KNOWLEDGE AND PRACTICE ON SAFE HANDLING OF CYTOTOXIC DRUGS AMONG HEALTH CARE WORKERS AT KENYATTA NATIONAL HOSPITAL

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November, 2016

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DEDICATION

To my parents, for their unconditional love, motivation and unwavering support.

To my daughter, Nafisa and my son, Abdulrahman for filling my life with light moments.

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ABBREVIATIONS AND ACRONYMS

BSC: Biological Safety Cabinet.

CME: Continuous Medical Education.

GFC: Kenyatta National Hospital Ground Floor Ward C which serves ambulatory cancer patients.

GFD: Kenyatta National Hospital Ground Floor Ward D which serves hospitalized cancer patients.

ISOPP: International Society of Oncology Pharmacy Practitioners.

IARC: International Agency for Research on Cancer

KNH: Kenyatta National Hospital.

NIOSH: National Institute for Occupational Safety and Health.

PPE: Personal Protective Equipment.

UoN/KNH-ERC: University of Nairobi/Kenyatta National Hospital Ethics & Research Committee.

Ward 1B: Adult gynecology ward located on the 1st floor of Kenyatta National Hospital.

Ward 1E: Pediatric oncology ward located on the 1st floor of Kenyatta National Hospital.

Ward 8C: Medical oncology ward located on the 8th floor of Kenyatta National Hospital.

Ward 9D: Ophthalmology ward located on the 9th floor of Kenyatta National Hospital.

WHO: World Health Organization.

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OPERATIONAL DEFINITION OF TERMS

Adequate Knowledge: The level of knowledge is above the average score of study participants.

Carcinogen: Cancer-causing substance or agent.

Cytotoxic: A substance or agent that is toxic to cells, synonymous to antineoplastic agent, chemotherapy and anticancer agent.

Day Room: Day care unit rooms located in each pediatric ward on the third floor of Kenyatta National Hospital which serves pediatric cancer patients.

Handling: Includes receiving, storage, compounding and preparation, administration, storage, cleaning and disposal.

Inadequate Knowledge: The level of knowledge is below the average score of study participants.

Registrar: A postgraduate medical student pursuing a master's degree specialization in internal medicine, pediatrics or obstetrics & gynecology.

Teratogen: A substance or agent that causes developmental malformations.

ABSTRACT

Background: Cytotoxic drugs are carcinogenic, mutagenic and teratogenic. Improper handling and use of these drugs leads to occupational health hazards among workers in cancer management settings. No study has been published to evaluate knowledge and practice on safe handling of cytotoxic drugs among workers in Kenyatta National Hospital.

Study Objective: The objective of this study was to assess knowledge, practice and challenges on safe handling of cytotoxic drugs among health care workers at KNH.

Methodology: A cross-sectional study design using a self-administered structured questionnaire was used to collect data from 109 workers at Kenyatta National Hospital units handling cytotoxic drugs. Stratified random sampling was employed to categorize the workers and simple random sampling to select the study participants, respectively. Data were collected on workers knowledge, practice and challenges. Analysis was done using Stata version 13.0 and Fisher's exact test used to compare the relationship between practice, knowledge and other characteristics. The level of significance was determined at $p < 0.05$

Results: Overall, there was female predominance at 73 (66.97%). There were 18 (16.51%) medical officer registrars, 4 (3.67%) pharmacists, 70 (64.22%) nurses, 6 (5.5%) pharmaceutical technologists, 2 (1.83%) supply chain officers and 9 (8.26%) cleaners.

Although only 38.53% of the study participants were trained on safe handling of cytotoxic drugs, 104 (95.41 %) had adequate knowledge. However, only 54 (49.54%) scored "good" on practice with 37 (33.94%) scoring "fair" and 18 (16.51%) scoring "poor" on practice. High workload and unavailability of personal protective equipment (PPE) were the main challenges reported.

Conclusion: There is a big know-do-gap as workers in cytotoxic units have sufficient knowledge on safe handling but they do not practice it. The main challenges affecting healthcare workers in KNH were high workload and unavailability of PPE.

CHAPTER ONE: INTRODUCTION

1.1 Background

Cancer is currently the leading cause of death worldwide accounting for approximately 8.2 million deaths in 2012 [1]. The global cancer burden is projected to continue rising with 23.6 million new cases expected to be diagnosed annually by the year 2030 [2]. In Kenya, cancer takes third place in major causes of death in the country [3]. With cancer cases on the rise, the overall use of cytotoxic drugs and other treatment modalities is expected to rise to cater for the new cancer cases.

Cytotoxic drugs have extensively been used in the treatment of cancer patients and this has led to occupational hazards associated with exposure such as abortions, infertility, premature labor, developmental and behavioral abnormalities among children of the workers [4, 5]. Furthermore, several studies have reported widespread contamination of working areas which leads to health worker exposure to these hazardous drugs [6 - 15].

The risk of occupational exposure by workers who handle cytotoxic drugs may vary depending on the frequency and duration of use among other factors. The main routes of exposure to cytotoxic drugs include; inhalation of aerosolized cytotoxic drug, absorption through the skin and needle injuries [16]. Safe practices are not followed consistently despite several guidelines having been developed [17].

Some of the challenges which prevent health care workers from adhering to safety practices include inconvenience, availability and access to protective equipment [18]. Other reasons cited include lack of knowledge of health hazards implicated when handling antineoplastics, comfortability of (Personal Protective Equipment) PPE, belief and work pressure [19, 20]. Other studies have shown there is a know-do-gap among workers when handling cytotoxics [6].

This study therefore evaluated the knowledge and practice on safe handling of cytotoxic drugs during receiving, storage, compounding and preparation, administration, cleaning and disposal among health care workers at the Kenyatta National Hospital.

1.2 Problem statement

Evidence from several studies has shown that workers are exposed to cytotoxic hazard through preparation, administration, cleaning of working area and disposal of cytotoxic drugs due to unsafe handling practices [21]. Studies involving biological monitoring of staff and their working environment have demonstrated the presence of adverse health effects on the health care workers as well as cytotoxic drug residues on the work surfaces [5, 22, 23].

Other evidence has also shown both acute and long-term hazards associated with occupational exposure to cytotoxics [5]. Knowledge and safe practice in handling cytotoxic drugs is therefore of paramount importance to help prevent occupational hazards to self, patients and people who visit the oncology departments in the hospital.

1.3 Rationale/Justification

The number of patients being diagnosed of cancer is on the rise and therefore the use of cytotoxic medicines is expected to increase at KNH. Safety procedures not only protect the staff handling the medicines but also reduce exposure to hospital visitors and other patients in the wards who are not on cancer chemotherapy. Safe practices also reduce contamination of products. Cancer patients generally have low immunity and infections should be minimized by ensuring products are not contaminated in the process of handling them.

Studies to assess health care workers' knowledge and practice on handling of anticancer drugs have not been done in Kenya. This study seeks to find out the level of knowledge and practice of health care workers at KNH in handling of cytotoxic drugs.

The findings of this study will be used to promote safe cytotoxic handling practice which will enable health care workers to reduce the level of hazardous exposure to themselves, their patients and the public. It will also strengthen the implementation of institutional guidelines through training of health care workers on correct cytotoxic handling procedures and practices.

1.4 Study objective

1.4.1 General objective

To assess the knowledge and practice on safe handling of cytotoxic drugs among health care workers at Kenyatta National Hospital.

1.4.2 Specific objectives

1. To determine the level of knowledge on safe handling of cytotoxic drugs by health care workers at KNH.

2. To assess the practice of handling cytotoxic drugs among health care workers at KNH.

3. To find out the challenges faced by healthcare workers when handling cytotoxic drugs in KNH.

1.5 Research questions

1. What is the level of knowledge of health workers in handling cytotoxic drugs at KNH?

2. What is the practice of handling cytotoxic drugs by healthcare workers at KNH?

3. Are there any challenges faced by healthcare workers when handling cytotoxic drugs in KNH?

1.6 Delimitations

The study was carried out at Kenyatta National Hospital (KNH). KNH has 50 wards and 22 outpatient units. However, the study was done in the following units; ward GFD, ward GFC, ward 1E, ward 1B, ward 8C, ward 9D, all pediatric ward day rooms, private wing pharmacy, main pharmacy, oncology pharmacy and the drug store.

CHAPTER TWO: LITERATURE REVIEW

2.1 Knowledge and Practice of Handling Cytotoxic Drugs

The International Society of Oncology Pharmacy Practitioners' (ISOPP) guidelines on safe handling of cytotoxic drugs state that all healthcare workers who handle cytotoxic drugs must undergo training before being permitted to work in a facility where cytotoxic drugs are prepared. The guidelines indicate that pharmacy, medical as well as nursing personnel and cleaners should all be trained [24].

According to the ISOPP standards, the training course for the healthcare workers should consist of the following elements; potential risks of exposure, utilization of a biological safety cabinet, working in a clean room, use of PPE, handling of cytotoxic waste, how to deal with cytotoxic spills, labeling, transport and cleaning procedure [24].

Most healthcare works are not properly trained on safe handling of cytotoxic drugs and this has a negative impact on their safety behavior when handling cytotoxic drugs. In a study done in Pakistan, nurses were found to be deficient in knowledge of handling cytotoxic drugs [25]. The study found that 20% of nurses were not trained on how to handle cytotoxic drugs and 43.33% believed that PPE was not necessary during work. Most of the nurses did not receive specialized training on safe handling of cytotoxic drugs. The same study found that only 33% were trained while 11% reported to have received information through media and 18% from professional associations [25].

The main source of information for safe handling of cytotoxic drugs is in-service training [26]. Studies have indicated that nurses have inadequate knowledge about the risks involved in handling cytotoxic drugs [27]. The International Agency for Research on Cancer (IARC) occupational safety and health administration guidelines state that all personnel involved in handling of hazardous drugs must be trained so as to increase workers' safety [28, 29].

It has been established that safe handling practices are not always followed despite the availability of several guidelines [17]. Nurses do not comply fully with the cytotoxic

drugs handling regulations [28]. Pharmacists have significantly better compliance to guidelines compared with nurses. The items in the guidelines which had poor compliance were wearing eye protection, hair cover and shoe covers. Full compliance with the guidelines was reported by only 10.7% of the study participants [30].

