarce infrastructures and supply chains, lack of healthcare providers and trained staff tops the list among the challenges of handling cytotoxic drugs and wastes.

2.5 Disposal Guidelines on Handling of Cytotoxic Agents and Wastes

In the provision of the healthcare services various kind of wastes both liquid and solid are generated. These includes sharps, blood, body parts chemical, radio-active materials and pharmaceuticals (WHO, 2015). WHO recommends that government and various institutions should have practical document(s) that lists responsibilities and duties of staff, segregation, storage and transport procedures and color coding.

Cytotoxic waste is to be discarded in purple bins or yellow bin with a purple lid or any bins covered with purple liner bags and should be handled by persons with special training about the same (Chartered Institution of Waste Management, 2014). The bins additionally should have a cytotoxic/hazardous sign to ensure each and every person is alert and cautious when handling it.

A study carried out in Iran on management of cytotoxic drugs and wastes showed that in developing countries there is persistent rise in the new cases of cancer and the usage of antineoplastic drugs. Despite availability of the various guidelines on how to manage the cytotoxic waste, studies reveal that there is low compliance on the same and it cuts across the government and private facilities (Askarian, Momeni and Danaei, 2013).

The Iranian study showed that segregation of the cytotoxic wastes from medical waste is a great challenge in many health facilities especially from their source of production. In this study, 76.9% of the wards disposed their wastes as infectious agents while the 23.1% disposed it the non-infectious waste despite availability of well labelled bins for cytotoxic waste. It further revealed that there were no appropriate bags recommended for cytotoxic drug wastes. The facilities sampled also did not have cytotoxic drug waste labels, hazardous symbols or the standard method of disposing of cytotoxic drug wastes (Askarian, Momeni and Danaei, 2013). This shows the risk of exposure to the people handling the cytotoxic waste without their knowledge.

According to Pediatric Oncology Group of Ontario (POGO) syringes, needles bags and solution administration sets should be discarded in containers that are labelled, leak proof and puncture proof. The protective gears used during drugs handling and administration should be disposed in a well labeled container (Pediatric Oncology Group of Ontario, 2018)

Patients may release some of the cytotoxic and radioactive materials through their feces and urine. This increases the risk of other patients with whom they share the toilets with and the staff who handle their linen (Askarian, Momeni and Danaei, 2013; Kieffer *et al.*, 2015a; Pediatric Oncology Group of Ontario, 2018). The three studies recommend that the linen filled with urine, feces or vomitus of the patients on chemotherapy should be labelled separated transported and cleaned separately without mixing with other linen. This helps reduce the risk of exposure to other patients and also the healthcare worker handling them.

2.6 Summary of Literature

There is limited literature especially in Africa and Kenya on the support of the employers/institutions handling cytotoxics drugs and waste to its employees so as to minimize the risk of exposure to the drugs in the process of handling them. The various ways of support identified includes: provision of the policy document to the healthcare workers for perusal, consistent provision of the right personal protective equipment for use, training healthcare workers on handling the cytotoxics and its waste and ensuring proper disposal of the cytotoxic drugs and wastes in line with national/institutional guidelines.

2.7 Theoretical Framework

The theory of the Health Promotion Model (HPM) and the Health Belief Model (HBM) are applicable and appropriate for this study. The HBM is grounded on threat-related beliefs about a given behavior (DeJoy, (1996) and has concepts associated with beliefs, attitude and individual expectations about their health threats.

There are contextual models that take into consideration the interaction between the person and the situation or environment that impacts on their behavior. HPM is an example of contextual model (Pender, Murdaugh and Parsons, 2006) which shows that humans are biopsychosocial beings who are shaped by the environment in which they live in. This model focuses on: the individual experiences and characteristics and, behavior-specific cognitions and affect and the behavioral outcome which is the health promoting behavior.

The Factors Predicting Use of HD Safe Handling Precautions (PHDP) model (figure 1) will be adapted and customized for this study. It is a model derived from the HPM (Pender et al., 2006).

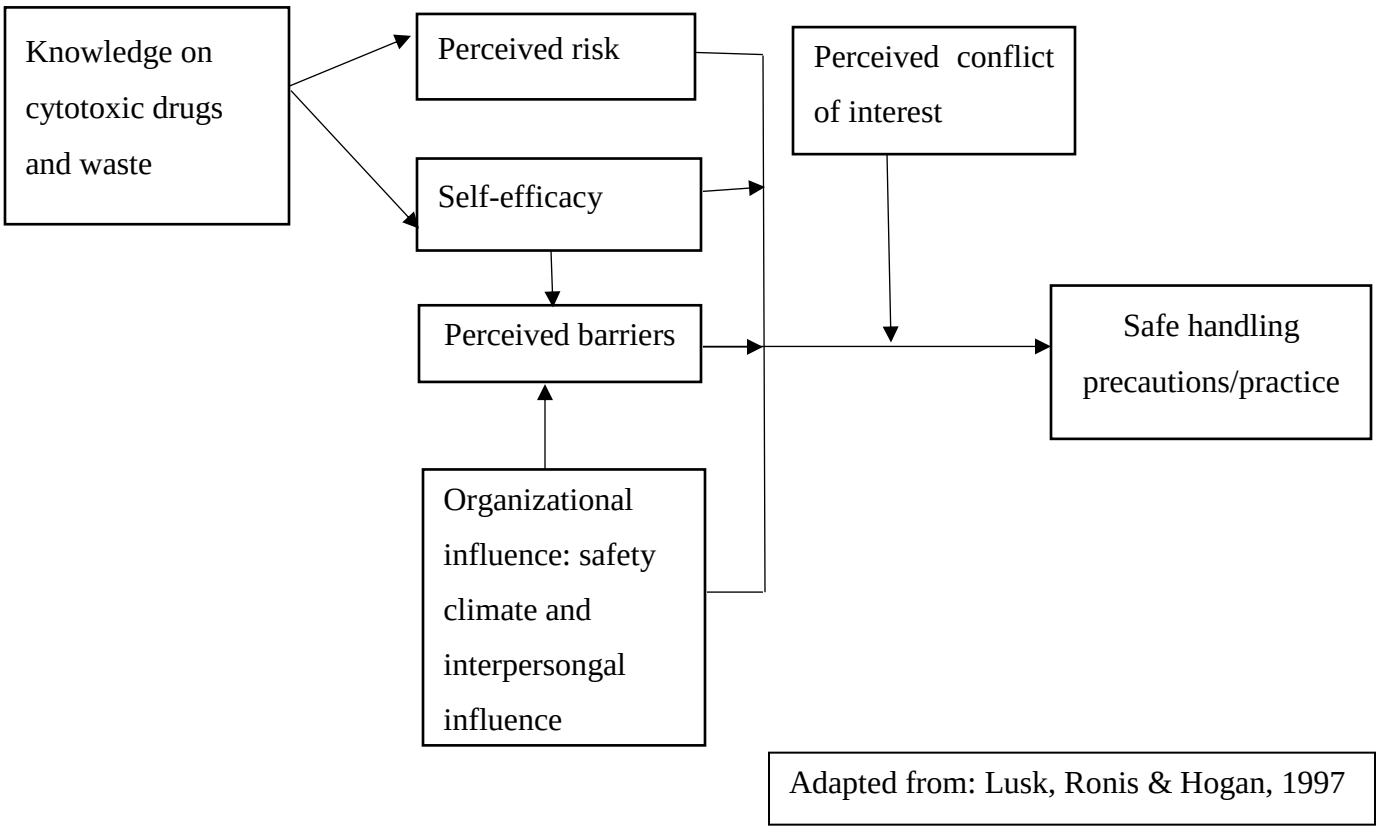


Figure 1: Factors Predicting Use of HD Safe Handling Precautions (PHDP Model)

Safe Handling Precautions: Safe handling precautions for cytotoxic drugs and related waste is the activity of concern. This is a self-protective behavior which pertains use of PPEs and other safety equipment in the workplace.

Knowledge about cytotoxic agents and related wastes. This is necessary for an individual to start taking precautionary measures. Knowledge on exposure and various protective mechanisms and their effectiveness will promote safe behavior.

Perceived risk: the individuals takes into consideration how serious threat is, how susceptible they are and the severity in both short term and long-term actions. Lack of personal susceptibility

reduces the likely hood of engaging in behaviors to reduce the risk. The motivation for engaging in self-protective behavior always considers the risk involved.

Self-efficacy is the judgment of personal capability to organize and execute a health-promoting behavior in this case the safe handling of cytotoxic wastes. It refers to the use of personal protective equipment in protection against chemotherapy exposure. This is related to prior knowledge and information the person had. The higher the self-efficacy is, the lower the act of perceiving barriers to practicing a health-protective behavior (Pender et al., 2006).

Perceived barriers: these are the imagined or real blocks for understanding a given behavior. They may include "difficulty, expense, unavailability, inconvenience, or time-consuming nature of a particular behavior/action" (Pender et al., 2006). Perceived barriers constrain commitment to action of self-efficacy and the use of safe handling precautions.

Organizational influence: this refers to characteristics of an organization that have the ability to influence behaviors of various individuals. The organizations should have safety guidelines e.g. on PPE use, training of staff as ways of protecting it workers, safety objectives and allocating adequate resources on the safety of its employees.

Interpersonal influence: this is the influence or the impact of the significant others at the workplace level as they form part of the organizational environment. Healthcare providers are more likely to use PPEs if their colleagues are using the same. Includes the norms and social support from the coworkers.

Perceived conflict of interest is the alternative actions over which individuals have reduced control over. E.g. need to provide medical care to patients and the HCW individual needs. When the perceived conflict of interest is high, it is anticipated to interfere with precautionary use of HD.

2.7 Conceptual Framework

Independent Variables **Confounding Variable** **Dependent variable**

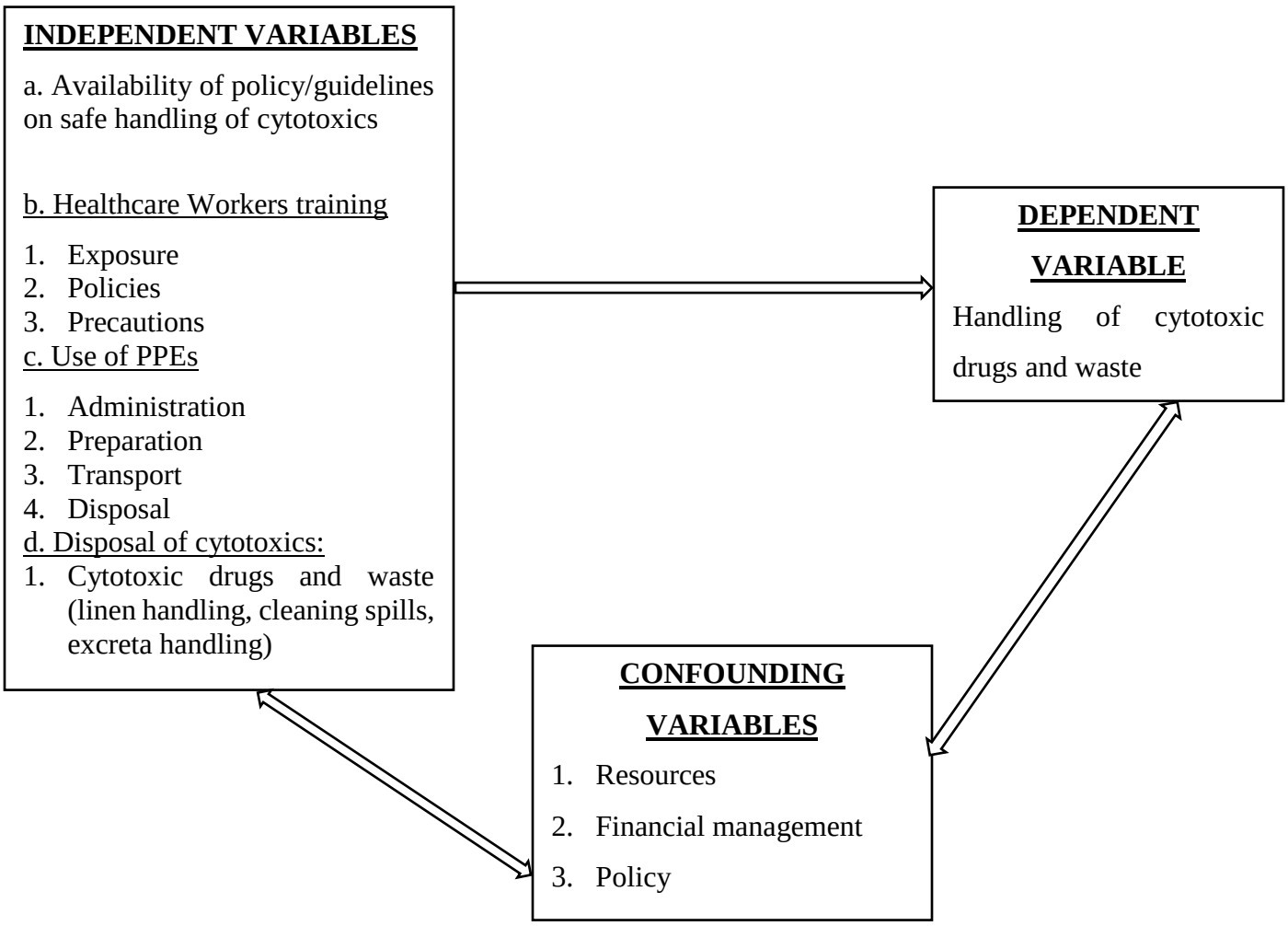


Figure 2: Conceptual Framework

Source: Author, 2019

CHAPTER THREE: METHODOLOGY

3.1 Study Design

Descriptive cross sectional study design was adopted and both qualitative and quantitative data was collected for a period of one month. Quantitative data was collected using questionnaires and observation checklists while qualitative data was collected by use of interview guide with the key informant. Methodological triangulation was used to give a deeper understanding from different viewpoints.