Although healthcare workers may possess the knowledge on safe handling of cytotoxic drugs, implementation during practice may be poor. A study conducted in Jordanian hospitals to assess compliance on safe handling of antineoplastic drugs reported that nurses' knowledge on the risks of exposure was satisfactory but the safety measures that were used were not in compliance with the guidelines [31].

2.2 ISOPP Guidelines on Safe Handling of Cytotoxic Drugs

2.2.1 Receiving and Storage

Strict procedures must be followed to ensure safety of stores personnel when handling cytotoxic drugs. Any person who is involved in unpacking or handling cytotoxic drugs should wear two pairs of gloves as a protective measure. The guidelines also recommend that stores personnel should wash their hands after handling vials containing cytotoxic drugs [31]. Some studies have found that the external surfaces of drug vials are contaminated [32, 33].Therefore appropriate safety measures should be taken when handling them.

Cytotoxic drugs should have warning labels and should be stored in a designated area so as to prevent hazardous contamination and exposure to personnel [34].

2.2.2 Preparation

The KNH guidelines (Appendix 3) recommend that compounding of cytotoxic drugs should take place in a designated room within the wards or clinic and should preferably be done in a biological safety cabinet. Proper protective equipment; gowns, gloves, overshoes, head cover, masks, and eyewear should be worn.

Gloves should be changed frequently and immediately in case of visible contamination. All work surfaces should be cleaned with water and 70% alcohol after finishing work.

2.2.3 Cleaning

Strict procedures should be followed by all cleaning personnel when decontaminating the cytotoxic preparation room. PPE should be worn at all times when cleaning and hands should be washed thoroughly with soap and water immediately after removing gloves [24, 34].

The guidelines recommend taking precautions when handling patient excreta up to 7 days after administration of cytotoxics, because the unchanged drug may be excreted by the patient. It is also recommended that one should wear a gown, gloves and goggles if there is a likelihood of body fluids to splash [24, 34].

2.2.4 Cytotoxic drug spill

All healthcare workers must be trained on the procedures to be followed in the event of a spill. In case of a spill occurs inside the safety cabinet, it should be cleaned up immediately. Absorbent gauze should be used for small spills while a spill pillow should be used for large spills. The area should then be washed with water and a detergent and then wiped with sterile isopropyl alcohol (70%) [24, 34].

According to the ISOPP guidelines, the cleanup procedure for a cytotoxic drug spill involves first alerting other staff in the area of the potential hazard. Access to the area should be restricted by placing a warning sign in a visible area. The contents of the spill kit are then removed and put on in the following order: the mask, the head cover, the goggles or face shield and the gloves [24].

Cleaning of the spill area should start from the outside and gradually work towards the center. The area of the spill should then be thoroughly washed with detergent water [24].

2.2.5 Disposal

Syringes, needles, gloves, single use gowns, masks and materials from the clean-up of cytotoxic spills should all be considered as hazardous waste when they come into contact anticancer agents [24].

Contaminated materials should be labeled, sealed and covered using disposal containers and must be handled by trained personnel only. Waste must be collected in dedicated containers with a recognizable color and symbol during transportation [24, 34].

2.3 Challenges associated with handling of cytotoxic drugs

Despite that nurses are knowledgeable about cytotoxic drug exposure, use of safety measures during handling of these drugs is low [35]. Some of the challenges reported by workers include: high workload, limited time, unavailability and comfortability of PPE [6,18, 19].

CHAPTER THREE: METHODOLOGY

This chapter describes the research design, data collection, analysis and presentation that were used in this study. It focuses on the methodology and steps taken to enhance validity and reliability of the data from the study.

3.1 Research Design

A cross sectional study was used. Data were collected using a standardized self-administered questionnaire (appendix 2) from consenting study participants who met the inclusion criteria.

3.2 Location of Study

The study was conducted at Kenyatta National Hospital (KNH) which is currently the largest national referral and teaching hospital in Kenya as well as the East African region and also serves as a primary healthcare facility for the residents of Nairobi County. The hospital has a staff capacity of 6000 with an average annual out-patient attendance of 600,000 and an in-patient attendance of 90,000. KNH has 50 wards, 22 outpatient units and a bed capacity of 1800.

The institution receives patients on referral from other hospitals and institutions countrywide for specialized healthcare services. It also provides teaching and research facilities for the University of Nairobi and other collaborating health institutions.

This research was conducted in the drug store, inpatient oncology ward GFD, outpatient oncology ward GFC, oncology pharmacy, main pharmacy, private wing pharmacy, ward 8C, ward 9D, ward 1E, ward 1B and all pediatric day rooms of KNH as described in table 1 below.

Table 1: Description of the study location

Location	Description	Staffing level/bed capacity
Drug store	Responsible for receiving and storage of all pharmaceutical supplies including cytotoxic drugs	4 supply chain officers, 3 pharmacists, 1 pharmaceutical technologist and 2 cleaners
Oncology ward GFD	Serves inpatient oncology patients	30 beds and a staff capacity of 18 nurses, 4 medical officer registrars and 2 cleaners
Oncology ward GFC	Serves outpatient oncology patients	Handles 50 patients in a day and is served by 8 nurses, 3 medical officer registrars and 2 cleaners
Ward 1B	Serves inpatient adult gynecology patients	32 beds and a staffing level of 18 nurses, 4 medical officer registrars and 2 cleaners
Ward 1E	Serves inpatient pediatric oncology patients	20 beds and a staffing level of 18 nurses, 2 medical officer registrars and 2 cleaners.
Ward 8C	Serves inpatient adult oncology patients	20 beds and a staffing level of 20 nurses, 4 medical officer registrars and 6 cleaners
Ward 9D	Serves ophthalmology patients	30 beds and a staffing level of 16 nurses, 4 medical officer registrars and 3 cleaners
Pediatric day rooms	Each day room handles outpatient pediatric oncology patients	Each day room has 14 beds and is served by 28 nurses, 6 medical officer registrars and 2 cleaners.
Oncology pharmacy	Responsible for compounding and dispensing cytotoxics for all oncology units in KNH except private wing.	Served by 3 Pharmacists and 4 Pharmaceutical technologists
Main pharmacy	Responsible for storage of all cold chain pharmaceutical	Served by 2 Pharmacists, 4 Pharmaceutical technologists and

	supplies including cytotoxic drugs as well as dispensing of drugs to patients	2 cleaners.
Private wing pharmacy	Responsible for compounding and dispensing all medicines for all patients in the wards located on the ninth and tenth floor of KNH.	Served by 1 Pharmacist and 6 Pharmaceutical technologists.

3.3 Study Population

The study participants of interest were all cadres of healthcare workers who handled cytotoxic drugs in KNH. The healthcare workers comprised of medical officer registrars, nurses, pharmacists, pharmaceutical technologists, supply chain officers and cleaners.

3.3.1 Inclusion criteria

All healthcare workers who handled cytotoxic drugs in KNH during the study period and gave an informed consent were considered eligible to participate in the study.

3.3.2 Exclusion criteria

Healthcare workers who worked in the oncology units of KNH and were not involved in handling cytotoxic drugs were excluded from participating in the study.

3.4 Sampling

3.4.1 Sample Size

The sample size for the study participants was drawn from healthcare workers who handle cytotoxic drugs in the oncology units of KNH during the study period.

From KNH records, the cadres of health care workers who were currently handling cytotoxic drugs included: 44 medical officer registrars, 9 pharmacists, 196 nurses, 15 pharmaceutical technologists, 22 cleaners and 4 supply chain officers.

According to Borg and Gall, at least 30% of the total population is representative for this type of study [36]. To cater for non-responders 40% was used.

The sample size for each cadre of health care worker was calculated as shown in table 2 below.

Table 2: Calculation of the study sample size

Cadre of healthcare workers	Total number (n)	Sample size (40% x n)
Medical registrars	44	18
Nurses	213	85
Pharmacists	9	4
Pharmaceutical technologists	15	6
Cleaners	22	9
Supply chain officers	4	2
Total	290	124

A calculated sample size of 124 health care workers was obtained and the number in each category is indicated in Table 1 above.

3.4.2 Sampling Process

The principal investigator obtained the list of names of healthcare workers who handled cytotoxic drugs from each head of the respective departments. From the list obtained, workers were stratified into categories depending on the cadre. The groups included; medical officer registrars, pharmacists, nurses, pharmaceutical technologists, supply chain officers and cleaners. Simple random sampling was employed to select the name of the respondent from the list in each category. This was accomplished by tossing a coin and whoever scored the head was selected. The selected respondent was approached and requested to consent after explanation regarding what the research entailed. After consenting, the study participant was given a questionnaire to fill and return as soon as possible to the chief investigator or research assistant.

3.4.3 Recruitment

The chief investigator or trained research assistant approached and introduced himself to the potential study participant and then explained what the study was all about, the risks and the benefits involved. The potential study participant was only included in the study if he/she fit the inclusion criteria and gave an informed and signed consent. The principal investigator or research assistant then gave the questionnaire to the study participant to fill. The process was done repeatedly until the required sample size was attained. Recruitment took place at each study site where the study participants were working.

3.5 Research Instruments

A self-administered, structured questionnaire was used to collect the required data to meet the study objectives. The questionnaire comprised of four sections; Socio-demographic details of healthcare workers, knowledge, practice and challenges on safe handling of cytotoxic drugs. All collected data was used only for the current study.

3.6 Pre-Test

The data collection tool was pre-tested on 10 healthcare workers prior to commencement of the study. The results were then analyzed to assess the clarity and comprehensibility of the items on the questionnaire.

3.7 Validity

Internal validity was established through comprehensive review of literature and peer review of the questionnaire by those considered experts in the field followed by a pre-test study.

KNH being the largest referral hospital in Kenya and having the largest number of staff handling cytotoxic drugs ensured external validity.

3.8 Reliability

In order to achieve reliability, closed ended questions were used. To achieve consistency, the data collection tool was pre-tested and necessary changes made after feedback from the participants.