3.2 Study Site

This study was conducted in KNH, an institution founded in 1901. KNH is one of the largest National Referral and Teaching Hospital located in Nairobi County, 3.5KM West from the Central Business District. KNH receives oncology patients from all over the country and east Africa where it provides specialized care for oncology patients, especially chemotherapy and radiotherapy.

This study was conducted in obstetrics and gynecology department, pediatric department, medicine department and the cancer treatment Centre department. The specific wards are adult oncology ward GFD, gynecology-oncology ward 1B, medical oncology ward 8C, and pediatric oncology ward 1E, 3A, 3B, 3C, 3D. Ward 1B and 1E are situated in the first floor of KNH towers; wards 3A, 3B, 3C and 3D are located in the 3rd floor while ward 8C is an adult ward located in the 8th floor.

3.3 Study Population

The study population composed all healthcare workers who handle cytotoxic drugs and wastes at KNH. It included consultant doctors, medical officer registrars, pharmacists, nurses, and cleaners in respective wards.

3.4 Eligibility Criteria

3.4.1 Inclusion

Healthcare workers who directly handled cytotoxic drugs and wastes during the period of study and gave consent to take part in the study.

3.4.2 Exclusion criteria

Healthcare workers working in oncology wards/units in KNH on leave or off duty during the study period or had worked in oncology units/wards for less than three months.

3.5 Sample Size Determination

Fisher's formula was used to determine a sample size representative of the population (Fisher's et al., 1998).

$$n = \frac{Z^2 Pq}{d^2}$$

In this case:

n = Sample size [for population >10,000]

Z = level of confidence according to the standard normal distribution. It was 95%, **Z**-Value at 95% is 1.96.

P = Proportion of the population estimated to have a characteristic of interest.

Q = Proportion of the population without characteristic of interest.

$\mathbf{d^2}$ = Tolerable margin of error; will be at 5%

The percentage of the HCW handling cytotoxic drugs and waste was unknown hence 50% of the population was included

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

n = I.96*1.96 [0.5] [0.5]

[0.05][0.05] = 384.16

Since the proportion HCW handling cytotoxic drugs and waste was less than 10,000 the sample adjustment was done using the following formula (Yamane's Formula).

$$nf = \frac{n}{1 + {}^{n}/_{N}}$$

Where:

nf = the intended sample size when population under study is less than 10,000

n = desired sample size when the total population >10,000

N = the calculated sample size.

$$nf = \frac{384}{1+{}^{384}/_{280}}$$

$$nf = 161.928$$

$$\sim 162$$

Sample size per cadre was a follows:

Table 1: Sample Size Calculation

Cadre of healthcare workers	**Total number**	**Sample size ((n/280)*162)**
Consultant doctors	14	8
Registrar doctors	41	24
Nurses	195	112
Pharmacists	4	2
Pharmaceutical technologists	3	2
Cleaners	22	14
Total	**280**	**162**

Distribution of the sample size per ward

Table 2: Distribution of Sample in Various Units

Ward	Nurses	Consultant Doctors	Registrar Doctors	Cleaners	Pharmacists	Pharmaceutical technologists
1B	10	2	3	2		
1E	11	1	1	2		
GFD	11	1	1	3		
8C	13	2	3	1		
3A	17		4	2		
3B	16	2	4	2		
3C	16		4	1		
3D	17		3	1		
Oncology Pharmacy				3	2	2
Totals	**112**	**8**	**24**	**14**	**2**	**2**

3.6 Sampling frame and sample size

The sampling frame included HCW i.e. doctors, nurses, pharmacists and cleaners in the respective wards. All HCW in various wards who consented to participate were eligible to participate in this study. Stratification of healthcare workers per respective ward was done first followed by stratification per cadre. Simple random sampling was used to determine the sample size of healthcare workers who would take part in this study. The respondents were informed about the study prior to their participation.

The in-charge of various wards/units who were Key informants were interviewed separately at their respective offices during their free time especially during tea or lunch breaks.

A structured observation checklist was used to collect data and corroborate some of the information obtained from the questionnaire and interview. The researcher was an inactive participant during the period of data collection.

3.7 Research Tools

3.7.1 Interview Guide

An interview guide containing the questions to be asked to key informants was used. The interview was conducted at the office of the in-charges of selected wards/units (8C, 1E, GFD and 1B) to ensure minimum interruption. These units were selected purposively because they deal with cancer patients only unlike others which have mixed number of patients i.e. patients diagnosed with cancer and patients with other diagnosis. There was tape recording and taking of notes during interviews with the key informants. The interview was conducted at the office of the key informants during tea break and lunch hours so as to ensure minimal noise and interruptions. The interviews lasted between 20-30 minutes.

3.7.2 Questionnaire

An interviewee-administered, semi-structured questionnaire was used for data collection. The questionnaires had four sections namely: socio-demographic data; training of healthcare workers; use of PPEs and disposal cytotoxic drugs and related wastes.

3.7.3 Observation Checklist

A structured observation checklist on handling of the cytotoxic drugs and waste was used. It is a modified checklist from the Queensland Workplace Health and Safety. The observation was done in wards 8C, 1E, GFD and 1B because they have high workload of dealing with cytotoxic drugs and related wastes. Wards 3B and 3A were also observed because they have a fairly low workload of handling cytotoxic dugs and related wastes. Observation of the healthcare workers as they handled chemotherapy drugs was done during the days of chemotherapy preparation and administration from around 10am-1pm. The observation was done twice in two weeks.

3.8 Pretesting Of Research Instruments

Pretesting of 10% of the questionnaire and interview guide was carried out at KNH private wing 9th floor oncology wards. The private wing is semi-autonomous and the staff do not interact readily.

Necessary adjustments to the data collection tools was made as informed by the findings of the pilot study to improve on the reliability of the data collected in the main study.

3.9 Data Collection and Storage

One main research assistant was recruited and training done on the purpose of the research and the tools used for collecting. These research assistant was a Bachelor of Science in nursing student on who was available for the entire period of data collection. All administered questionnaires were collected daily and stored in cabinets only accessible to the researcher. No authorized persons were allowed to access the data. The recorded interview session were replayed to the key informant to confirm their views and were allowed to propose what to delete from the recording.

3.10 Data analysis and presentation

Both quantitative and qualitative data obtained was analyzed. Data cleaning and sorting was done before entry to ensure questionnaires are properly filled without gaps and that there are no gaps in the observation checklist.

Data from observational checklist was presented inform of percentages of the number of 'present' and 'absent' observation and both compared per wards/unit. They were also be compared with the data obtained from the questionnaire.

Data from interviewee-administered questionnaire was computed, coded and analyzed using Statistical Package for Social Sciences (SPSS) computer package version 23.0 at 95% confidence interval and a P-value of equal/less than 0.05 was considered significant. Descriptive statistics

derived from SPSS e.g. mean, median and mode were used for data presentation. Inferential statistics e.g. Chi square was used to test the relationship between the study variables.

For qualitative, data from key informant interviews and notes taken by the principal researcher were counter checked with the recorded tape. Thematic analysis was used where data was summarized, coded and organized into various emerging themes as per the study objective.

3.11 Ethical Consideration

Ethical approval was sought from KNH-UON ERC to conduct the study. After approval the researcher further sought permission from KNH to carry the study. 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. Participants were not coerced in any way. Those who declined to participate did not suffer any negative consequences.

Participants were assured of confidentiality by anonymity, privacy during interview and safe guarding the study material both in soft and hard copies under lock and key. Anonymity was maintained throughout data collection process by ensuring that participants do not write their names on the questionnaire.

The researcher assured the participants that the risks would be minimized. Participants were also informed that there was no financial benefits due to them but that the research would be used to improve hospital support towards safe handling of cytotoxic drugs and wastes.

3.12 Dissemination Plan

A copy of report detailing the findings has been availed to ERC, SONS as well as UON libraries. The researcher intends to publish the findings in peer reviewed journals and make abstract presentation in scientific conferences.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter presents result and analysis of the study findings. The response rate of this study was 92.5% (n=150). The response rate for the pharmacists, pharmaceutical technologists and the cleaners was 100% (n=14) while that of the nurses was 96.5% (n=108), registrars 87.5% (n=21) and the consultant doctors had the lowest response rate of 37.5% (n=3).

4.2 Socio-Demographic Characteristics of the respondents

The demographic characteristics of the respondents are shown in **table 3**. Generally over two thirds, 77.3% (n=116) of the respondents were females. The mean age of the respondents was 35.9 years (SD=±9.98) and the median class was 26-35 years.

Regarding academic qualification 38.7% (n=58) of the respondents had a bachelor's degree and 34.7% (n=52) had a diploma. The HCW with the highest education level were at high likelihood of practicing safe handling of the cytotoxics drugs and waste (P=0.027).

In the general years of professional experience, 66% (n=99) of the respondents had more than five years of the professional experience. In the oncological experience, most 32.7% (n=49) had 1-3 years. The table three shows specific years of experience per cadre.

On specialized oncology training; all the consultants and 50% (n=1) of pharmacists and pharmaceutical technologist had been trained. The specific courses trained in are: 38.9% (n=7) had a fellowship in oncology, 33.3% (n=6) had a higher diploma in oncology and 11.1% (n=2) had a masters in an oncology and 16.7% (n=2) had other forms of training such short courses on safe handling of cytotoxic drugs and waste. Further analysis showed that HCW with specialized oncology training were at a high likelihood of practicing safe handling of cytotoxic drugs and waste (P=0.000).

Table 3: Socio-demographic characteristics of the respondents

		Consultant Doctor	*Registrars*	*Nurse*	*Pharmacist*	*Pharmaceutical Technologist*	*Cleaner*
	N(%)	*3(%)*	*21(%)*	*108(%)*	*2(%)*	*2(%)*	*14(%)*
Gender	Male	1(33.3)	8 (38.1)	22(20.4)	0	2 (100)	1 (7.1)
	Female	**2 (66.7)**	**13(61.9)**	**86 (79.6)**	**2(100)**	**0**	**13(92.9)**
Academic Qualification	Master's Degree	**3 (100)**	1(4.8)	3(2.8)	1(50)	0	0
	Bachelor's Degree	0	**20(95.2)**	37(34.3)	1(50)	0	0
	Higher Diploma	0	0	20(18.5)	0	0	0
	Diploma	0	0	**48(44.4)**	0	**2(100)**	2(14.3)
	Secondary	0	0	0	0	0	**11(78.6)**
	Primary	0	0	0	0	0	1 (7.1)
General Professional Experience	<1 Year	0	0	2 (1.9)	1(50)	0	1(7.1)
	1-3 Years	0	2(9.5)	10(9.3)	0	0	2(14.3)
	3-5 Years	0	12(57.1)	14(13)	0	1(50)	6(42.9)
	>5 Years	**3(100)**	**7(33.3)**	**82(75.9)**	**1(50)**	**1(50)**	**5(35.7)**
Oncological Experience	<1 Year	0	**13(61.9)**	23(21.3)	**2(100)**	0	4 (28.6)
	1-3 Years	0	8(38.1)	**35(32.4)**	0	1(50)	**5(35.7)**
	3-5 Years	0	0	20(18.5)	0	1(50)	3(21.4)
	>5 Years	**3(100)**	0	30(27.8)	0	0	2 (14.3)
Specialized Oncology Training	Yes	3**(100)**	1(4.8)	12(11.1)	1 (50)	1 (50)	0
	No	0	**20(95.2)**	**96(88.9)**	**1(50)**	**1(50)**	**14(100)**
Type of Specialized Oncology Training	Fellowship	**3(100)**	0	4 (33.3)	0	0	0
	Higher Diploma	0	0	**6(50)**	0	0	0
	Masters	0	**1 (100)**	0	**1 (100)**	0	0
	Others	0	0	2(16.7)	0	1**(100)**	0

Demographics of the key informants

All the key informants interviewed were nurses who were in-charge of various wards. Among the four ward in-charges three were females, number of staffs supervised ranged from 19 to 32 including nurses, support staff and the registrars. All the key informants had a title of Assistant chief nurses. All the key informants had an average age of 49.5 years with professional experience between 20 and 33 years presented in **Table 4**.

Table 4: Key informants demographics

	1B	**1E**	**GFD**	**8C**
Gender	Male	Female	Female	Female
Age	45	50	46	57
Years in Current position	2	4	1.5	7
Years of Experience	25	20	20	33
Number of employees supervised	20	23	19	32

4.3 Availability and accessibility of policy/guidelines on Handling of Cytotoxics

Most, (71.4%, (n=10)), of cleaners were not aware whether the institution has any policy regarding handling of cytotoxic drugs and waste, 70% (n=7) of registrars affirmed that the policy was inaccessible for perusal by all staff as presented in **Table 5**.

Table 5: Availability and accessibility of Institutional policy regarding safe handling of cytotoxic drugs and wastes

		Consultant Doctor	***Registrars***	***Nurse***	***Pharmacist***	***Pharmaceutical Technologist***	***Cleaner***
Institutional Policy availability	Yes	3 (100)	10(47.6)	49(45.4)	1(50)	1(50)	4(28.4)
	I don't Know	0	**11(52.4)**	**59(54.6)**	**1(50)**	**1(50)**	**10(71.4)**
Accessibility of Institutional Policy	Yes	2(100)	3 (30)	27(45)	1(100)	0	1(25)
	No	0	**7(70)**	**33(55)**	**0**	**1(100)**	**3(75)**

Most of the managers reported that there were no guidelines in place within the hospital on safe handling of the cytotoxic drugs and wastes. Even for the ones who acknowledged the existence of the policies in form of standard operating procedures, they reported that policy is not readily available in the ward for use and perusal by the staff working in those units as supported by the following quotes:

*"…actually the whole document is in the Pharmacy that's where we borrow..." **(NO-2).***

Some of the wards had prepared their own guidelines which were reported as being inaccessible to the healthcare workers by the key informants in the quotes below:

*"It is available, though we were planning to laminate it because it is something that we generated on our own and we wanted to escalate it to see whether it is acceptable to be used by the hospital. We are using it but, we are yet to do the formal things to make it readily available to the nurses here and the rest of hospital" (**NO-4**).*

There was no formal way for monitoring whether the staff are following the stipulated guidelines on handling of the cytotoxic drugs and waste. For those who reported to be enforcing the available guideline it was through sensitization via continuous medical education and sometimes by use of checklist as reported below:

*"We ensure that they comply by constant supervision and CMEs by updating and reminding ourselves what we should be doing" (**NO-3**).*

*"Sometimes we have a checklist where we check what is supposed to be done as per policy" (**NO-3**).*

*"Lack of measures in place to monitor the staff on the level of exposure" (**NO-2**).*

Further analysis with Chi-Square showed that no association (P>0.05) between availability of policy document and safe handling of cytotoxic wastes (**Table 6**). This means that availability of policy document does not have any influence on safe handling of cytotoxic wastes across cadres.

Table 6: Chi-Square test for association between availability of policy document and safe handling

			Safe handling			
Cadre			*Yes*	*No*	X^2	p-value
Registrars	Accessibility of Institutional Policy	Yes	1(33.3)	2(66.7)	0.476	0.49
		No	1(14.3)	6(85.7)		
Nurse	Accessibility of Institutional Policy	Yes	7(25.9)	20(74.1)	2.439	0.118
		No	15(45.5)	18(54.5)		
Cleaner	Accessibility of Institutional Policy	Yes	0	1(100)	0.444	0.5
		No	1(33.3)	2(66.7)		
Total	Accessibility of Institutional Policy	Yes	8(25)	24(75)	2.217	0.137
		No	19(41.3)	27(58.7)		

4.4 Training Opportunities on Safe Handling of Cytotoxic Drugs and Wastes

4.4.1 Training on handling of cytotoxic drugs and wastes

Majority, 54% (n=81), of the respondents had no any form of training on handling of the cytotoxic drugs and the related wastes (**Figure 3**). Of the respondents, 71.4% (n=15) of registrars and 55.6% (n=60) of nurses who had no training on handling cytotoxic drugs and waste.

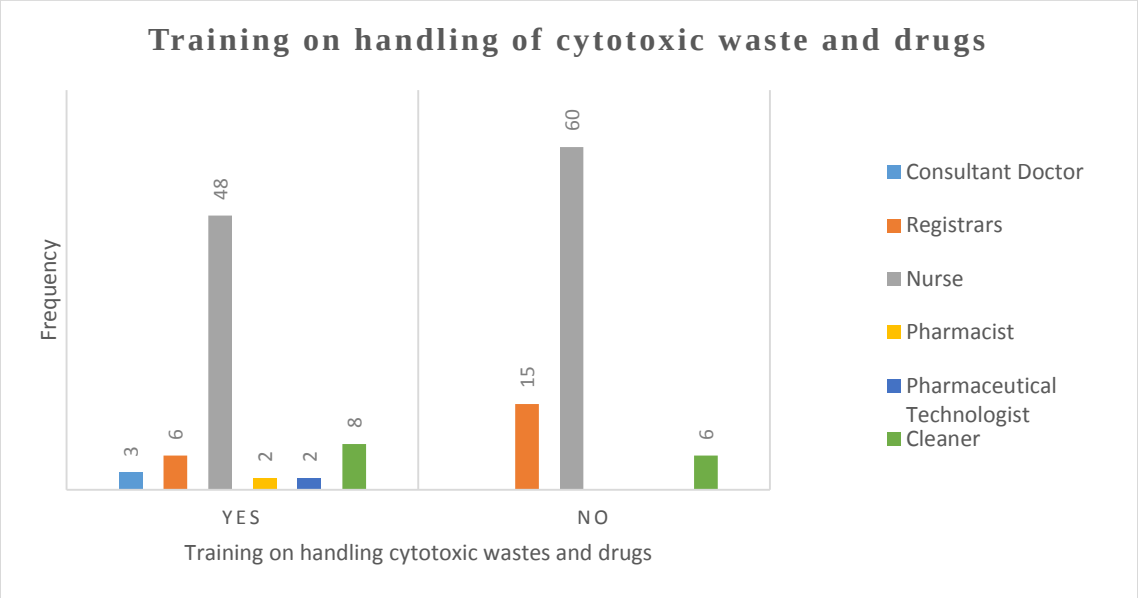


Figure 3: Training on handling of the cytotoxics drugs and related wastes per cadre

All the pharmacists, pharmaceutical technologists and cleaners as well as 81.3% (n=39) of the nurses who had trained on handling of cytotoxic drugs and waste received training in hospital organized workshops while 50% (n=3) of the registrars had been trained at the university. The hospital organized training were in form of seminars, workshops and continuous medical education lasting from 6 hours to 5 days across the respondents. The areas covered were “chemotherapy safety, waste disposal and safety precaution in chemotherapy preparation and administration.”

Topics covered during training

The topics taught during trainings were: 87.3% (n=62) disposal of cytotoxic waste, 84.5% (n=60) general knowledge about the cytotoxic risks and 80.3% (n=57) use of PPEs (**Table7**).

Table 7: Topics covered in various trainings of safe handling of cytotoxic drugs and wastes

Topic	Category	Frequency (n=71)	Percentage (%)
General knowledge about the cytotoxic risk	Yes	60	**84.5**
	No	11	15.5
Use of PPE	Yes	57	**80.3**
	No	14	19.7
Cleaning techniques and management of excreta	Yes	33	46.5
	No	**88**	53.5
Cleaning of spills	Yes	**36**	**51.4**
	No	34	48.6
Chemotherapy preparation and administration	Yes	**35**	**50.7**
	No	34	49.3
Transport and storage of chemotherapy	Yes	**37**	**53.6**
	No	34	46.4
Disposal of cytotoxic waste	Yes	**62**	**87.3**
	No	9	12.7

The managers revealed that there are limited training opportunities for the health care workers on handling of the cytotoxic drugs and waste. This is was due to financial constraints as supported by the quotes below:

> *"Capacity building is also an issue we would like to train more oncology nurses but there are no funds" (**NO-4**).*

> *"… We need frequent trainings and sensitization on chemo safety or safe handling of cytotoxic materials. At least every staff working in oncology should have that training frequently" (**NO-1**).*

A further analysis was conducted to determine the relationship between training and safe handling of cytotoxic waste across the cadre. The outcome showed that there was no significant association (**X^2=0.26, P=0.61**). Training across cadre was not associated with increased safe handling of cytotoxic drugs and wastes as shown in **table 8**.

Table 8: Association between training and safe handling of cytotoxic wastes

Cadre			*Safe handling*			
			Yes	*No*	X^2	P-value
Registrars	Training on Handling of Cytotoxic drugs and waste	Yes	1(16.7)	5(83.3)	0.031	0.861
		No	3(20)	12(80)		
Nurse	Training on Handling of Cytotoxic drugs and waste	Yes	17(35.4)	31(64.6)	0.051	0.821
		No	20(33.3)	40(66.7)		
Cleaner	Training on Handling of Cytotoxic drugs and waste	Yes	2(25)	6(75)	0.117	0.733
		No	2(33.3)	4(66.7)		
Total	Training on Handling of Cytotoxic drugs and waste	Yes	24(34.8)	45(65.2)	0.26	0.61
		No	25(30.9)	56(69.1)		

4.4.2 Knowledge on chemotherapy exposure

The respondents were knowledgeable about various ways of chemotherapy exposure with a score of 88%-95% (**table 9**). Of the respondents, 92.6% (n=100) of nurses cited that "chemotherapy can enter the body through breathing and ingesting it" which is true. However, 83.3% (n=90) of the nurses wrongly said that "all types of gloves offer the same level of protection" and 71.4% (n=15) of the registrars and 61.1% (n=66) of the nurses wrongly answered that "alcohol hand sanitizer is as effective as soap and water in removing chemotherapy".

Table 9: Knowledge on chemotherapy exposure

		Consultant Doctor	*Registrars*	*Nurse*	*Pharmacist*	*Pharmaceutical Technologist*	*Cleaner*
Enter the body through Breathing it in	True	**3 (100)**	**18(85.7)**	**100(92.6)**	**2(100)**	**2(100)**	**11(78.6)**
	False	0	1(4.8)	4(3.7)	0	0	0
	I don't know	0	2(9.5)	4(3.7)	0	0	3(21.4)
Enter the body through Ingesting it	True	**3(100)**	**20(95.2)**	**100(92.6)**	**2(100)**	**2(100)**	**1(85.7)2**
	False	0	0	4(3.7)	0	0	1(7.1)
	I don't know	0	1(4.8)	4(3.7)	0	0	1(7.1)
Though Contact with	True	0	8(38.1)	29(26.9)	0	0	4(28.6)
	False	**3(100)**	**12(57.1)**	**73(67.6)**	**2(100)**	**2(100)**	**7(50)**

Contaminated Surfaces	I don't know	0	1(4.8)	6(5.6)	0	0	3(21.4)
Though contact with spills and splashes	True	**3(100)**	**19(90.5)**	**98(90.7)**	**2(100)**	**2(100)**	**13(92.9)**
	False	0	1(4.8)	8(7.4)	0	0	0
	I don't know	0	1(4.8)	2(1.9)	0	0	1(7.1)
Chemo gas can enter the body through skin and mucous membranes	True	**3(100)**	**17(81)**	**94(87)**	**1(50)**	**1(50)**	**4(28.6)**
	False	0	0	7(6.5)	0	0	2(14.3)
	I don't know	0	4(19)	7(6.5)	1(50)	1(50)	8(57.1)
Oral forms can be absorbed on the skin	True	0	6(28.6)	26(24.1)	0	1(50)	3(21.4)
	False	**3(100)**	**11(52.4)**	**62(57.4)**	**2(100)**	**1(50)**	**4(28.6)**
	I don't know	0	4(19)	20(18.5)	0	0	7(50)
liquid Forms absorbed through the skin	True	**3(100)**	**19(90.5)**	**95(88)**	**2(100)**	**2(100)**	**12(85.7)**
	False	0	0	8(7.4)	0	0	1(7.1)
	I don't know	0	2(9.5)	5(4.6)	0	0	1(7.1)
Surgical masks provide protection from Chemo aerosols	True	0	**11(52.4)**	**54(50)**	**2(100)**	**1(50)**	**7(50)**
	False	3(100)	5(23.8)	45(41.7)	0	1(50)	2(14.3)
	I don't know	0	5(23.8)	9(8.3)	0	0	5(35.7)
All types of gloves offer the same level of protection	True	1(33.3)	1(4.8)	16(14.8)	0	0	4(28.6)
	False	**2(66.7)**	**19(90.5)**	**90(83.3)**	**2(100)**	**2(100)**	**6(42.9)**
	I don't know	0	1(4.8)	2(1.9	0	0	4(28.6)
enters easily through damaged skin	True	**3(100)**	**21(100)**	**103(95.4)**	**2(100)**	**2(100)**	**13(92.9)**
	False	0	0	3(2.8)	0	0	0
	I don't know	0	0	2(1.9)	0	0	1(7.1)
alcohol hand sanitizer is as effective as soap and water in removing chemotherapy	True	0	2(9.5)	27(9.5)	0	0	3(21.4)
	False	**3(100)**	**15(71.4)**	**66(61.1)**	**1(50)**	**1(50)**	**4(28.6)**
	I don't know	0	4(19)	15(13.9)	1(50)	1(50)	7(50)
Through contaminated foods, beverages or cosmetics	True	**3(100)**	**15(71.4)**	**74(68.5)**	**2(100)**	**1(50)**	**9(64.3)**
	False	0	4(19)	22(20.4)	0	1(50)	3(21.4)
	I don't know	0	2(9.5)	12(11.1)	0	0	2(14.3)

4.5 Availability of Personal protective equipment

Majority (57.1%, (n=8)) of the cleaners and registrars (55%, (n=11)) reported that the hospital does not provide personal protective equipment for use in handling chemotherapy as presented in **figure 4**.