3.9 Data Collection

3.9.1 Research Assistants

The principal investigator was assisted by two research assistants. Both research assistants were trained on the procedure by the principal investigator prior to the actual study. Research assistants assisted in the sampling and recruitment of study participants, distribution and collection of questionnaires. The principal investigator was the overall coordinator of the project.

3.9.2 Data collection

The research instrument was a pre-tested, self-administered, structured questionnaire (Appendix 2). The questionnaire used to collect the data comprised of four sections;

1. Socio-demographic variables; age, gender, marital status, level of education, occupation, years of experience in the profession and years of experience in handling cytotoxic drugs and training.
2. Knowledge items regarding safe handling of cytotoxic drugs; use of PPE, hand washing, cleaning and effects of exposure to cytotoxic drugs.
3. Practice items were sub divided into 5 sections; receiving and storage, preparation, administration, cleaning and disposal.
4. Challenges on safe handling of cytotoxic drugs.

3.10 Data Management and Analysis

Data from completely filled questionnaires by the study participants was entered into a password protected Microsoft Excel spread sheet (version 2013) and then exported to STATA version 13.0 for analysis. Data entering process was conducted concurrently as the data collection continued. Upon completion of data entry, hard copy forms were compared with the entered data to identify errors and any corrections were made appropriately. A biostatistician was involved at various stages of data analysis for purposes of authentication and credibility of the analysis process.

Data cleaning and validation was also performed to achieve a clean set of data which was then backed-up in a Compact Disk (CD) and a flash disk.

Descriptive statistics were used to describe data using frequency tables and pie-charts. For inferential statistics, Fisher's exact test was used. In all analyses, a p-value of <0.05 was considered statistically significant.

Knowledge was assessed in two categories; adequate or inadequate. All categories of study participants were required to answer the knowledge section. The knowledge assessment section in the questionnaire comprised of ten questions. If a study participant responded correctly to a question, he/she was given a score of one point. A score of 5 points and above was assessed as adequate and those below 5 points as inadequate.

Practice was assessed in three categories; good, fair and poor. Each category of study participant was required to respond to a set of questions applicable to their scope of practice of handling cytotoxic drugs. If a study participant responded correctly to a question, he/she was given a score of one point. An overall score was determined for each study participant by adding up the scores across the practice questions which were applicable to each study participant. A score of above 75% was considered good, 50% to 75% as fair and below 50% as poor.

3.11 Ethical Considerations

3.11.1 Ethical approval

Permission to carry out the study was sought from the Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee and a reference letter number KNH-ERC/A/243 was granted (Appendix 4).

3.11.2 Informed Consent

Informed consent from study participants who meet the inclusion criteria was sought. Each participant was requested to sign a consent form (Appendix 1) before inclusion into the study. This was done after the risks, benefits and ethical considerations were fully explained and understood by the participant.

3.11.3 Risks involved

There were no risks involved for the participants since the research only involved data collection from questionnaires.

3.11.4 Confidentiality

The information regarding the study participant's identity was kept confidential. Identification information such as participants names were not included in the data collection forms. Serial numbers were assigned to each participant.

CHAPTER FOUR: RESULTS

4.0 Introduction

This section describes the results obtained from analysis of the study. It provides a summary of the demographic data, knowledge, practice and challenges in safe handling of cytotoxic drugs among healthcare workers at KNH. The level of knowledge and practice were each scored across all respondents. The findings are presented according to objectives of the study.

Fisher's exact test was used to determine whether there was any association between knowledge and practice scores and demographic characteristics. In all analyses, a p-value of <0.05 was considered statistically significant.

4.1 Socio-demographic profile of study participants

A total of 109 respondents participated in the study, representing a 90.83% response rate from the 124 original sample size. The mean age was 38.3 years (SD 9.5) while the range was from 24 to 58 years. Majority of the study participants were female. A third (36.7%) were between the ages of 31 and 40 years while 76 (69.72%) were married. Most (64.2%) of the healthcare workers were nurses and half (51.38%) were diploma certificate holders.

Table 3 below depicts the demographic profile of the study participants.

Table 3: Demographic characteristics of the study participants

Characteristics	Classification	n	Percentage (%)
Age Category (Years)	21 – 30	28	25.69
	31 – 40	40	**36.70**
	41 – 50	25	22.94
	>50	16	14.68
Age Distribution	Mean = **38.28** SD = 9.544 Max = 58 Min = 24		
Gender	Male	36	33.03
	Female	73	**66.97**
Marital Status	Single	22	20.18
	Married	76	**69.72**
	Divorced	2	1.83
	Widowed	8	7.34
	Separated	1	0.92
Education level	Primary certificate	3	2.75
	Secondary certificate	5	4.59
	Diploma certificate	56	**51.38**
	Bachelor's degree	35	32.11
	Master's degree	10	9.17
Cadre	Medical Officer Registrar	18	16.51
	Pharmacist	4	3.67
	Nurse	70	**64.22**
	Pharmaceutical technologist	6	5.50
	Supply chain officer	2	1.83
	Cleaner	9	8.26
Department	Medical	49	44.95
	Pediatric	32	29.36
	Gynecology	9	8.26
	Pharmacy	9	8.26
	Medical stores	4	1.83
	Cleaning	8	7.34
Years of experience in handling cytotoxic drugs:	Less than 1 year	22	20.18
	1 to 3 years	25	22.94
	3 to 5 years	17	15.60
	more than 5 years	45	**41.28**

4.2 Training on safe handling of cytotoxic drugs

Amongst the study participants, 42 (38.53%) reported having received some training on safe handling of cytotoxic drugs (Table 4).

Table 4: Training on safe handling of cytotoxic drugs

Cadre	N	Percentage (%)
Medical officer registrars	2	1.83
Pharmacists	1	0.92
Pharmaceutical technologists	3	2.75
Nurses	29	26.61
Supply chain officers	0	0
Cleaners	7	6.42
Total	42	**38.53**

Thirty three (75%) had received training more than 12 months before the time of research and 11 (25%) within the last 12 months. Twenty eight (63.64%) obtained their training from workshops (Figure 1).

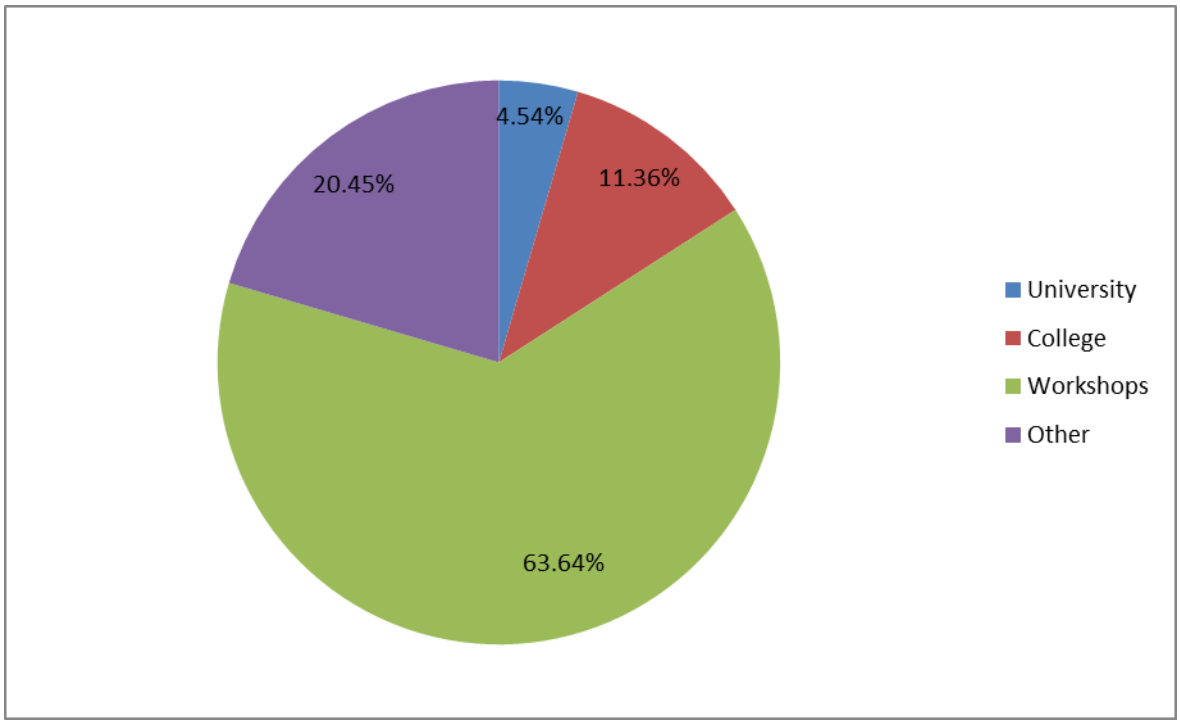


Figure 1: Training on Safe Handling of Cytotoxic Drugs

4.3 Level of knowledge on safe handling of cytotoxic drugs

Generally, the level of knowledge was high, with 104 (95.4%) healthcare workers scoring adequately (≥ 5 points). Figure 2 below provides a summary of the workers' level of knowledge.