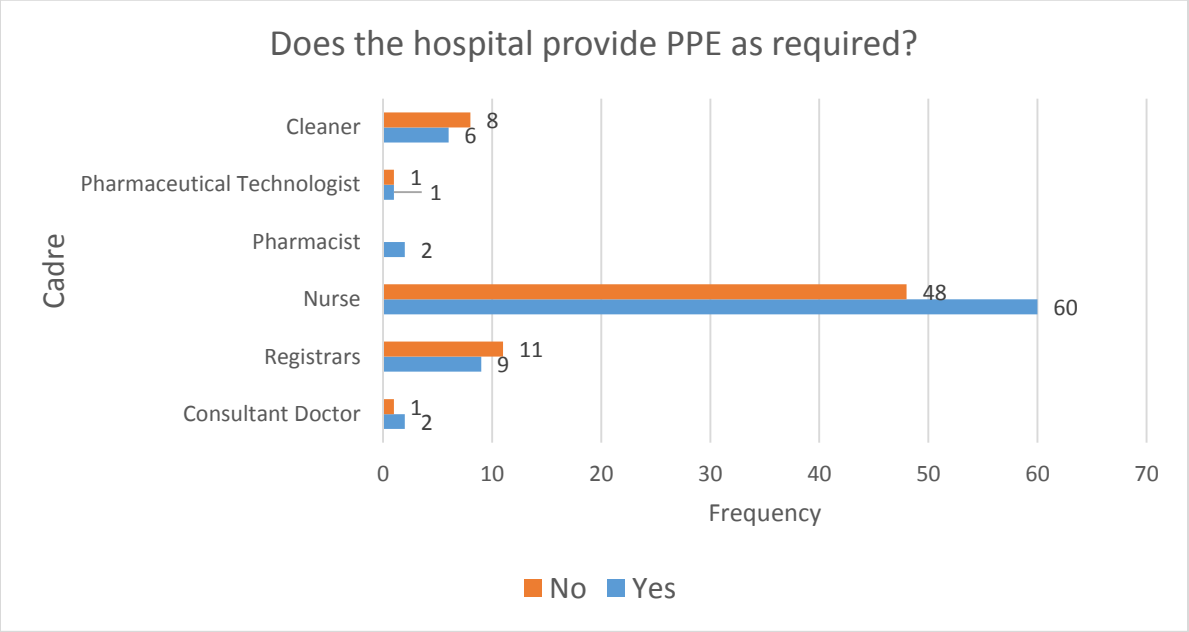


Figure 4: Provision of PPE as required

Personal Protective Equipment frequently unavailable

Frequency of stock outs was reported to be mainly two times a week 37.8% (n=48) and once weekly 32.3% (n=41). Of the respondents, 41.1% (n=37) of nurses and 36.8% (n=7) of registrars reported stock-outs of two times a week. Most of cleaners (85.7%, (n=12)) and registrars (73.7%, (n=14)) reported ward/unit in-charge as the one responsible for ordering personal protective equipment from the stores as shown in **table 10**.

Table 10: Respondents view on stock out and ordering of personal protective equipment

		Cadre					
		Consultant Doctor	*Registrars*	*Nurse*	*Pharmacist*	*Pharmaceutical Technologist*	*Cleaner*
Frequency of Stock outs	Once Weekly	1 (50)	4(21.1)	29(32.2)	1(50)	2(100)	4(33.3)
	Two times a week	0	**7(36.8)**	**37(41.1)**	0	0	4(33.3)
	3-4 times a week	1(50)	4(21.1)	15(16.7)	1(50)	0	3(25)
	>4 times a week	0	4(21.1)	9(10)	0	0	1(8.3)
Ordering of PPEs from the stores	Ward/Unit in-charge	**3(100)**	**14(73.7)**	**57(52.8)**	**0**	**2(100)**	**12(85.7)**
	Team Leader	0	4(21.1)	47(43.5)	2(100)	0	1(7.1)
	Others	0	1(5.3)	4(3.7)	0	0	1(7.1)
Place for Chemotherapy preparation in the Ward	Pharmacy	0	3(14.3)	25(23.1)	0	0	2(14.3)
	Drugs prepared in an off-site location	0	1(4.8)	14(13)	0	0	1(7.1)
	Specially designated room separate from the patients care area	**2(66.7)**	**10(47.6)**	**53(49.1)**	**2(100)**	**2(100)**	**7(50)**
	Within Patient treatment room	1(33.3)	7(33.3)	16(14.8)	0	0	4(28.6)

It was observed that the reconstituted chemotherapy drugs are stored in the same cabinets with other non-cytotoxic drugs in the most of the wards. The wards that had a storage cabinet for chemotherapy drugs sometimes they mixed with other non-cytotoxic drugs due to lack of enough space. No ward had a specific fridge for cytotoxic drugs.

Supplies reported to frequently run out

Shoe covers (70.4%, (n=95)), eye and face shields (73.3%, (n=99)) and hair covering (56.3%, (n=76)) are the supplies reported to be mostly run out of stock (**figure 5**).

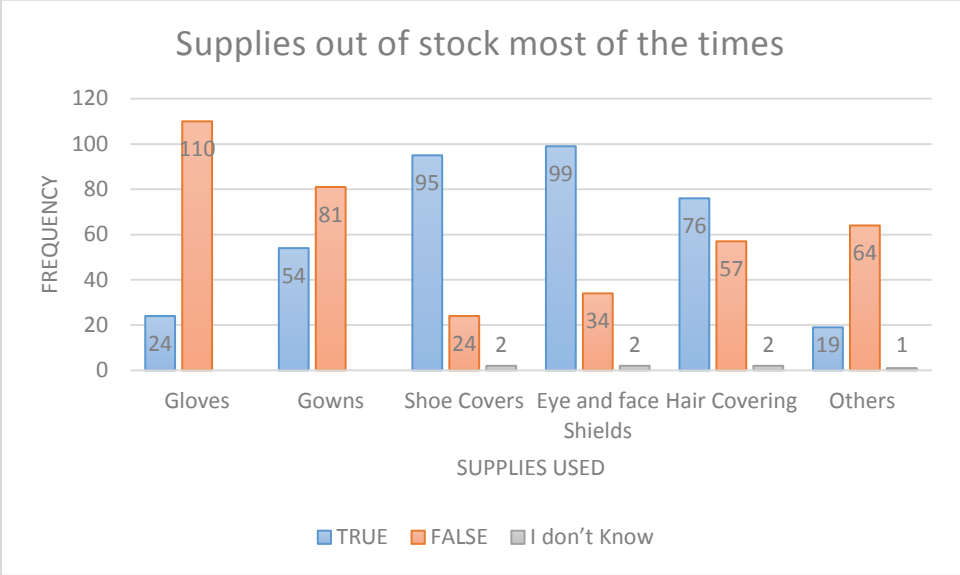


Figure 5: Supplies reported to frequently run out

A further analysis with Chi-square test for association showed that there was statistically significant association between provision of PPEs and safe handling among nurses **(P=0.049)**. Thus among nurses, the provision of PPEs by the hospital increases the level of practice of safe handling of the cytotoxic drugs and waste as presented in **Table 11**.

Table 11: Provision of PPEs as Required and safe handling

			Safe handling			
Cadre			*Yes*	*No*	X^2	P-value
Registrars	Provision of PPEs as Required	Yes	2(22.2)	7(77.8)	0.51	0.822
		No	2(18.2)	9(81.8)		
Nurse	Provision of PPEs as Required	**Yes**	**16(26.7)**	**44(73.3)**	**3.46**	**0.049**
		No	**21(43.8)**	**27(56.3)**		
Cleaner	Provision of PPEs as Required	Yes	2(33.3)	4(66.7)	0.117	0.733
		No	2(25)	6(75)		
Total	Provision of PPEs as Required	Yes	23(28.8)	57(71.3)	1.34	0.247
		No	26(37.7)	43(62.3)		

From the checklist administered in various wards, there were no written guidelines/procedures available in the wards concerning management of patients on chemotherapy, chemotherapy administration, PPE use, spill management, waste management or linen/laundry handling.

4.6 Assessment of the disposal of cytotoxic wastes

Majority, 66.8% (n=99) of the respondents reported that they were responsible for disposing chemotherapy drugs and waste including all the cleaners and 64.8% (n=70) of nurses (**Table 12**). When disposing the cytotoxic drugs and waste, all the pharmaceutical technologists and pharmacists and ninety percent of nurses wore the PPEs as required. Majority of the nurses, registrars and cleaners practiced waste segregation before disposal and handwashing after handling of the waste.

Among the respondents: majority, 68.9% (n=73), of the nurses and 92.9% (n=13) of the cleaners handled the excreta of the patients in the ward. Majority, 82.7% (n=124) of the respondents reported that there are no spill kits available in work stations. Chemotherapy cleaning was mostly done by the cleaners (85.7%).

Majority, 76.5% (n=101) of the respondents were aware of the technique of the chemotherapy spill cleaning. Of the respondents, 90.5% (n=19) of the registrars and 85.7% (n=12) of the cleaners did not demarcate chemotherapy spill area before cleaning (**Table 12**).

From the observation checklist there were no spill kit and written procedures written procedure on how to handle and mange chemotherapy spills in the ward.

Table 12: Waste disposal practice

		Cadre					
		Consultant Doctor	*Registrars*	*Nurse*	*Pharmacist*	*Pharmaceutical Technologist*	*Cleaner*
Wearing PPEs during disposal	Yes	**1(33.3)**	**13(86.7)**	**87(90.6)**	**2(100)**	**2(100)**	**12(85.7)**
	No	2(66.7)	2(13.3)	9(9.4)	0	0	2(14.3)
Segregation of cytotoxic waste before disposal	Yes	0	**10(55.6)**	**69(75.8)**	0	0	**9(64.3)**
	No	1(100)	8(44.4)	22(24.2)	2(100)	2(100)	5(35.7)
Hand Washing Immediately after Disposal	Yes	0	**14(77.8)**	**87(93.5)**	**0**	**0**	**13(92.9)**
	No	1(100)	4(22.2)	6(6.5)	2(100)	2(100)	1(7.1)
Sharps Disposal	Sharps Container	**1(100)**	**16(88.9)**	**90(98.9)**	**2(100)**	**2(100)**	**14(100)**
	Others	0	2(11.1)	1(1.1)	0	0	0
Availability of Chemotherapy Spill kit	Yes	1(33.3)	2(9.5)	20(18.5)	0	0	3(21.4)
	No	**2(66.7)**	**19(90.5)**	**88(81.5)**	**2(100)**	**2(100)**	**11(78.6)**
Cleaning Chemotherapy Spill	Cleaner	0	**6(28.6)**	**67(62.6)**	**0**	**0**	**12(85.7)**
	Nurse	0	1(4.8)	31(29)	0	0	1(7.1)
	Medical Doctor	0	11(52.4)	6(5.6)	0	0	0
	Others	3(100)	3(14.3)	3(2.8)	2(100)	2(100)	1(7.1)
Demarcation of Cytotoxic spill area before Cleaning	Yes	0	2(9.5)	31(28.7)	0	0	2(14.3)
	No	**3(100)**	**19(90.5)**	**77(71.3)**	**2(100)**	**2(100)**	**12(85.7)**
Technique for cleaning Spill area	From Centre of spill gradually towards the outer	0	5(29.4)	22(22.2)	0	0	4(40)
	From the Outer of the spill gradually towards the centre	**2(100)**	**12(70.6)**	**77(77.8)**	**2(100)**	**2(100)**	**6(60)**

The key informants revealed that there is a challenge in getting PPEs for use in handling of cytotoxic waste as presented in the quotes below:

*"... sometimes the PPE run out; there are no goggles for the eyes" (**NO-4**).*

*"Because we lack proper spill kit. When anything happens we are supposed to have a kit where we use some granules to make sure the chemo is absorbed" (**NO-3**).*

*"…on the issue of spillage and waste disposal no standard guideline…" (**N0-2**.*

Others issues coming up on exposure of the patients and staff to cytotoxic drugs and wastes were sharing of the beds/wards by oncology patients and other patients sometimes, sharing of toilets between patients on chemotherapy and those not on any chemotherapy, young expectant nurses being sent to chemotherapy handling wards and need for more training to all staff so as to help prevent the same.

*"Sharing of toilets among the patients, posting of expectant nurses to work in oncology ward poses a risk and something needs to be done on this and gynecology patients are sharing the wards with patients on chemotherapy I think we need to separate" **(NO-2)**.*

*"Patients on chemo should not mix toilets with other pts not on chemo but here we are constrained because we don't have enough toilets so they mix" (**NO-4**)*

Further analysis showed that there is an association between wearing PPEs during disposal and safe handling across all the cadres (**P=0.032**). Increase in wearing PPEs during disposal across all cadres improves the level of safe handling of cytotoxic wastes as shown in **table 13**.

Table 13: Association between disposal of cytotoxic wastes and safe handling

			Safe handling			
Cadre			***Yes***	***No***	**X^2**	**P-value**
Registrars	Wearing PPEs during disposal	Yes	3(23.1)	10(76.9)	0.577	0.448
		No	0	2(100)		
Nurse	**Wearing PPEs during disposal**	**Yes**	**27(31)**	**60(69)**	**4.59**	**0.032**
		No	**6(66.7)**	**3(33.3)**		
Cleaner	Wearing PPEs during disposal	Yes	3(25)	9(75)	0.525	0.469
		No	1(50)	1(50)		
Total	**Wearing PPEs during disposal**	**Yes**	**35(29.9)**	**82(70.1)**	**5.415**	**0.02**
		No	**9(60)**	**6(40)**		
Registrars	Segregation of cytotoxic waste before disposal	Yes	1(10)	9(90)	0.72	0.396
		No	2(25)	6(75)		
Nurse	Segregation of cytotoxic waste before disposal	Yes	22(31.9)	47(68.1)	0.151	0.7
		No	8(36.4)	14(63.6)		
Cleaner	Segregation of cytotoxic waste before disposal	Yes	4(44.4)	5(55.6)	3.11	0.08
		No	0	5(100)		
Total	Segregation of cytotoxic waste before disposal	Yes	27(30.7)	61(69.3)	0.006	0.94
		No	12(30)	28(70)		
Registrars	Hand Washing Immediately after Disposal	Yes	3(21.4)	11(78.6)	1.029	0.31
		No	0	4(100)		
Nurse	Hand Washing Immediately after Disposal	Yes	29(33.3)	58(66.7)	0.6	0.66
		No	2(33.3)	4(66.7)		
Cleaner	Hand Washing Immediately after Disposal	Yes	4(30.8)	9(69.2)	0.43	0.51
		No	0	1(100)		
Total	Hand Washing Immediately after Disposal	Yes	36(31.6)	78(68.4)		
		No			0.29	0.59
Registrars	Availability of Chemotherapy Spill kit	Yes	1(50)	1(50)	1.373	0.24
		No	3(15.8)	16(84.2)		
Nurse	Availability of Chemotherapy Spill kit	Yes	4(20)	16(80)	2.22	0.14
		No	33(37.5)	55(62.5)		
Cleaner	Availability of Chemotherapy Spill kit	Yes	1(33.3)	2(66.7)	0.042	0.84
		No	3(27.3)	8(72.7)		
Total	Availability of Chemotherapy Spill kit	Yes	7(26.9)	19(73.1)	0.47	0.49
		No	42(33.9)	82(66.1)		
Registrars	Demarcation of Cytotoxic spill area before Cleaning	Yes	0	2(100)	0.94	0.33
		No	4(21.1)	15(78.9)		
Nurse	Demarcation of Cytotoxic spill area before Cleaning	Yes	7(22.6)	24(77.4)	0.22	0.64
		No	30(39)	47(61)		
Cleaner	Demarcation of Cytotoxic spill area before Cleaning	Yes	0	2(100)	0.63	0.43
		No	4(33.3)	8(66.7)		
Total	Demarcation of Cytotoxic spill area before Cleaning	Yes	7(20)	28(80)	1.14	0.29
		No	42(36.5)	73(63.5)		

Concerning the handling of the linen contaminated with the vomitus and urine from patients under chemotherapy; 93% (n=13) of the cleaners reported that they mixed all the linen together without segregation before it is taken to the laundry. From the observation checklist it was observed that there is mixing of all the linen and lack of any written guide towards the same.

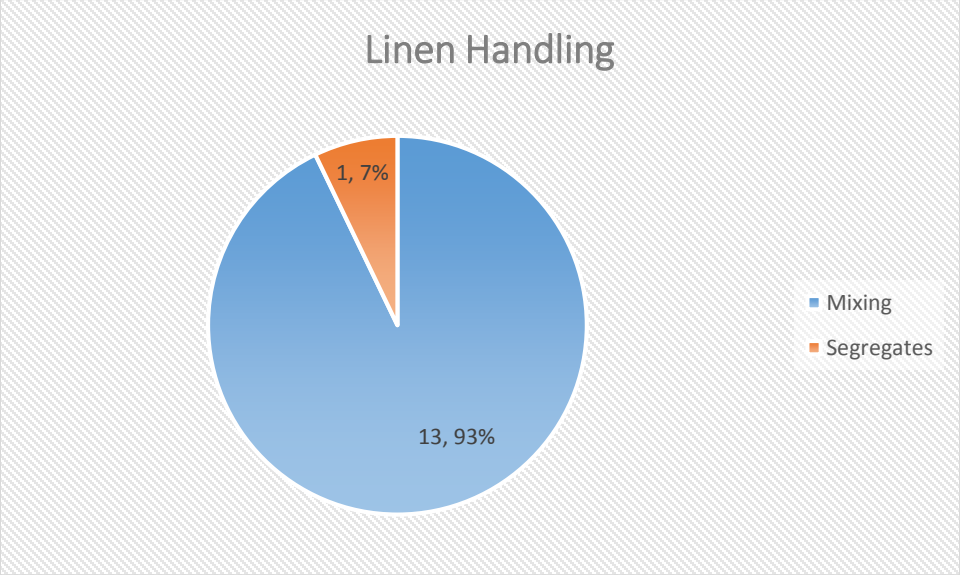


Figure 6: Handling of the linen

The cleaners who segregated the linen reported that they put the contaminated linen in purple liner bags and labelled it with a cytotoxic label awaiting collection by the laundry team.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the discussion of the study findings on the Assessment of institutional support on healthcare workers in safe handling of cytotoxic agents and related waste at Kenyatta National Hospital. The discussion is organized into sociodemographic factors, policy guidelines, training opportunities, personal protective equipment and disposal of cytotoxic drugs and related wastes.

5.2 Discussion

5.2.1 Sociodemographic Factors

The mean age of the study participants in this study is 35.9±9.98 years. This compares with those of the (Mohsen and Fareed, 2013) who showed that the mean age of their study population was 31.91±7.49 years and that of Polovich whose range of study participants was 23-70 years (Polovich, 2016). This could be due to the recent recruitments done by the hospital prior to the study. Regarding the sex of the participants, Mohsen and Fareed, (2013) reported that most of their respondents were females and this compares with the current study findings where majority of the respondents were females. This is because majority of the healthcare workers were nurses in whom majority are females.

Key informants were nurse managers of respective wards handling chemotherapy drugs, their age ranged from 45-57 years, with professional experience of 20-33 years (mean=24.5) and had management experience of 1.5-7 years. The findings differs with those of Polovich who revealed that most of the managers age ranged from 30-70 years and have management experience range of 1-29 years and professional experience of 49 years (Polovich, 2016). The decreased

management experience by managers in the respective wards is due to the frequent reshuffles done to the managers from one ward to another.

Regarding the education level, most of the respondents in this study had bachelor's degree followed by diploma. This was consistent with the study by (Chaudhary *et al.*, 2012; Polovich, 2016) who showed majority of the participants had baccalaureate degree but it also differs with the findings of two different studies which showed minority of their study participants had baccalaureate degree (Mohsen and Fareed, 2013; Sheikh, 2016). This could be because majority of the respondents were nurses and in Kenya majority of the nurses are trained at the diploma level and they make up majority of the healthcare workers. Healthcare workers with the highest education level were at a high likelihood of practicing safe disposal of cytotoxic waste (P=0.027).

Oncology training in Kenya is done at a higher diploma level, master's level and fellowship. Majority of the respondents had no form of specialized training in oncology and this is contrary with findings by Polovich who revealed that most of the nurses had specialized training in oncology (Polovich, 2016). It also differs with Australian guidelines that recommends that only healthcare workers who have received suitable training and have achieved the appropriate level of competency and proficiency should be allowed to handle cytotoxic drugs and related waste (South Australia Health, 2015). Lack of specialized training could be due to few training institutions offering oncology specialization and lack of enough funds to sponsor the willing staff to advance their studies

Further analysis revealed that HCW with specialized oncology training were likely to practice safe handling compared to those who lack specialized training (P=0.000). Specialized training increases one level of knowledge on the effects of cytotoxics hence increase the probability of the staff protecting themselves.

5.2.2 Availability/accessibility of Policy/Guidelines

Policy and guidelines should be readily available and accessible to healthcare workers to guide their practice. In this study majority of the respondents reported that the institutional policy document was not readily available for perusal and reference by the staff working in oncology wards. Majority of the healthcare workers were not practicing safe handling of the cytotoxic drugs and wastes. In this study, the availability of policy document does not have any influence on the practice of safe handling of cytotoxic wastes across cadres. This study contradicts a study carried out in Pakistan that showed that for successful handling of the chemotherapy and related wastes the healthcare workers must be provided with the appropriate guidelines and policies (Fauzia Barket Ali, Shireen Arif, 2015). This could be due to the ignorance on the part of the part of healthcare workers or lack of knowledge on the possible effects of chemotherapy in the body.

Majority of the respondents who reported that the policy document was readily accessible for perusal by the staff did not practice safe handling of the cytotoxic waste and drugs. These findings compare with those of an Iranian study which showed that despite the policies being available they were not accessible to the most of the staff hence contributing to poor compliance with safe handling of cytotoxic drugs and waste (Askarian, Momeni and Danaei, 2013). This could be due to poor dissemination of the guidelines to each and every unit by the management.

The findings of inaccessibility of the policy at the wards levels goes against Occupational Safety Health Administration (OSHA) guidelines that recommends that the document should be made available at the operational level for purposes of staff familiarizing themselves with the guidelines. This could help improve compliance leading to safe work practices (OSHA, 2016).

5.2.3 Training Opportunities for Healthcare Workers on Handling of Cytotoxic Agents and Waste Products

Training opportunities provides the healthcare workers with skills and knowledge on the safe handling of cytotoxic drugs and waste. The study findings show that majority of the respondents had no training in handling of the cytotoxic drugs and related wastes. These findings are similar to a study carried out in Karachi Pakistan which showed that only 43.33% of the nurses working in oncology units were trained on handling of the cytotoxic drugs and related wastes (Fauzia Barket Ali, Shireen Arif, 2015). There was no relationship between training and safe handling of cytotoxic waste across the cadre. The findings are inconsistent with the Melbourne hospital guidelines and that states training the healthcare workers improves safe handling cytotoxic drugs and related wastes hence reducing exposure to the environment, staffs and the patients (The Royal Children's Hospital Melbourne, 2018).

In this study, most of the workers were knowledgeable about various ways of chemotherapy exposure. The findings are differ with an Indian study that revealed knowledge and practice of hospital staff about cancer drugs were not to the level required to mitigate the risks associated with handling of these drugs (Kiran *et al.*, 2017).

Training on safe handling of cytotoxic drugs and waste can also be done through short courses. In this study, most of the healthcare workers were trained through hospital organized workshops, continuous medical education and having mentorship programs. A study in Nepal revealed that most health care workers knowledge on handling cytotoxics drugs and related wastes was through hospital organized trainings (Chaudhary and Karn, 2012). The findings are consistent with the South Australian government recommendations that states that it is the duty of institutions dealing with cytotoxics to provide information, instruction, training and supervision of all healthcare workers handling cytotoxic drugs and related waste (South Australia Health, 2015; The Royal Children's

Hospital Melbourne, 2018). This is may be because most of the trainings are free, accessible and a requirement by the hospital management for the healthcare workers to attend.

5.2.4 Availability of Personal Protective Equipment

Personal protective equipment (PPEs) are meant for protection of the health care workers when handling cytotoxic drugs and waste. The Ministry of health recommends the following PPEs for safe handling of cytotoxic drugs and waste: powder free gloves, face shields, N95 masks, shoe covers, gowns and hair covers (Ministry of Health Kenya, 2013). Majority of the respondents reported that the hospital does not provide all the PPEs as required for use when handling (mixing, administration, spill cleaning and disposal) of the cytotoxic drugs and the related wastes. According to ASHP correct and consistent use of the PPEs when handling the cytotoxic drugs and waste reduces the risk of getting cancer due to exposure (American Society of Health-Sytem Pharmacists, 2006). Lack of continuous provision of the PPEs required hinders the practice of safe handling of the cytotoxic drugs and waste. Poor planning by the hospital management can lead to the reported stock-outs. Nurses provided with the appropriate PPEs by the hospital are more likely to practice safe handling.

Shortage of supplies such as the N95 respirator masks, appropriate gloves (vinyl) and biosafety cabinets was reported by most of the respondents. It was observed that chemotherapy drugs are reconstituted in the ward and stored with non-cytotoxic drugs. The results are inconsistent with NIOSH guidelines of continuous supply of the appropriate PPEs to promote careful and consistent use hence minimizing occupational exposure to cytotoxic agents (National Institute for Occupational Safety and Health, 2004). Lack of the biosafety cabinets could be related to the fact that these wards were not constructed as oncology wards but as general medical wards. Some of these wards have been converted to oncology wards while others are combining oncology patients and patients with other medical and surgical conditions.

In this study, most of the healthcare workers are exposed when cleaning spills, administering cytotoxic drugs and disposing the cytotoxic wastes as reported by the key informants. The findings were compared to Pan American Health Organization that showed most of the workers are exposed during drug preparation or while cleaning up spills (Pan American Health Organization, 2012). This is because during cleaning of spills, administration and preparation of the cytotoxic drugs there is generation of vapors, droplets and aerosols which workers are likely to inhale if they lack of the appropriate PPE during those procedures.

5.2.5 Disposal of Cytotoxic Drugs and Wastes

Safe disposal of the cytotoxic drugs and waste reduces exposure to the staff, patient and the environment. Minority of the respondents did not practice waste segregation before disposal. This is against the guidelines that recommends that all the wastes must be segregated before disposal and disposed in the appropriate color coded bins (Ministry of Health Kenya, 2017). Most studies have reported lack of waste disposal segregation by the healthcare workers handling cytotoxic waste at the point of generation (Hill and Scuffham, 2012; Sheikh, 2016; Ministry of Health Kenya, 2017). The good practice could be due to the effectiveness of the trainings offered in the hospital.

In this study it was also revealed that there is lack of chemotherapy spill skits in all the units and lack of demarcation of the cytotoxic spill areas before cleaning. These findings are similar to study conducted in KNH which showed only 25% of the staff demarcated the areas of cytotoxic waste spill before cleaning so as to caution others members of staff and reduce the risk of exposure (Sheikh, 2016). Lack of demarcation could be associated to lack of appropriate knowledge on how to manage the cytotoxic spills without exposing oneself and the rest of the staff.

Increase in wearing PPEs during disposal across all cadres improved the level of safe handling of cytotoxic wastes (P=0.02). There was no separation of linen contaminated with chemotherapy and the rest of linen by the house keepers. This practice goes against recommendations in several

studies that the linen should be separated well and labeled with a cytotoxic label (Askarian, Momeni and Danaei, 2013; Kieffer *et al.*, 2015b; Pediatric Oncology Group of Ontario, 2018). This could be due to of lack of knowledge among the cleaners who handled the contaminated linen and lack of appropriate guideline in the wards.

5.3 Limitations of the Study

Some respondents declined to take part in the study. This was addressed by observations made by the researcher in the wards as the practice and from the interview with the key informant.