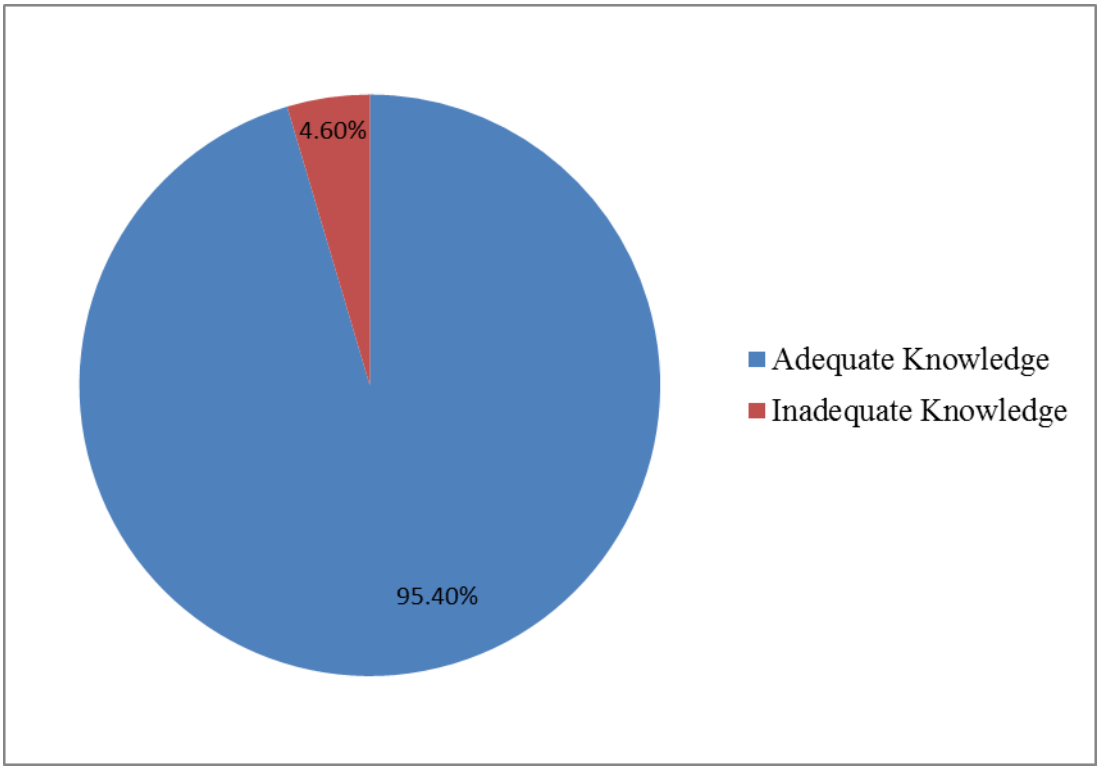


Figure 2: Healthcare workers level of knowledge

4.4 Association between knowledge and demographic characteristics

There was no statistically significant association observed between the level of knowledge and the various demographic characteristics (Table 5).

Table 5: Association between knowledge levels and demographic characteristics

Demographic characteristics		Adequate knowledge (n, %)	Inadequate knowledge (n, %)	P-value
Gender	Male	35 (32.11)	1 (0.92)	1.000
	Female	**71 (65.14)**	4 (3.67)	
Education level	Master's degree	10 (9.17)	0 (0)	1.000
	Bachelor's degree	34 (31.19)	2 (1.83)	
	Diploma certificate	**53 (48.62)**	3 (2.75)	
	Secondary certificate	6 (5.50)	0 (0)	
	Primary certificate	3 (2.75)	0 (0)	
Cadre	Medical Officer Registrar	18 (16.51)	1 (0.92)	1.000
	Pharmacist	4 (3.67)	0 (0)	
	Nurse	**65 (59.63)**	4 (3.67)	
	Pharmaceutical technologist	6 (5.50)	0 (0)	
	Supply chain officer	3 (2.75)	0 (0)	
	Cleaner	10 (9.17)	0 (0)	
Years of experience	Less than 1 year	20 (18.35)	2 (1.83)	0.067
	1 to 3 years	24 (22.02)	1 (0.92)	
	3 to 5 years	15 (13.76)	2 (1.83)	
	> 5 years	**45 (41.28)**	0 (0)	
Total		**104 (95.41)**	5 (4.59)	

4.5 Practice in safe handling of cytotoxic drugs

The study participants answered questions related to their scope of practice in handling cytotoxic drugs. The scope entailed receiving and storage, preparation, administration, cleaning and disposal. Some of the study participants were involved in more than one scope of practice. Most (n= 77, 70.64%) workers were involved in receiving and storage, followed by 73 (66.97%) in administration (figure 3).

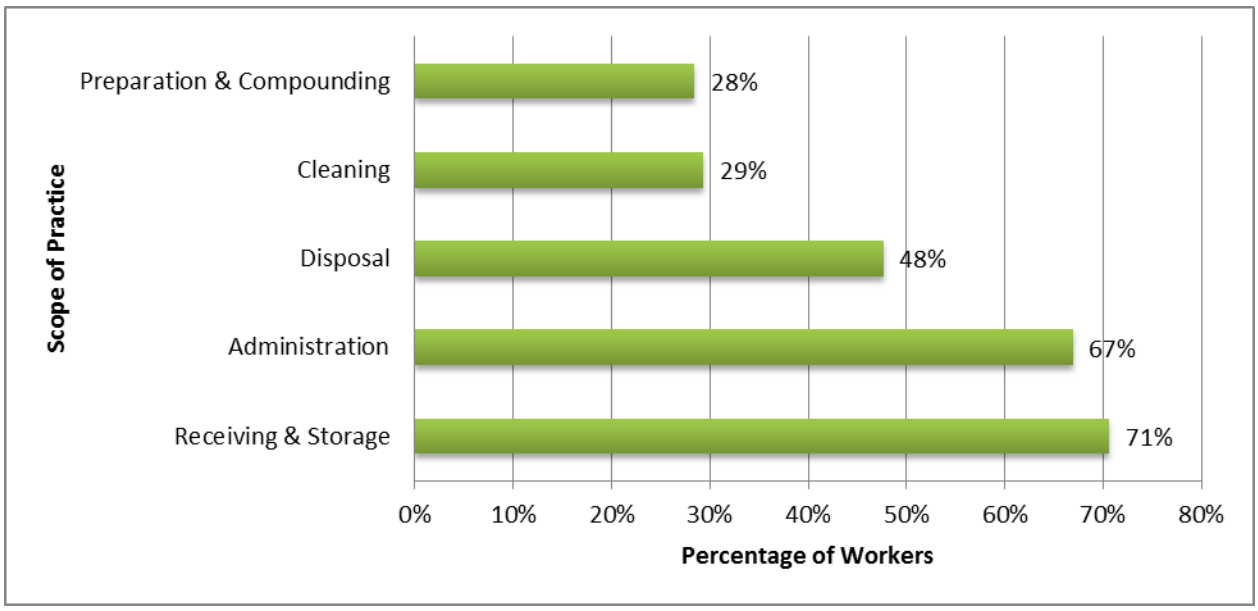


Figure 3: Workers scope of practice

4.5.1 Practice score

Almost half (49.54%) healthcare workers scored good practice while 18 (16.51%) had poor practice (Figure 4).

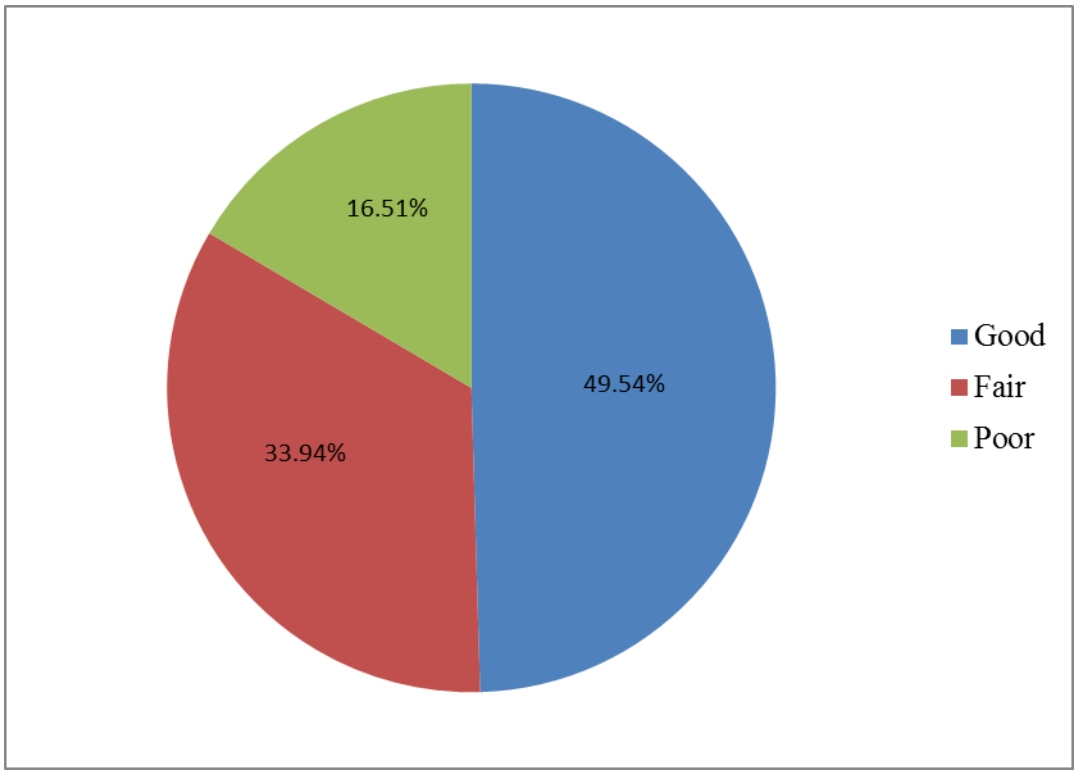


Figure 4: Practice Score

4.5.2 Receiving and Storage of Cytotoxic Drugs

Seventy seven respondents were involved in receiving and storage of cytotoxics. Among them, thirty seven (48.05%) reported wearing PPE while receiving cytotoxic drugs. Sixty seven (87.01%) washed their hands after handling and 37 (48.05%) labelled the cytotoxic drug with a hazard product identifier (Figure 5).

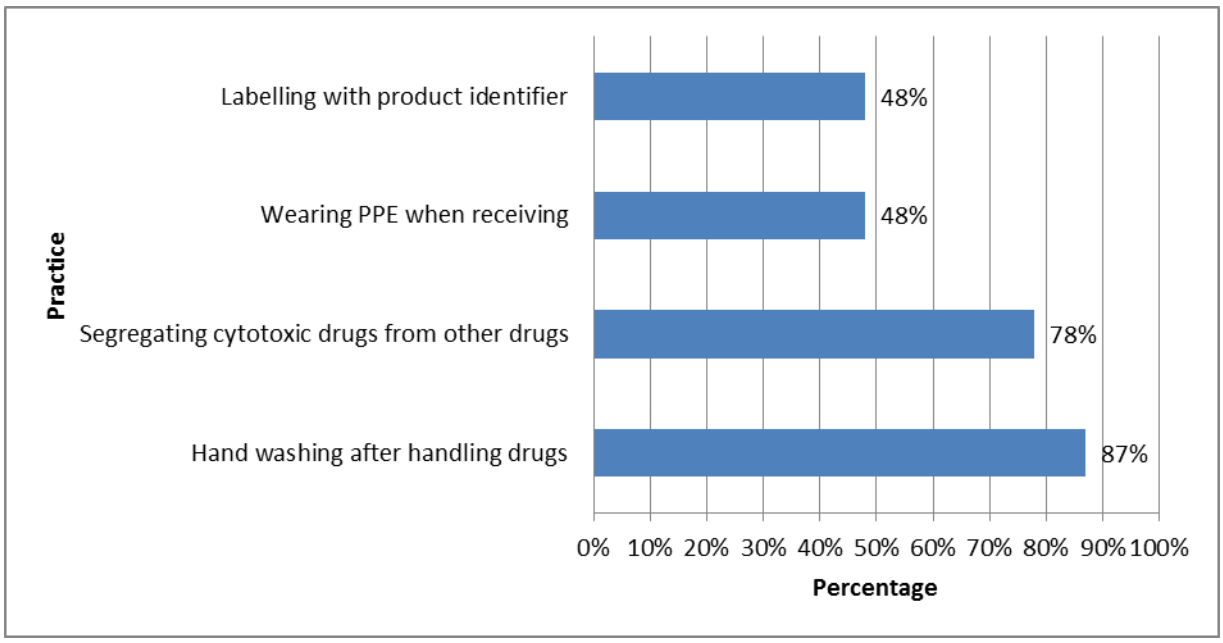
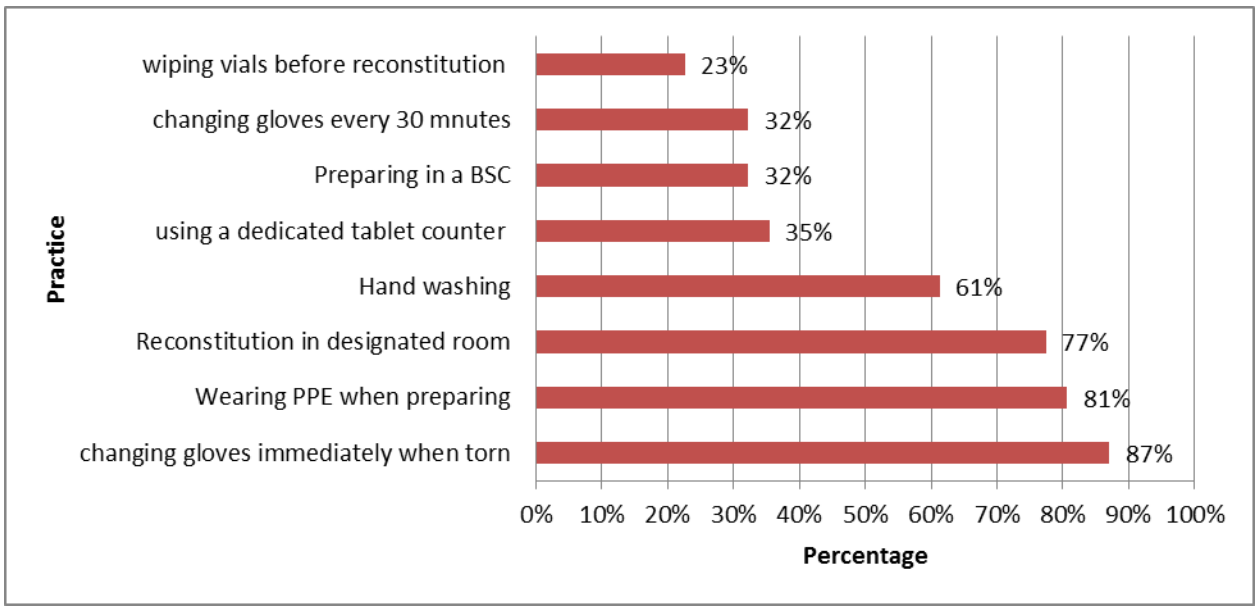


Figure 5: Practice in receiving and storage

4.5.3 Preparation and compounding of cytotoxic drugs

These activities involved thirty one respondents and 25 (80.65%) among them used PPE while preparing cytotoxic drugs. Only 10 (32.26%) prepared the drugs in a biological safety cabinet. Furthermore, 7 (22.58%) wiped the vials before reconstitution while 10 (32.26%) changed gloves every 30 minutes during reconstitution as shown in figure 6 below.



Key: BSC - Biological Safety Cabinet

PPE – Personal Protective Equipment

Figure 6: Practice in preparation and compounding

4.5.4 Administration of cytotoxic drugs

Out of 73 respondents 62 (84.93%) used PPE when administering cytotoxic drugs and 49 (67.12%) when handling excreta from cancer patients. Eighteen (24.66%) reported touching cytotoxic tablets with their bare hands (figure 7).

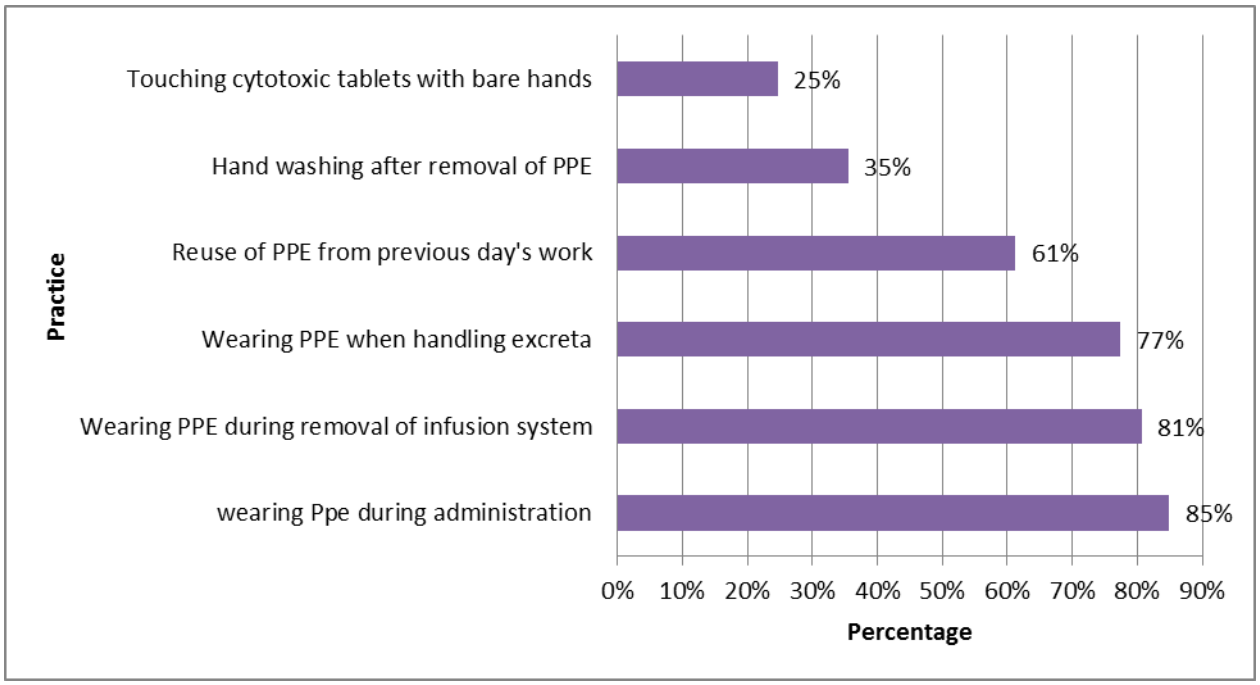


Figure 7: Practice during administration and compounding

4.5.5 Cleaning of Preparation Area and Spills

Thirty two respondents were involved in cleaning of the preparation area and spills. Nine (28.33%) among them had a cytotoxic spill kit available while 22 (68.75%) wore PPE during cleaning. Only 7 (21.86%) demarcated the spill area before cleaning (figure 8).

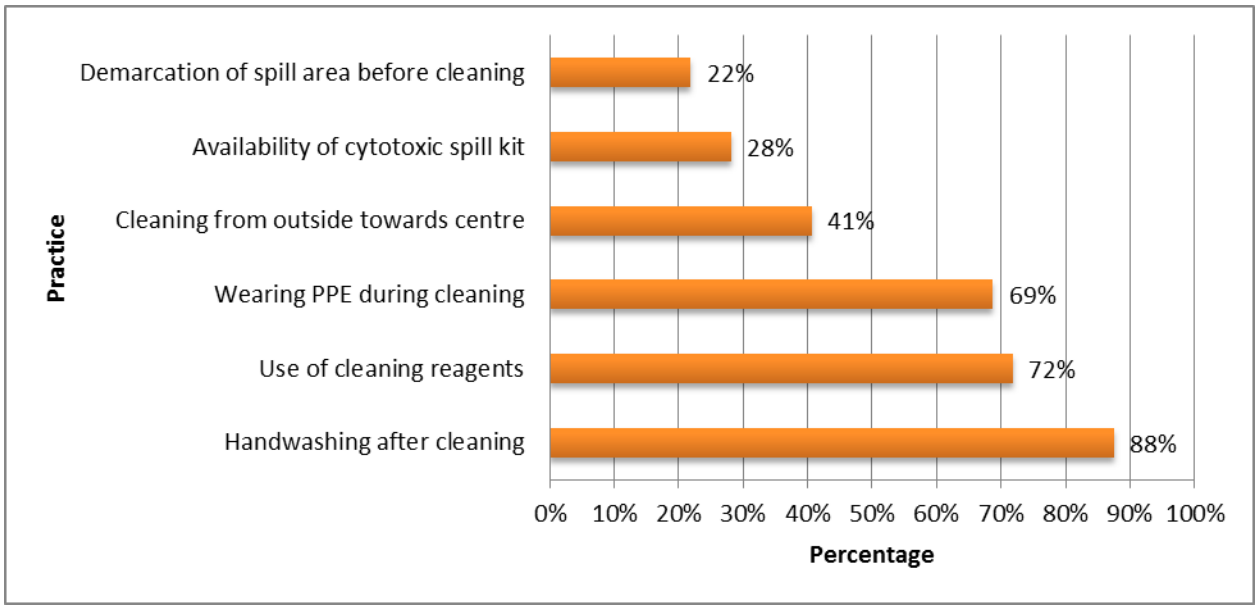


Figure 8: Cleaning Practice

4.5.6 Disposal of cytotoxic drugs

Fifty two respondents were involved in disposal of cytotoxic drugs. Fifteen (28%) of them disposed sharps in container while 21 (40.63%) incinerated cytotoxic waste in an approved facility (figure 9).