5.4 Conclusion

There is a hospital policy in place regarding cytotoxic drugs and waste though the policy is not accessible to the staff at the ward level. There are training opportunities within the hospital in terms of continuous medical education and workshops on safe handling of the cytotoxic drugs and waste though most of the healthcare workers lack specialized training in oncology and a basic training in the handling of the cytotoxics drugs and related wastes. There is shortage and lack of appropriate personal protective equipment in the various wards for handling cytotoxic drugs as recommended hence putting the healthcare workers in those wards at high risk of exposure. There is good disposal of cytotoxic waste within the wards though handling of the chemotherapy spills is not in accordance with the recommended guidelines due to lack of spill kits. Also there is mixing of the linen contaminated with the excreta of patients on chemotherapy with the uncontaminated ones.

5.5 Recommendations

5.5.1 Policy and Practice

i. KNH management needs to ensure that the available policy is more accessible to the staff at the ward level and increase sensitization on its availability among the staff.

ii. KNH needs to train more staff on safe handling of cytotoxic drugs and related wastes and sponsor more staff for specialized training in oncology.

iii. There is need for KNH management to avail the recommended personal protective equipment and other exposure control measures to the staff all the time in order to reduce the risk of exposure to healthcare workers and the patients.

iv. Hospital should maintain the good disposal of the cytotoxic drugs and waste and ensure proper handling of the chemotherapy spills with the use of spill kits and ensure contaminated linen is segregated and labelled appropriately at the point of use and cleaned separately from other linen in the hospital.

5.5.2 Further Research

Further research should be conducted by the KNH management or institutions of higher learning to assess the levels of exposure in the body among healthcare workers handling cytotoxic drugs and waste.

REFERENCES

Al-Azzam, S. I. *et al.* (2015) 'Compliance with safe handling guidelines of antineoplastic drugs in Jordanian hospitals', *Journal of Oncology Pharmacy Practice*, 21(1), pp. 3–9. doi: 10.1177/1078155213517128.

American Society of Health-Sytem Pharmacists (2006) *Drug Distribution and Control: Preparation and Handling-Guidelines ASHP Guidelines on Handling Hazardous Drugs*. Available at: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx (Accessed: 26 January 2019).

Askarian, M., Momeni, M. and Danaei, M. (2013) 'The management of cytotoxic drug wastes in Shiraz, Iran: an overview of all government and private chemotherapy settings, and comparison with national and international guidelines', *Waste Management & Research*. SAGE PublicationsSage UK: London, England, 31(6), pp. 541–548. doi: 10.1177/0734242X13476747.

Bray, F. *et al.* (2018) 'Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries', *CA: A Cancer Journal for Clinicians*. American Cancer Society, 68(6), pp. 394–424. doi: 10.3322/caac.21492.

Chartered Institution of Waste Management (2014) *An Introductory Guide to Healthcare Waste Management in England & Wales*. Northampton. Available at: www.ciwm-journal.co.uk (Accessed: 29 January 2019).

Chaudhary, R. *et al.* (2012) 'Chemotherapy-Knowledge and Handling Practice of Nurses Working in a Medical University of Nepal', *Journal of Cancer Therapy*. Scientific Research Publishing, 03(01), pp. 110–114. doi: 10.4236/jct.2012.31014.

Chaudhary, R. and Karn, B. K. (2012) 'Chemotherapy-Knowledge and Handling Practice of Nurses Working in a Medical University of Nepal', *Journal of Cancer Therapy*. Scientific Research Publishing, 03(01), pp. 110–114. doi: 10.4236/jct.2012.31014.

Connor, T. H. and McDiarmid, M. A. (2006) 'Preventing Occupational Exposures to Antineoplastic Drugs in Health Care Settings', *CA: A Cancer Journal for Clinicians*. American Cancer Society, 56(6), pp. 354–365. doi: 10.3322/canjclin.56.6.354.

Easty, A. C. *et al.* (2015) 'Safe handling of cytotoxics: guideline recommendations.', *Current oncology (Toronto, Ont.)*. Multimed Inc., 22(1), pp. e27-37. doi: 10.3747/co.21.2151.

European Union (2013) *Preventing occupational exposure to cytotoxic and other hazardous drugs*

European Policy Recommendations. Available at: https://www.europeanbiosafetynetwork.eu/wp-content/uploads/2016/05/Exposure-to-Cytotoxic-Drugs_Recommendation_DINA4_10-03-16.pdf (Accessed: 24 January 2019).

Fauzia Barket Ali, Shireen Arif, F. P. (2015) 'Association of Knowledge on the Attitude and Practice of Registered Nurses Regarding Handling of Cytotoxic Drugs in a Tertiary Care Hospital in Karachi Pakistan Association of Knowledge on the Attitude and Practice of Registered Nurses Regarding Handling', *International Journal of Novel Research in Heathcare and Nursing*, 2(December), pp. 2010–2013.

Fürthauer, J., Flamm, M. and Sönnichsen, A. (2013) 'Patient and physician related factors of adherence to evidence based guidelines in diabetes mellitus type 2, cardiovascular disease and prevention: a cross sectional study.', *BMC family practice*. BioMed Central, 14, p. 47. doi: 10.1186/1471-2296-14-47.

Goodin, S. *et al.* (2011) 'Safe Handling of Oral Chemotherapeutic Agents in Clinical Practice: Recommendations From an International Pharmacy Panel', *Journal of Oncology Practice*, 7(1), pp. 7–12. doi: 10.1200/JOP.2010.000068.

Hill, K. and Scuffham, A. (2012) *Standard Operating Procedure Safe Handling Of Cytotoxic Drugs And Related Waste*. Available at: http://www.massey.ac.nz/massey/fms/Colleges/College of Sciences/IVABS/vetschool/IVMA /3_ SOP CYtotoxic Drugs.pdf (Accessed: 24 January 2019).

Jamah, A. (2014) 'Cancer patients to wait two years for treatment at KNH : The Standard', *Standard*, 2 December. Available at: https://www.standardmedia.co.ke/health/article/2000143246/cancer-patients-to-wait-two-years-for-treatment-at-knh (Accessed: 22 August 2019).

Kieffer, C. *et al.* (2015a) 'Preventing the contamination of hospital personnel by cytotoxic agents: evaluation and training of the para-professional healthcare workers in oncology units', *European Journal of Cancer Care*. John Wiley & Sons, Ltd (10.1111), 24(3), pp. 404–410. doi: 10.1111/ecc.12249.

Kieffer, C. *et al.* (2015b) 'Preventing the contamination of hospital personnel by cytotoxic agents: evaluation and training of the para-professional healthcare workers in oncology units', *European Journal of Cancer Care*. John Wiley & Sons, Ltd (10.1111), 24(3), pp. 404–410. doi: 10.1111/ecc.12249.

King Edward Memorial Hospital (2017) *Women And Newborn Health Service Medication Safety Cytotoxic Agents: Safe Handling Of Cytotoxic Waste*. Available at: http://www.deir.qld.gov.au (Accessed: 4 February 2019).

Kiran, D. R. *et al.* (2017) 'An intervention to evaluate & improve handling of cancer drugs in a tertiary care hospital in India', *Indian Journal of Medical Research*. Medknow Publications and Media Pvt. Ltd., 146(2), p. 285. doi: 10.4103/ijmr.IJMR_1592_15.

Ministry of Health Kenya (2013) *National Guidelines For Cancer Management Kenya*. Nairobi. doi: 10.2202/1943-3867.1074.

Ministry of Health Kenya (2017) *Health Care Waste Management Plan*. Nairobi. Available at: https://healthservices.uonbi.ac.ke/sites/default/files/centraladmin/healthservices/HEALTH CARE WASTE.pdf (Accessed: 1 February 2019).

Mohsen, M. M. and Fareed, M. E. (2013) 'Chemotherapy Safety Protocol for Oncology Nurses: It's Effect on Their Protective Measures Practices', *International Journal of Medical and Health Sciences*, 7(9).

National Institute for Occupational Safety and Health (2004) *Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings.* doi: 10.26616/NIOSHPUB2004165.

Nsw SafeWork (2017) *Cytotoxic Drugs And Related Waste-Risk Management*. Available at: www.legislation.nsw.gov.au (Accessed: 4 February 2019).

OSHA (2016) *Controlling Occupational Exposure to Hazardous Drugs, United States Department of Labour*. Available at: https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html#mgmt (Accessed: 6 February 2019).

Pan American Health Organization (2012) *Safe Handling of Hazardous Chemotherapy Drugs in Limited-Resource Settings*. Available at: https://www.paho.org/hq/dmdocuments/2014/safe-handling-chemotherapy-drugs.pdf.

Pediatric Oncology Group of Ontario (2018) *3.1 Safe Handling, Administration and Disposal of Chemotherapy Agents | POGO*. Available at: https://www.pogo.ca/satellite-manual/3-0-chemotherapy-administration/3-1-safe-handling-administration-and-disposal-of-antineoplastic-agents/ (Accessed: 26 January 2019).

Pender, N. J., Murdaugh, C. L. and Parsons, M. A. (2006) *Health Promotion in Nursing Practice*. 4th edn. Upper Saddle River, N.J. : Prentice Hall, 2002.

Polovich, M. (2016) *Nurses' Use Of Hazardous Drug Safe Handling Precautions*, *Oncology Nursing Forum*. Georgia State University. doi: 10.1188/16.ONF.43-03AP.

Sheikh, Y. A. (2016) *Knowledge And Practice On Safe Handling Of Cytotoxic*. University of Nairobi.

South Australia Health (2015) *A Risk Management Guide for Cytotoxic Drugs and Related Waste Safe Handling*. Available at: www.sahealth.sa.gov.au/hazardousdrugs (Accessed: 4 February 2019).

The Royal Children's Hospital Melbourne (2018) *Clinical Guidelines (Nursing) : Cytotoxic Drugs - The Management Of*. Available at: https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/cytotoxic_drugs_the_management_of/ (Accessed: 5 February 2019).

Vaz da Conceição, A. (2015) 'Oncology pharmacy units: a safety policy for handling hazardous drugs and related waste in low- and middle-income African countries—Angolan experience', *ecancermedicalscience*, 9. doi: 10.3332/ecancer.2015.575.

WHO (2015) 'Status of health-care waste Management In selected Countries in West Africa', pp. 1–61.

Workplace Health and Safety Queensland (2014) 'Guide for handling cytotoxic drugs and related waste', (February), p. 90.

APPENDICES

Appendix 1: Work Plan

Time / Activity	Aug-Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	March 2019	April 2019	May 2019	June 2019	July 2019	Aug 2019	Sept 2019
Topic identification	■											
Concept Paper development		■	■									
Proposal writing			■	■	■							
UON/KNH ERC review					■	■	■					
Study pretest and data collection							■	■				
Data analysis and presentation								■				
Report writing									■			
Defense of thesis at SONS										■		
Dissemination/Submission /Publication											■	■

Appendix 2: Budget

ACTIVITY	ACTIVITY DESCRIPTION	ITEM	UNIT OF MEASUREMENT	UNIT COST	TOTAL IN KSH
Literature Review	Search for literature in libraries	Transport Subsistence	25 days	700@	17,500
	Internet services	Browsing	6GB	200@	1200
	Stationary	A_4 notebooks Biro pens Pencils Rubber Proposal printing Photocopying Questionnaire Translation	2 10 5 2 6 drafts 200 pages 2	200@ 15@ 25 25@ 400@ 3@ 3000	400 150 125 50 1600 600 6000
Approval		KNH/UON ERC	1	2000@	2000
Sub Total					**29,625**
Data Collection and analysis	Pre-testing	Transport and Subsistence	2 days	700@	1400
		Printing and typing questionnaires	20 copies	10	200
	Questionnaires	Photocopying	400 copies	3@	1,200
	Data collection	Transport and subsistence Research Assistant	15 days 15 days	700@ 500	31,500 7,500
	Data processing and Analysis	Statistician			25,000
Sub Total					**65,200**
Reports	Draft report Final report	Printing and photocopying Printing and binding	5 copies 4 copies	400 500	2000 2,000
Miscellaneous					10,000
Sub Total					**14,000**
Grand Total					**108, 825**

Appendix 3: Consent Form for Participants

Title of the study: Assessment of institutional support on healthcare workers in safe handling of cytotoxic agents and related wastes at KNH

Researcher: Henry Kilemi Mitheu (Master of Science in Nursing (Oncology) student, Year II)

Institution of Study: University of Nairobi

Introduction to the study

You are invited to fill in the questionnaire as a part of a research study, carried out by Henry Kilemi Mitheu who is a student pursuing Master of Science in Nursing (Oncology), at the University of Nairobi. The research is being carried out at wards GFD, 1B, 1E, 3A, 3B, 3C, 3D, 8C and Oncology Pharmacy.

This consent form gives you information about the study, the risks and benefits, and the process will be explained to you. Once you understand the study, and if you agree to take part, you will be asked to sign or use your thumb finger to put a mark (thumb print) on the consent form.

Purpose of the study:

The purpose of this research study is to assess the institutional support for safe handling of cytotoxic agents and waste products at Kenyatta National Hospital. The study will help KNH to know the areas of improvement towards its support on safe handling of cytotoxic agents.

Time

The questionnaire filling will take between 15-30 minutes through guidance of the researcher or the assistant.

Study Objective

The specific objectives will be: to determine the use personal protective equipment in various wards/units handling chemotherapy at Kenyatta National Hospital; to assess healthcare workers knowledge on handling of cytotoxic agents and waste products at Kenyatta National Hospital and

to evaluate safe disposal and handling of cytotoxic agents and wastes at Kenyatta National Hospital.

Benefits of the study

There are no direct benefits for you as an individual participant. However, the findings of this study can be used to sensitize the institution where staffs deal with cytotoxic agents and wastes to come up with policies/guidelines or improve on the existing guidelines on safe handling of cytotoxic drugs and waste and come up with ways of enforcing the policy/guidelines to protect its workers.