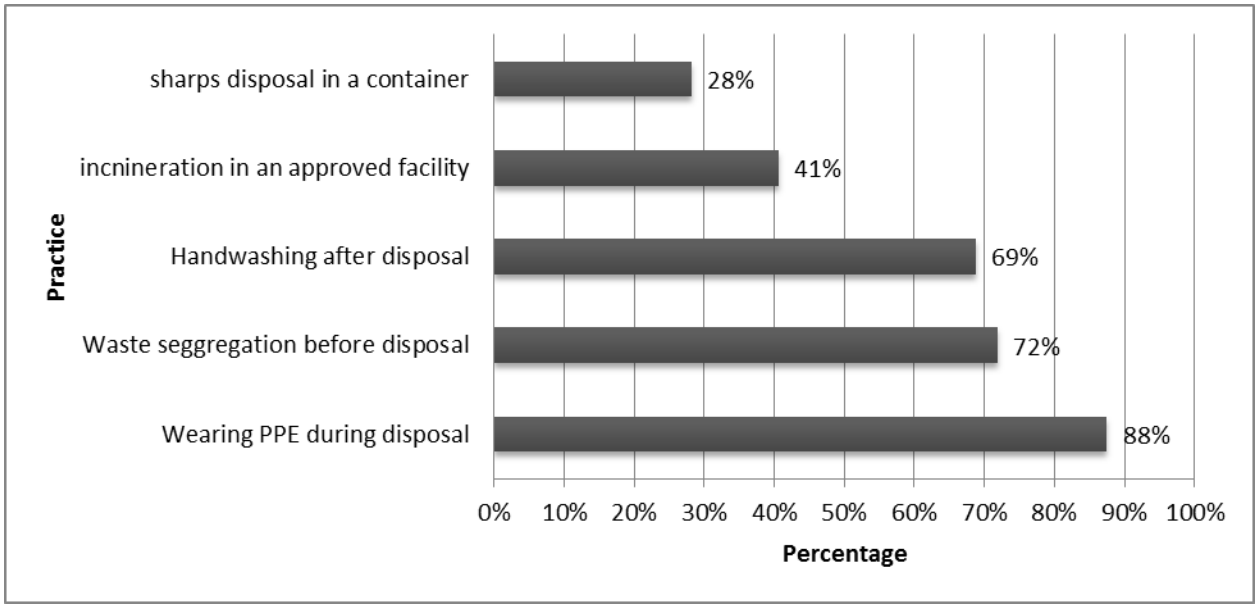


Figure 9: Disposal Practice

4.6 Association between practice and demographic characteristics

Relating the practice score with different demographic characteristics using fishers' exact test indicated there was no statistically significant association between demographic variables and practice (Table 6).

Table 6: Association between practice and demographic characteristics

Characteristics	Category	Practice Score			P-value
		Good (n, %)	Fair (n, %)	Poor (n, %)	
Cadre	Medical officer-registrars	15 (6.56)	3 (2.75)	0 (0)	0.094
	Pharmacists	2 (1.83)	2 (1.83)	0 (0)	
	Nurses	28 (25.69)	27 (24.77)	15 (13.76)	
	Pharmaceutical-technologists	3 (2.75)	2 (1.83)	1 (0.92)	
	Supply chain-officers	2 (1.83)	0 (0)	0 (0)	
	Cleaners	4 (3.67)	3 (2.75)	2 (1.83)	
Gender	Male	19 (17.43)	10 (9.17)	7 (6.42)	0.628
	Female	35 (32.11)	27 (24.77)	11 (10.09)	

Years of experience in handling cytotoxic drugs	< 1 year	10 (9.17)	8 (7.34)	4 (3.67)	0.785
	1 to 3 years	15 (13.76)	8 (7.34)	2 (1.83)	
	3 to 5 years	8 (7.34)	7 (6.42)	2 (1.83)	
	>5 years	**21 (19.27)**	14 (12.84)	10 (9.17)	
Level of education	Master's degree	6 (5.50)	4 (3.67)	0 (0)	0.663
	Bachelor's degree	17 (15.60)	13 (11.93)	5 (4.59)	
	Diploma certificate	28 (25.69)	17 (15.60)	11 (10.09)	
	Secondary-certificate	2 (1.83)	1 (0.92)	2 (1.83)	
	Primary certificate	1 (0.92)	2 (1.83)	0 (0)	

4.7 Association between knowledge and practice

Comparing knowledge and practice, 46.79% of healthcare workers who had adequate knowledge had good practice while 16.51% had poor practice (Table 7). Furthermore, 2.75% of the proportion of healthcare workers who had inadequate knowledge had good practice. There was no statistically significant association between knowledge and practice (F=0.853).

Table 7: Association between knowledge and practice

Knowledge	**Practice Score**			**P-value**
	Good	**Fair**	**Poor**	
Adequate (n, %)	51 (46.79)	35 (32.11)	18 (16.51)	0.853
Inadequate (n, %)	3 (2.75)	2 (1.83)	0 (0)	
Total	54 (49.54)	37 (33.94)	18 (16.51)	

4.8 Challenges in safe handling of cytotoxic drugs

Fifty seven (52.29%) participants considered high workload as a major challenge in safe handling of cytotoxic drugs while 51 (46.79%) reported availability of personal protective equipment. Figure 10 below indicates the various challenges faced by workers.

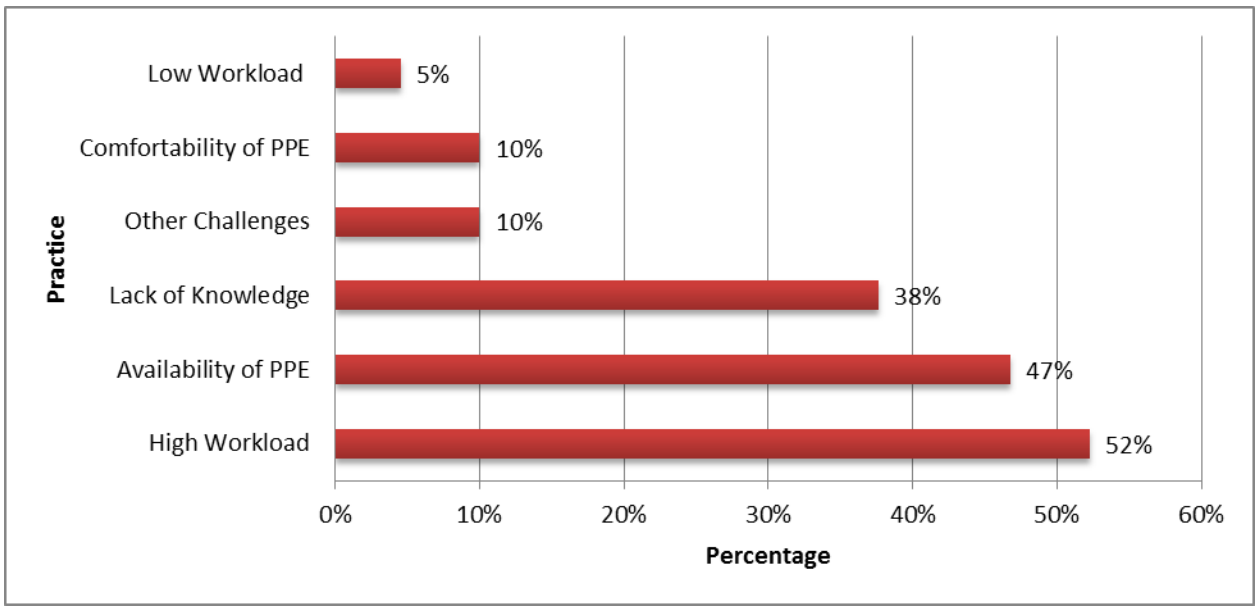


Figure 10: Challenges reported by workers at KNH

4.9 Association between practice and challenges

There was no statistically significant association between healthcare workers practice and challenges (Table 8).

Table 8: Association between practice and challenges

Challenges	Practice Score			P-value
	Good	Fair	Poor	
Low work load (n, %)	1 (0.92)	3 (2.75)	1 (0.92)	0.306
High work load (n, %)	25 (22.94)	20 (18.35)	12 (11.01)	0.308
Availability of PPE (n, %)	27 (24.77)	17 (15.60)	7 (6.42)	0.756
Lack of knowledge (n, %)	21 (19.27)	16 (14.68)	4 (3.67)	0.308
Comfort ability of PPE (n, %)	5 (4.59)	2 (1.83)	4 (3.67)	0.160
Others (n, %)	4 (3.67)	4 (3.67)	3 (3.75)	0.473

CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

5.0 Introduction

This section discusses the findings of the study. It gives a comparison of the study results with other similar studies which have been done elsewhere. Conclusion and recommendations on the research findings are also provided.

5.1 Discussion

There were more female participants compared to males similar to other studies [30, 32]. One study reported a ratio of approximately one of males to females [31]. Young participants were more with 36.7% between the ages of 31 – 40 years. This implies majority of the findings are based on participants who are in their peak reproductive age.

Only 44 (40.37%) healthcare workers had been trained on safe handling of cytotoxic drugs. This did not comply with the ISOPP guidelines which require all healthcare workers who handle cytotoxic drugs to be trained [21]. Findings from other studies depict a mixed picture where different proportions underwent training [31, 37].

Results showed that 28 (63.64%) of the healthcare workers in KNH were trained through workshops. This approach was contrary to other studies which reported in-service training, text books and the internet as important sources of information for nurses [36,37]. There was a lower percentage of training in safe handling of cytotoxic drugs in academic institutions similar to a finding by Verity *et al* [37]. Workshops and other training forums such as Continuous Medical Education meetings (CMEs) are important for training healthcare workers in KNH.

The level of knowledge on safe handling of cytotoxic drugs was satisfactory with 104 (95.4%) respondents scoring adequately. This was higher compared to other studies which have demonstrated that workers' level of knowledge was not satisfactory [22, 26, 27]. Another study done in Egypt on two group of nurses found the majority scored fair and poor, respectively before being trained on the protocols [38]. The proportion of those with adequate knowledge in the current study was higher than the ones formerly trained probably due to access to other sources of information for

healthcare workers such as medical representatives, colleagues, internet and reference books.

Our study found that 71% of workers were involved in receiving and storage, 28% in preparation, 67% in administration, 29% in cleaning and 48% in disposal. One study reported that 88% of the health care personal involved in preparation and administration were nurses while physicians and pharmacists comprised of the remaining 12% [32].

Practice was assessed in three categories, good, fair and poor. Almost half (49.4%) of healthcare workers scored good under practice. This finding was similar to a study done in Jordan where 46.6% of workers showed full compliance to guidelines [29]. Although results indicated there was no significant association between demographic characteristics and practice, it is of concern to note that more than half of the workers did not practice safe handling despite having adequate knowledge on the hazardous effects of cytotoxic drugs. This could be related to poor attitude, lack of work safety behaviour or work related challenges.

In receiving and storage, 37 (48.05%) reported wearing PPE while receiving cytotoxic drugs while sixty seven (87.01%) washed their hands after handling. This raises concern since studies have shown that the outside of vials are contaminated with cytotoxic drugs [33, 39]. Thirty seven (48.05%) labelled the cytotoxic drug with a hazard product identifier. This suggests that the KNH workers' attitude and behaviour on safety practices is poor.

The present study found that majority of those involved in preparation of cytotoxics wore PPE. This was similar to a study by Shahrasbi et al which reported high level of use of PPE [40].

Previous studies have reported a lower compliance with use of a BSC in preparation of cytotoxic drugs [4, 36]. This finding was similar to our current study where 32.26% prepared the drugs in a biological safety cabinet. This was significantly lower compared to a study done in Cyprus which reported 98.8% complying with this requirement [32]. The difference could be attributed to non-availability of BSCs in the hospital.

In administration of cytotoxics, it was found that almost a quarter of the participants reported touching cytotoxic tablets with their bare hands. This could be attributed to lack of knowledge on handling oral chemotherapy as found in a similar study where only 25% knew on the special handling procedure [41].

A third of the healthcare workers who were involved in cleaning had a cytotoxic spill kit available. However, less than 25% of them demarcated the spill area before cleaning. This suggests that there is a shortage of cytotoxic spill kits in the hospital. The fact that workers did not demarcate the spill area before cleaning also suggests that workers are not aware of the importance of this procedure or have a poor attitude while practicing and require sensitization.

The current study reported 15 (28%) workers disposed sharps in container while 21 (40.63%) incinerated cytotoxic waste in an approved facility. This is of high concern since guidelines recommend disposal of all cytotoxic drugs in an approved facility. One study reported that most of the staff (98%) were not aware of segregation and disposal of biomedical waste [42].

Regarding challenges faced by healthcare workers, high workload was the major one followed by availability of personal protective equipment. Studies have reported several challenges such as availability of handling equipment, time limitation, comfortability, attitudes and beliefs as well as work pressure [6, 18, 19].

5.2 Limitations

The study involved a self-administered questionnaire to health care workers and some declined to participate in the study due to unexplained reasons. This was minimized by addition of 10% to the sample size. Furthermore, the study was based on a self-administered questionnaire which might have led to reporter bias. Future studies should incorporate observation to allow a precise assessment of what is actually practiced.

5.3 Conclusion

The level of knowledge on safe handling of cytotoxic drugs among healthcare workers in KNH is adequate. Majority of healthcare workers at KNH obtained their knowledge on safe handling of cytotoxic drugs from workshops. A fair number of

healthcare workers scored good under practice. The main challenges affecting healthcare workers in KNH were high workload and availability of personal protective equipment.

5.4 Recommendations

5.4.1 Recommendations for policy and practice

1. Additional PPE as well as biological safety cabinets for the safety of the workers should be provided.

2. All medical registrars and freshly recruited healthcare workers in the oncology department should be trained on safe handling of cytotoxic drugs.

3. Current workers in the cytotoxic units should be sensitized on the importance of complying with the institutional guidelines.

5.4.2 Recommendations for further research

This study was a self -report and did not examine the healthcare workers actual practice at work. Moreover, the study did not assess the behaviour and attitude of healthcare workers in KNH. Further research needs to be done in order to compare the actual practice with knowledge as well as the workers' attitude and behaviour of handling cytotoxic drugs.

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APPENDICES

Appendix 1: Consent Form

Title of the study: Assessment of Knowledge and Practice of Safe Handling of Cytotoxic Drugs among Healthcare Workers at Kenyatta National Hospital.

Investigator: Dr. Yaakub Abdulhamid Sheikh.

Institution: Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi, P.O BOX 30197-00400, Nairobi. Tel: 0202119317

Ethical Approval: This study will be done only after approval from the Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee, P.O Box 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102

Introduction

My name is Dr. Yaakub A. Sheikh. I am a postgraduate student in the Department of Pharmaceutics and Pharmacy Practice, University of Nairobi. I am pursuing a degree of Master of Pharmacy in Clinical Pharmacy. I am conducting a study on Assessment of Knowledge and Practice of Safe Handling of Cytotoxic Drugs among Healthcare Workers at Kenyatta National Hospital. Permission is requested from you to enroll in this medical research study.

Objective of the study

The objective of this study is to assess your knowledge and practice on safe handling of cytotoxic drugs.

Procedure

With your consent, I will provide you with a questionnaire to assess your knowledge and practice on safe handling of cytotoxic drugs. The questionnaire is composed of 4 sections; socio-demographic data, knowledge, practice and challenges. You will be required to completely fill all sections of the questionnaire applicable to you. All information provided will be handled with strict confidentiality.

The information will then be analyzed by the principal investigator and the results will be presented to the University of Nairobi as part of the requirements for the award of degree of Master of Pharmacy in Clinical Pharmacy.

On completion of this study, all the data collected (hard copies) will be kept under lock and key in a cabinet in the lead investigator's office for confidentiality for a period of 5 years and then shredded after this period. Data available on soft copy will be kept in a password protected database for confidentiality and shall be deleted after the same period.

Benefits

You may not benefit from this study immediately but the results obtained will aid policy makers and the management of KNH to improve healthcare workers knowledge and practice of safe handling of cytotoxic drugs in the hospital.

Risks

There will be no risks involved during your participation in this study.

Voluntarism

Your inclusion in this study is purely at your own free will and you have a right to decline to participate without any consequences or penalty. If you agree to participate in the study, you are still free to withdraw at any point for whatever reason without any consequences or penalties.

Assurance of confidentiality

All information obtained from you will be kept in confidence. At no point will your name or any identifying information be mentioned or used during data handling or in any resulting publications. Codes will be used instead.

Contacts:

In case you need to contact me, the supervisors or the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee concerning this study please feel free to use the contacts provided below.

1. Principal Investigator: Dr. Yaakub Abdulhamid Sheikh, Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi, P.O. Box 19676-00400, Nairobi. Mobile Number: 0721777986
2. Supervisors:
   i. Dr. P. N. Karimi, Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi, P.O. Box 19676-00202, Nairobi. Tel: 0202119217
   ii. Dr. D.G Nyamu, Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi. P.O. Box 19676-00202, Nairobi. Tel: 0202119217
   iii. Dr I. W. Weru, Department of Pharmacy, KNH. P.O. Box 2073-00202, Nairobi. Tel: 0202726300 – 9 Ext 44365.

3. Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee, P.O Box 20723-00100 Nairobi, Tel: 2726300/2726450 Ext: 44102.

After you have read the explanation above, please feel free to ask any questions that will enable you to understand the nature of this study clearly.

I now kindly request you to sign the consent form below.

Consent Form

I hereby voluntarily agree to participate in the study as explained to me by Dr. Yaakub Abdulhamid Sheikh. My signature is a confirmation that I have understood the nature of the study and whatever information that I give will remain confidential and my identity will not be revealed in this study.

I also confirm that no monetary or material gains have been promised or given to me for participating in the study.

Signed: ……..…… Date:……

I have explained the nature and purpose of this study to the above study participant and have sought his/her understanding for informed consent.

Signature of principal investigator: …….……Date:……..…

Appendix 2: Data Collection Form

For The Study "Assessment of Knowledge and Practice of Safe Handling of Cytotoxic Drugs among Health care Workers at Kenyatta National Hospital"

Serial No.:…….. **Date**:…….

Instructions:

1. Kindly read each question carefully.

2. Clearly mark your responses (**Tick where appropriate**) from the options provided.

Section 1: Socio-demographic Data

1. Age (Years)……
2. Gender: Male [ ] Female [ ]
3. Marital status:
   A. Single [ ] B. Married [ ] C. Divorced [ ] D. Widowed [ ] E. Separated [ ]
4. Highest level of Education:
   A. Master's degree [ ] B. Bachelor's degree [ ] C. Diploma Certificate [ ]
   D. Secondary Certificate [ ] E. Primary certificate [ ]
5. Cadre:
   A. Medical Officer Registrar [ ] B. Pharmacist [ ] C. Nurse [ ]
   D. Pharmaceutical Technologist [ ] E. Supply chain officer [ ] F. Cleaner [ ]
6. Department:
   A. Medical [ ] B. Pediatric [ ] C. Gynecology [ ]
   D. Pharmacy [ ] E. Medical Stores [ ] F. Cleaning [ ]
7. Years of experience in handling cytotoxic drugs:
   A. Less than 1 year [ ] B. 1 to 3 years [ ] C. 3 to 5 years [ ] D. > 5 years [ ]
8. Have you received any formal training on safe handling of cytotoxic drugs?
   A. Yes [ ] B. No [ ]
9. If you answered yes in question 8 above, which formal training on safe handling of cytotoxic drugs did you receive?
   A. University [ ] B. College [ ] C. Workshop [ ] D. Other [ ]
10. If you answered yes in question 8 above, when did you receive your last training?
    A. Less than 12 months ago [ ] B. More than 12 months ago [ ]

Section 2: Knowledge on Safe Handling of Cytotoxic drugs

Circle one answer to each of the following statements about safe handling of cytotoxic drugs.