Risks

There are no directly foreseen risks for you participating in this study. If there are any questions you do not want to answer, you skip them. In addition, you have the right to decline giving information.

Confidentiality

Data, including questionnaires and file from the study will be kept in locked cabinets during the study. You data will be labeled with your study code not your name. Your identity will be kept confidential. Any relevant additional information you will volunteer to offer to the researcher will remain confidential and will only be disclosed with your permission.

Questionnaire Procedure

The questionnaire will be self-administered and you will be required to understand before answering them. The questionnaires is numbered (coded) thus you will not be required to give any personal information like writing your name. The questionnaire will contain both open and close ended questions. The questionnaire will be divided into different sections.

Voluntary Participation and Withdrawal

Remember, your participation is entirely voluntary. Should you change your mind, you have the right to drop out at any time without facing any consequences. You may skip questions or stop participating at any time.

Sharing the results

The results of this study may be presented during scientific and academic forums and may be published in scientific journals and academic papers

Contact Person

If you have any further questions during or after the research feel free to contact the investigator, the supervisor or the KNH/UON Ethics and Research Committee on the contacts given below.

1. **Investigator**

   Name: Henry Kilemi Mitheu
   Phone No. +254 726 205 542
   Email: mitheuhk@gmail.com
   Physical Address: School of Nursing Sciences
   University of Nairobi, College of Health Sciences
   Kenyatta National Hospital Campus

2. **Supervisors**

   Name: Dr. Lucy Bitok Kivuti
   Phone No. +254 710 499 700
   Email: lkivutibitok@gmail.com
   Physical Address: School of Nursing Sciences
   University of Nairobi, College of Health Sciences
   Kenyatta National Hospital Campus

   Name: Dr. James Mwaura
   Phone No. +254 722 790 202
   Email: jmwaura@uonbi.ac.ke

Physical Address: School of Nursing Sciences
University of Nairobi, College of Health Sciences
Kenyatta National Hospital Campus

3. **Ethics Committee**

Prof. M.L. Chindia,
The Secretary,
KNH/UON Ethics and Research Committee
Tel No. +254 726300-9
Email: uonknh_erc@uonbi.ac.ke

Physical Address: School of Pharmacy
University of Nairobi, College of Health Sciences
Kenyatta National Hospital Campus

Consent Confirmation

I hereby confirm that I have full knowledge of the study being undertaken, that I have read and understood the information sheet supplied above and that the study investigator informed me about the nature, conduct and benefits of the study. I have read and understood the contents of the information sheet.

I am aware that participation is voluntary and that I can withdraw from the study should I wish to do so. I am also aware that the information that I will be giving will be confidential and that the results of the study will be anonymously processed. I have had sufficient opportunity to ask questions and declare myself prepared to participate in the study.

I agree to participate in the study. I have read and everything is clearly explained to me.

Signature …… Date……

I Investigator/Research Assistant 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 voluntarily participate without any coercion or undue pressure.

Signature _____ Date _____

Appendix 4: Consent Form for Key Informants

Title of the study: Assessment of institutional support on healthcare workers in safe handling of cytotoxic agents and related wastes at KNH

Researcher: Henry Kilemi Mitheu (Master of Science in Nursing (Oncology) student, Year II)

Institution of Study: University of Nairobi

Introduction to the study

You are invited to participate in Key Informant Interview as a part of a research study, carried out by ***Henry Kilemi Mitheu*** who is a student pursuing Master of Science in Nursing (Oncology), at the University of Nairobi. The research is being carried out at wards GFD, 1B, 1E, 3A, 3B, 3C, 3D, 8C and Oncology Pharmacy. You have been selected to participate as a key informant because you supervise staffs handling chemotherapy in your unit/ward. Key informant interviews are being carried out in units/wards handling chemotherapy or with Cancer patients only.

This consent form gives you information about the study, the risks and benefits, and the process will be explained to you. Once you understand the study, and if you agree to take part, you will be asked to sign or use your thumb finger to put a mark (thumb print) on the consent form.

Purpose of the study:

The purpose of this research study is to assess the Institutional support for safe handling of cytotoxic agents and waste products at Kenyatta National Hospital. The study will help KNH to know the areas of improvement towards its support on safe handling of cytotoxic agents.

Time

The interview will take between 20-30 minutes through guidance of the researcher.

Study Objective

The specific objectives will be: to determine the use personal protective equipment in various wards/units handling chemotherapy at Kenyatta National Hospital; to assess healthcare workers knowledge on handling of cytotoxic agents and waste products at Kenyatta National Hospital and to evaluate safe disposal and handling of cytotoxic agents and wastes at Kenyatta National Hospital.

Benefits of the study

There are no direct benefits for you as an individual participant. However, the findings of this study can be used to sensitize KNH and other institutions where staffs deal with cytotoxic agents and wastes to come up with policies/guidelines or improve on the existing guidelines on safe handling of cytotoxic drugs and waste and come up with ways of enforcing the policy/guidelines to protect its workers.

Risks

There are no directly foreseen risks for you participating in this study. If there are any interview questions you do not want to answer, you are free to skip them. In addition, you have the right to decline giving information. Any part of the recording you would like not to be included in the study will be expunged.

Confidentiality

The interview data recorded via tape recorder or through notes taken will be kept in locked cabinets during the study. Your identity will be kept confidential. Any relevant additional information you will volunteer to offer to the researcher will remain confidential and will only be disclosed with your permission.

Interview Procedure

The interview will be carried out in your office during break time to avoid interruptions. During the interview, a tape recorder will be used to record the interview conversations and the researcher will also take notes during the interview period. At the end of the interview the researcher will replay the recorded interview and you will be allowed to listen and recommend any part of the interview to be expunged from the record.

Voluntary Participation and Withdrawal

Remember, your participation is entirely voluntary. Should you change your mind, you have the right to drop out at any time without facing any consequences. You may skip questions or stop participating at any time.

Sharing the results

The results of this study may be presented during scientific and academic forums and may be published in scientific journals and academic papers

Contact Person

If you have any further questions during or after the research feel free to contact the investigator, the supervisor or the KNH/UON Ethics and Research Committee on the contacts given below.

1. **Investigator**

   Name: Henry Kilemi Mitheu
   Phone No. +254 726 205 542
   Email: mitheuhk@gmail.com
   Physical Address: School of Nursing Sciences
   University of Nairobi, College of Health Sciences
   Kenyatta National Hospital Campus

2. Supervisors

Name: Dr. Lucy Bitok Kivuti

Phone No. +254 710 499 700

Email: lkivutibitok@gmail.com

Physical Address: School of Nursing Sciences

University of Nairobi, College of Health Sciences

Kenyatta National Hospital Campus

Name: Dr. James Mwaura

Phone No. +254 722 790 202

Email: jmwaura@uonbi.ac.ke

Physical Address: School of Nursing Sciences

University of Nairobi, College of Health Sciences

Kenyatta National Hospital Campus

3. Ethics Committee

Prof. M.L. Chindia,

The Secretary,

KNH/UON Ethics and Research Committee

Tel No. +254 726300-9

Email: uonknh_erc@uonbi.ac.ke

Physical Address: School of Pharmacy

University of Nairobi, College of Health Sciences

Kenyatta National Hospital Campus

Consent Confirmation

I hereby confirm that I have full knowledge of the study being undertaken, that I have read and understood the information sheet supplied above and that the study investigator informed me about the nature, conduct and benefits of this study. I have read and understood the contents of the information sheet.

I am aware that participation is voluntary and that I can withdraw from the study should I wish to do so. I am also aware that the information that I will be giving will be treated with confidentiality and that the results of the study will be anonymously processed. I have had sufficient opportunity to ask questions to principal researcher and declare myself prepared to participate in the study.

I agree to participate in the study. I have read and everything is clearly explained to me.

Signature …… Date……

I ***Henry Kilemi Mitheu***, *the* ***Principal Investigator*** 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 voluntarily participate without any coercion or undue pressure.

Signature _____ Date _____

Appendix 5: Questionnaire

Serial Number …… **Date ……**

INSTRUCTIONS

Please follow the instructions below

i. Please tick in the appropriate response in the space provided

ii. Do not indicate your name anywhere in the questionnaire.

SECTION A: SOCIO-DEMOGRAPHIC DATA

1. What is your gender? Male [ ] Female [ ]
2. What is your age in years? _____
3. What is your cadre?

   [ ] Consultant doctor

   [ ] Registrar

   [ ] Nurse

   [ ] Pharmacist

   [ ] Pharmaceutical technologists

   [ ] Cleaner

4. What is your highest level of professional qualification?

   [ ] Master's degree [ ] Bachelor's Degree [ ] Higher Diploma

   [ ] Diploma [ ] Secondary [ ] Primary

   [ ] PHD

5. How many years of professional experience do you have? (Generally)

   [ ] <1 year [ ] 1-3 Years [ ] 3-5 years [ ] >5 Years

6. How many years of oncology experience do you have?

   [ ] <1 year [ ] 1-3 Years [ ] 3-5 years [ ] >5 Years

7. Do you have any form of specialized training in oncology?

   [ ] Yes [ ] No

8. If Yes in the above, which one?

    [ ] Fellowship

    [ ] Higher diploma

    [ ] Masters

    [ ] Others, specify_____

SECTION B: Training of Healthcare Workers and Policy Availability and Accessibility

9. Do you have any form of training on handling of cytotoxic drugs and wastes?

    [ ] Yes [ ] No *if No proceed to Q15*

10. If Yes, specify the training _____

11. If YES in Q10 above where were you trained?

    [ ] University

    [ ] College

    [ ] Hospital organized Workshop

    [ ] Others, Specify_____

12. If hospital organized training, is it at KNH or another hospital? Specify

    _____

13. If hospital organized training, how long did the training that you attended take (in days or hours) _____

14. What areas were covered in the training you attended

    [ ] General knowledge about the cytotoxic risk;

    [ ] Use of PPE;

    [ ] Cleaning techniques and management of excreta; and

    [ ] Cleaning of spills

    [ ] Chemotherapy preparation and administration

    [ ] Transport and storage of chemotherapy

    [ ] Disposal of cytotoxic waste

    [ ] Any other. Please specify_____

15. Does your institution have any policy regarding handling of cytotoxic drugs and waste?

[ ] Yes [ ] I don't know

16. If yes, is the policy document available for perusal by all staffs?

[ ] Yes [ ] No

17. Knowledge on chemotherapy exposure. Please select one answer

	True	False	Don't Know
Chemotherapy can enter the body through breathing it in			
Chemotherapy can enter the body through ingesting it			
Chemotherapy cannot enter the body through contact with contaminated surfaces			
Chemotherapy can enter the body through contact with spills and splashes			
Chemotherapy gas and vapor in air can enter the body through skin and mucous membranes			
Oral forms of chemotherapy do not have the potential to be Absorbed on the skin			
Chemotherapy in liquid form can be absorbed through the skin			
A surgical mask provides protection from chemotherapy aerosols			
All types of gloves provide the same level of protection			
Chemotherapy can more easily enter the body through damaged skin			
Chemotherapy can more easily enter the body through damaged skin			
Alcohol hand sanitizer is as effective as soap and water in removing chemotherapy residue			
Chemotherapy can enter the body through contaminated foods, beverages, or cosmetics			

18. Do you think that you practice safe handling of cytotoxic drugs and waste?

[ ] Yes [ ] No

SECTION C: Use of Personal Protective Equipment (PPEs)

19. Does your institution provide personal protective equipment all the time as required?

[ ] Yes [ ] No

20. Are there days you run out of PPEs stock?

[ ] Yes [ ] No

21. If Yes in the Q20 above, how frequent?

[ ] Once weekly

[ ] Two times a week

[ ] 3-4 times per week

[ ] >4 times in a week

22. Which items are mostly out of stock?

[ ] Gloves

[ ] Gowns

[ ] Shoe covers

[ ] Eye and face shields

[ ] Hair covering

[ ] Others, specify_____

23. Who makes orders of the PPEs you use daily from the stores?

[ ] Ward/unit in-charge

[ ] Team leader

[ ] Others, specify_____

24. Where is chemotherapy prepared in your workplace?

[ ] Pharmacy

[ ] Drugs are delivered to the infusion area (prepared in an off-site location)

[ ] Specially designated room separate from the patient care area

[ ] Area within the patient treatment area / room

[ ] Other (specify) _____

25. Indicate your level of agreement with each of these statements about using personal protective equipment (PPE) when handling chemotherapy.

SA = Strongly Agree; A = Agree; D = Disagree; SD = Strongly Disagree

	SA	**A**	**D**	**SD**
I am confident that I use PPE properly				
I am confident that I protect myself from chemotherapy exposure				
I am given enough information on how to protect myself from chemotherapy exposure				
My supervisor goes out of his/her way to make sure I am protected				
Reuse of disposable PPE makes me feel less protected				

I am provided with the best available PPE				
My supervisor goes out of his/her way to make sure I am provided with proper fitting PPE				

SECTION D: Disposal of Cytotoxic Drugs and Related Waste

26. Are you responsible for disposing of chemotherapy drugs and waste?

[ ] Yes [ ] No

Complete this section ONLY if you dispose of chemotherapy.

27. Do you wear PPE when disposing cytotoxic drugs?

[ ] Yes [ ] No

28. If yes in question 28 above, which PPEs do you wear?

Type of PPE	**Yes**	**No**
Gown		
Gloves		
Googles/face shield		
Surgical mask		
N95 mask		
Head cover		
Cover shoes		
Others, specify		

29. Do you segregate cytotoxic waste before disposal?

[ ] Yes [ ] No

30. Do you wash your hand with soap and water immediately after disposal of cytotoxic drugs?

[ ] Yes [ ] No

31. Do you dispose sharps in a sharps container?

[ ] Yes [ ] No

Handling contaminated excreta (Emptying Urinals, bedpans…,)

32. Are you responsible for handling chemotherapy contaminated excreta?

[ ] Yes, if Yes proceed to Q34

[ ] No, if Yes proceed to Q35

Complete this section only if you handle chemotherapy contaminated excreta

33. Please indicate how frequently you use the following PPEs when **handling excreta:**

	Sometimes	Always	Never
Gloves labeled for use with chemotherapy			
Other gloves (e.g. vinyl)			
Double gloves			
Gowns labeled for use with chemotherapy			
Other gowns (e.g. isolation)			
Do you re-use disposable gowns?			
Eye protection			
Respirator/mask			
Others, specify _____			

34. If never in any of the above, what made you not use? Explain

_____

_____

35. Are chemotherapy spill kits available in your work area?

[ ] Yes [ ] No

36. During the most recent chemotherapy spill in your workplace, did you use the materials in the spill kit?

[ ] Yes [ ] No

37. Who cleans the chemotherapy spill first before the cleaners clean?

[ ] Cleaner

[ ] Nurse

[ ] Medical doctor

[ ] Others, specify_____

38. Do you demarcate the area of cytotoxic spill before cleaning?

[ ] Yes [ ] No

39. How do you clean the spill area?

[ ] From the center of spill gradually towards the outer

[ ] From the outer of the spill gradually towards the center

FOR CLEANERS ONLY

40. Do you mix linen contaminated with vomitus or urine of patients under chemotherapy with from other linen?

    [ ] Yes [ ] No

41. If no in the above, how do you handle them? Explain _____

    _____

    _____

42. How many times in a day do you clean the toilets used by the patients on Chemotherapy?

    _____

43. How many times do you flush the toilets after use by patients on chemotherapy?

    _____

44. What do you use to clean contaminated basins with?

    [ ] Hypochlorite solution

    [ ] Soap and water

    [ ] Water only

45. Any comment on this study? _____

    _____

Thank you very much for participating in this study

Appendix 6: Interview Guide with Key informants

Instructions

My Name is ***Henry Kilemi Mitheu***, a student at the University of Nairobi pursuing Master of Science in Nursing (Oncology). You have been selected to participate in this interview because you supervise staff handling cytotoxic drugs and wastes. The title of the study is 'Assessment of institutional support on Healthcare workers in safe handling of cytotoxic agents and related waste products at KNH.'

This interview will be carried out in your office during tea breaks to avoid interruptions and I will record as I also take notes.

Questions

1. The following questions are about your work site.
    a. Gender [ ] Female [ ] Male
    b. What is your cadre? _____
    c. Your age in years:_____
    d. Number of years in your current position:_____
    e. Years of experience:_____
    f. How many employees do you supervise? _____
2. Do you manage or supervise healthcare workers who handle chemotherapy, including preparation, administration, disposal or handling of contaminated excreta?

If answer is yes, continue with question 2.

3. What is official title for the position you hold at work _____
4. Have you personally handled chemotherapy, including preparation, administration, disposal or handling contaminated excreta in the past year?

(By chemotherapy preparation I mean transferring chemotherapy drugs from vials or ampoules to syringes or IV container. By administration, I mean giving chemotherapy to patients by IV, injection, or other route. By handling excreta, I mean activities like emptying bedpans, urinals or emesis basins).

5. If yes, : Is this a regular part of your responsibility_____
6. How frequently do you personally handle chemotherapy?
7. Do the HCW that you supervise prepare or mix chemotherapy?

8. If no, who prepares chemotherapy in your ward?
9. Do the staff that you supervise administer chemotherapy? By administration, I mean giving chemotherapy to patients by IV, injection, or other route.
10. Do the staff that you supervise handle contaminated excreta (emptying bedpans, urinals or emesis basins) of patients who receive chemotherapy?
11. Are there policies/guidelines regarding safe handling of chemotherapy in your workplace? Are the policies the same for everyone in the workplace such as pharmacy, if applicable? Are the policies readily available to the pharmacists/nurses/doctors/cleaners? What aspects of chemotherapy handling are addressed in the policies?
12. Does your policy specifically address: who may give chemotherapy? What personal protective equipment is required when handling chemotherapy? Disposal, transporting chemotherapy, spill cleanup, exposure management, health monitoring of employees
13. How do you ensure that the policies regarding safe handling of chemotherapy are complied with? (Such as planned, formal evaluation of practice? Informal "spot checks."
14. How often are policies regarding safe handling reviewed and updated?
15. Tell me about the training and orientation that a new nurse, doctors and cleaners you receive in your workplace go through before handling chemotherapy. (Who conducts; how long is it. Does it include safe handling precautions?)
16. Do you think that chemotherapy exposure is a problem in your work site? (Why or why not?)
17. Is there anything else you would like to tell me about safe handling precautions in your workplace?

Thank you very much for participating in this study.

Appendix 7: Observation Checklist

The following modified checklist adopted from 2014 Queensland Workplace and Health Safety (Workplace Health and Safety Queensland, 2014) for handling cytotoxic drugs and waste will be used.

Ward/unit: _____ Date: _____

		Present	Absent	Others specify
A.	**Controlling Exposure**			
	Use of PPEs			
	Biological safety cabinets			
	Designated rooms for chemotherapy preparation			
B.	**PPEs in use:**			
	Gloves			
	Gowns			
	Facemasks			
	Shoe covers			
	Hair covers			
	Instructions on use of PPEs displayed on the walls/notice boards			
	Supervision of workers to ensure that PPE is worn when being exposed to cytotoxic drugs and related waste			
	Control measures, including engineering controls, safe work practices and PPE effectively maintained			
C.	**Chemotherapy Administration**			
	Cytotoxic drugs supplied in pre-prepared doses			
	Cytotoxic drugs prepared by trained workers in a cytotoxics drug safety cabinet (CDSC) or pharmaceutical isolator			
	Clear labelling of IV solution flasks, syringes, pump cartridges containing cytotoxic drugs			
	Written procedures for: • training requirements • selection, use, maintenance and disposal of PPE • administration of parenteral, oral and topical cytotoxic drugs • extravasation incidents • management of skin penetrating injuries and blood or body substance exposures • management of cytotoxic drug exposures • spill management • incident reporting			
D.	**Patient care**			
	Written procedures for: • training requirements • selection, use, maintenance and disposal of PPE • management of patient waste • cleaning or disposal of equipment used in patient care			

	• transportation of patients with chemotherapy is situ • management of skin penetrating injuries and blood or body substance exposures • management of cytotoxic drug exposures • incident reporting			
E.	**Spill management**			
	Spill kit availability where cytotoxic drugs and related waste are handled, stored, transported and disposed of			
	Written instruction for workers such as cleaners, and porters and waste handlers to report spills to supervisors			
F.	**Waste management**			
	Designated person responsible for ensuring waste disposal complies with hospital guidelines			
	Disposal of cytotoxic sharps in a designated approved sharps container			
	Storage of cytotoxic waste in a secure dedicated area			
	Written procedures for: • identification, segregation and containment of cytotoxic waste • on-site transport of waste to collection area • spill management • training requirements for waste handlers • management of skin penetrating injuries and cytotoxic drug and related waste exposures • incident reporting • cleaning procedure (e.g. trolleys, wheelie bins, and storage area) • location and requirements for cytotoxic waste collection area) • Arrangements for waste disposal			
G.	**Laundry/Linen Handling**			
	Systems in place to ensure that cytotoxic contaminated linen is isolated from other linen			
	Availability of written procedures for: • identification, segregation and containment of cytotoxic contaminated linen • safe handling of linen contaminated with cytotoxic drugs and related waste • training requirements for linen handlers			

Appendix 8: Approval letter from KNH-UON ERC

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

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

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 725300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 25 APR 2019 KNH/UoN-ERC P.O. BOX 20723 - 00202 NAIROBI

Ref: KNH-ERC/A/154

25th April, 2019

Henry Kilemi Mitheu
Reg. No.H56/6776/2017
School of Nursing Sciences
College of Health Sciences
University of Nairobi

Dear Henry

RESEARCH PROPOSAL: ASSESSMENT OF INSTITUTIONAL SUPPORT ON HEALTHCARE WORKERS IN SAFE HANDLING OF CYTOTOXIC AGENTS AND RELATED WASTE AT KENYATTA NATIONAL HOSPITAL (P126/02/2019)

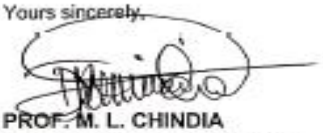
This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 25th April 2019 – 24th April 2020.

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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
g. 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 Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Director, School of Nursing Sciences, UON
Supervisors: Dr. James Mwaura, Lucy Kivuti Bitok

Appendix 9: Approval from KNH Department of Medicine

KNH/R&P/FORM/01

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

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

Study Investigators Certificate

1. Name of the Principal Investigator/Researcher
   HENRY KILONZI MUTUA
2. Email address: [illegible] Tel No. 0721205543
3. Contact person (If different from PI)
4. Email address: Tel No.
5. Study Title
   ASSESSMENT OF INSTITUTIONAL CAPACITY ON HEALTHCARE WORKERS ON SAFE HANDLING OF CYTOTOXIC AGENTS AND RELATED WASTES AT KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted MEDICINE
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
   Name: Signature Date
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: Dr. K. [illegible] Signature Date 2/5/19
9. KNH UoN Ethics Research Committee approved study number P151/2/2019
   (Please attach copy of ERC approval)
10. I HENRY KILONZI MUTUA 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 22/04/2019
11. Study Registration number (Dept/Number/Year) medicine /182/ 2019
    (To be completed by Research and Programs Department)
12. Research and Program Stamp

KENYATTA NATIONAL HOSPITAL Research Resource Centre

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.

Version 2: August, 2014

Appendix 10: Approval from KNH Department of Pediatrics

KNH/R&P/FORM/01

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

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

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   HENRY KILEMI MITHEU
2. Email address: mitheukg@gmail.com Tel No. 0726 20 55 42
3. Contact person (if different from PI)
4. Email address: Tel No.
5. Study Title
   ASSESSMENT OF INSTITUTIONAL SUPPORT ON HEALTHCARE WORKER IN-SAFE HANDLING OF CYTOTOXIC AGENTS AND RELATED WASTE AT KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted PEDIATRICS
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
   Name: Signature Date
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: DR. IGATWA A Ag HOD Signature Date 25/5/19
9. KNH UoN Ethics Research Committee approved study number P126/02/2019
   (Please attach copy of ERC approval)
10. I HENRY KILEMI MITHEU 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 29/04/2019
11. Study Registration number (Dept/Number/Year) Peds / 191/2019
    (To be completed by Research and Programs Department)
12. Research and Program Stamp

KENYATTA NATIONAL HOSPITAL P.O. Box 20723 - 00202 Nairobi Research Resource Centre

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.

Version 2: August, 2014

Appendix 11: Approval from Department of Reproductive Health KNH

KNH/R&P/FORM/01

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

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

Security Investigational Committee

1. Name of the Principal Investigator/Researcher
HENRY KILONZI MUTHEU

2. Email address: MUTHEULH@GMAIL.COM Tel No. 0726 26 65 42

3. Contact person (If different from PI)

4. Email address: Tel No.

5. Study Title
ASSESSMENT OF INSTITUTIONAL SUPPORT IN MANAGEMENT
NURSES IN SAFE HANDLING OF CYTOTOXIC AGENTS AMONG
ONCOLOGY NURSES AT KENYATTA NATIONAL HOSPITAL

6. Department where the study will be conducted REPRODUCTIVE HEALTH
(Please attach copy of Abstract)

7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
Name: DR. IKOL ADUNGO Signature Date 2/05/19

8. Endorsed by KNH Head of Department where study will be conducted.
Name: Dr. Mango Fiso Signature Date 3/5/19

9. KNH UoN Ethics Research Committee approved study number P1117/2/2019
(Please attach copy of ERC approval)

10. I HENRY KILONZI MUTHEU 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 29/4/2019

11. Study Registration number (Dept/Number/Year) Obs Gyne /199/2017
(To be completed by Research and Programs Department)

12. Research and Program Stamp

KENYATTA NATIONAL HOSPITAL 06 MAY 2019 P.O. Box 20723 - 00202 Nairobi Research Resource Centre

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.

Version 2: August 2014

Appendix 12: Approval from KNH Cancer Treatment Centre Department

KNH/R&P/FORM/01

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

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

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   HENRY KILONZI MUTHEU
2. Email address: [illegible] Tel No. [illegible]
3. Contact person (if different from PI)
4. Email address: Tel No.
5. Study Title
   ASSESSMENT OF INSTITUTIONAL SUPPORT ON HEALTHCARE WORKERS ON SAFE HANDLING OF CYTOTOXIC AGENTS AND RELATED WASTE AT 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 KNH Department where the study will be conducted.
   Name: D Signature Date
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: Dr Catherine Bukusi Signature Date 30/4/19
9. KNH UoN Ethics Research Committee approved study number P126/12/2019
   (Please attach copy of ERC approval)
10. I HENRY KILONZI MUTHEU 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 29/4/2019
11. Study Registration number (Dept/Number/Year) CTC /59/2019
    (To be completed by Research and Programs Department)
12. Research and Program Stamp

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.

KENYATTA NATIONAL HOSPITAL Research & Programs Office P.O. Box 20723 - 00202 Nairobi

Version 3: August 2014