Question	True	False	Don't Know
1. Gloves should be worn when handling cytotoxic drugs	1	2	3
2. All types of gloves provide the same level of protection when handling cytotoxic drugs	1	2	3
3. A surgical mask provides protection from cytotoxic aerosols	1	2	3
4. Hands should be washed before and after handling cytotoxic drugs	1	2	3
5. A disposable safety gown for handling cytotoxic drugs can be re-worn	1	2	3
6. Cleaning of cytotoxic spills should be done by trained personnel only	1	2	3
7. Safe handling of cytotoxic drugs is important because it protects health care workers from hazardous drug exposure	1	2	3
8. Safe handling of cytotoxic drugs is important because it protects the environment from hazardous materials	1	2	3
9. Safe handling of cytotoxic drugs is important because it protects patients from hazardous drug exposure	1	2	3
10. Safe handling of cytotoxic drugs is important because it protects the community from hazardous drug exposure	1	2	3

To be completed by the Lead Investigator:

Score: Adequate [ ] Inadequate [ ]

Section 3: Practice on Safe Handling of cytotoxic drugs.

Section 3.1: Receiving and Storage of Cytotoxic Drugs

Are you responsible for receiving cytotoxic drugs?

Yes [ ] No [ ]

If you answered "No" **proceed to section 3.2**

Complete this section ONLY if you are responsible for receiving and storage of cytotoxic drugs

1. Do you wear personal protective equipment (PPE) when receiving cytotoxic drugs?
   Yes [ ] No [ ]
2. If you answered 'Yes' in question 2 above, which PPE do you wear?
   Tick the appropriate answer(s)
   Gown [ ] Gloves [ ] Goggles / Face shield [ ] Mask [ ] Head cover [ ]
3. Do you segregate other medicines from cytotoxic drugs during storage?
   Yes [ ] No [ ]
4. Do you wash your hands after handling cytotoxic drugs?
   Yes [ ] No [ ]
5. Do you label cytotoxic drugs with a product identifier and hazard statement / signal word? Yes [ ] No [ ]

Section 3.2: Preparation/Compounding of Cytotoxic Drugs

Are you responsible for preparation / compounding of cytotoxic drugs?

Yes [ ] No [ ]

If you answered "No" **proceed to section 3.3**

Complete this section ONLY if you are responsible of preparation/compounding of cytotoxic drugs.

1. Do you reconstitute cytotoxic drugs in a designated room?
   Yes [ ] No [ ]
2. Do you wear PPE when preparing cytotoxic drugs?
   Yes [ ] No [ ]
3. Do you prepare cytotoxic drugs in a biological safety cabinet?
   Yes [ ] No [ ]
4. Do you wash your hands before wearing PPE?
   Yes [ ] No [ ]
5. Do you wipe vials or ampoules after removing the outer packaging material before reconstitution?
   Yes [ ] No [ ]
6. Do you use a dedicated tablet counter for counting cytotoxic tablets?
   Yes [ ] No [ ]
7. Do you change your gloves every 30 minutes when reconstituting cytotoxic drugs?
   Yes [ ] No [ ]
8. When handling cytotoxic drugs, do you change torn gloves immediately?
   Yes [ ] No [ ]

Section 3.3: Administration of Cytotoxic drugs to Cancer Patients

Are you responsible for administration of cytotoxic drugs and nursing of cancer patients?

Yes [ ] No [ ]

If you answered "No" **proceed to section 3.4**

Complete this section ONLY if you are responsible of administration of cytotoxic drugs

1. Do you wear PPE when administering cytotoxic drugs?

Yes [ ] No [ ]

2. If you answered 'Yes' in question 1 above, which PPE do you wear?

Type of PPE	Yes	No
Gown		
Gloves		
Goggles / face shield		
Surgical mask		
N95 mask		
Head cover		
Over shoes		

3. Do you wear PPE when removing the infusion system used for cytotoxic administration?

Yes [ ] No [ ]

4. If you answered 'Yes' in question 3 above, which PPE do you wear?

Type of PPE	Yes	No
Gown		
Gloves		
Goggles / face shield		
Surgical mask		
N95 mask		
Head cover		
Over shoes		

5. Do you wear PPE when handling excreta from a cancer patient who is receiving cytotoxic drugs? Yes [ ] No [ ]
6. Do you re-use PPE used during the previous day's work?
   Yes [ ] No [ ]
7. Do you wash your hands with soap and water immediately after removing PPE?
   Yes [ ] No [ ]
8. Do you touch cytotoxic tablets with bear hands? Yes [ ] No [ ]

Section 3.4: Cleaning of Cytotoxic preparation area and/or Cytotoxic Spills

Are you responsible for cleaning of the cytotoxic preparation area and cytotoxic spills? Yes [ ] No [ ]

If you answered "No" **proceed to section 3.5**

Complete this section ONLY if you are responsible for cleaning of the cytotoxic preparation area and/or cytotoxic spills.

1. Do you have a cytotoxic spill kit available?
   Yes [ ] No [ ]
2. Do you wear PPE when cleaning cytotoxic spills / cytotoxic preparation area?
   Yes [ ] No [ ]
3. If you answered 'Yes' in question 3 above, which PPE do you wear?
   Tick the appropriate answer(s)

Type of PPE	Yes	No
Gown		
Gloves		
Goggles / face shield		
Surgical mask		
N95 mask		
Head cover		
Over shoes		

4. Do you clearly demarcate the area of cytotoxic spill before cleaning?
   Yes [ ] No [ ]
5. Do you begin cleaning from outside the spill area gradually towards the center?
   Yes [ ] No [ ]
6. Do you use cleaning reagents when cleaning the cytotoxic preparation area?
   Yes [ ] No [ ]

7. If you answered 'Yes' in question 7 above, which reagents do you use?

Type of reagent	Yes	No
Sodium thiosulphate		
Sodium hypochlorite		
Powdered soap		
Isopropyl alcohol		

8. Do you wash your hands with soap and water immediately after cleaning cytotoxic spills?

Yes [ ] No [ ]

Section 3.5: Disposal of Cytotoxic Drug Waste

Are you responsible for disposal of cytotoxic drug waste?

Yes [ ] No [ ]

Complete this section ONLY if you are responsible for the disposal of cytotoxic drug waste.

1. Do you wear PPE when disposing cytotoxic drugs?

   Yes [ ] No [ ]

2. If you answered 'Yes' in question 1 above, which PPE do you wear?

   Tick the appropriate answer(s)

Type of PPE	Yes	No
Gown		
Gloves		
Goggles / face shield		
Surgical mask		
N95 mask		
Head cover		
Over shoes		

3. Do you segregate cytotoxic waste before disposal?

   Yes [ ] No [ ]

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

   Yes [ ] No [ ]

5. Do you incinerate cytotoxic waste in a facility approved by the environmental protection

authority for the destruction of cytotoxic waste?

Yes [ ] No [ ]

6. Do you dispose sharps in a sharps container?

Yes [ ] No [ ]

To be completed by the Lead Investigator:

Total Score: Good [ ] Fair [ ] Poor [ ]

Section 4: Challenges in safe handling of cytotoxic drugs

1. Which challenges prevent you from handling cytotoxic drugs safely?

Tick the appropriate answer(s)

A. Low workload [ ] B. High workload [ ] C. Availability of PPE [ ]

D. Lack of knowledge [ ] E. Comfort ability of PPE [ ] F. Others [ ]

If 'Others', please specify:

……

……

Appendix 3: KNH Guidelines on Handling Cytotoxic Drugs

KENYATTA NATIONAL HOSPITAL	SOP/KNH/PHARM/001 REVISION:01 PHARMACY

DISPENSING AND HANDLING OF CYTOTOXIC DRUGS

Authorized by: Dr. T. B. Menge
Head of Department

Issued by: D.R. WATA DAVID
Process Owner

Signature: TBMenge

Signature:

Date: 01/09/2014

Date: 1/9/2014

Copy No.: 1 Copy Holder: Chief Pharmacist CONTROLLED

1. **Scope**
   This procedure covers handling cytotoxic drugs at KNH.

2. **Purpose**
   This procedure will provide guidelines for handling and dispensing of cytotoxic drugs at KNH.

3. **Terms & Definitions**

3.1 **Generic Name:** International Non-Proprietary Name INN) of medicines as recommended for international use by the World Health Organization or as listed in the KNH Formulary List

3.2 **KNH 253:** Drug & Revenue Register

3.3 **KNH:** Kenyatta National Hospital

4. **Responsibilities**
   The chief pharmacist shall ensure that the procedure is implemented.

5. **Method**

5.1 **Dispensing Cytotoxic Medicines to Inpatients**

NOTE:

- Inpatients can receive both injectable and oral cytotoxic medicines from the pharmacy.
- All packages containing cytotoxic agents must have a visibly clear warning on the label.
- Tablets must be handled with powder free latex gloves on a dedicated cytotoxic drug tablet counter.
- A plastic bag shall be used if tablets need to be broken.
- Counted tablets shall be packed separately from other medicines.
- New stock for oral cytotoxic medicine shall be issued when the balance left is for 3 days or less.

5.2 Issues per patient

The designated pharmacist or pharmaceutical technologist shall:

- Receive an appropriately signed S11, patient's treatment sheet, medical record file and non – schedule form from the ward nurse.
- Confirm that all documents are in order.
- Confirm the regimen and dosages are correct and that the patient is adequately prepared to receive chemotherapy. If either is not correct, then a comment is written in the file for correction to be done.
- Control on the S11 the correct amount of medicines needed for one complete course according to the dosage and the regimen.
- Charge, record and issue the medicines in the HMIS.
- Retrieve and label the medicines appropriately. Pack Medicines separately for different patients.
- Issue the medicines and ensure S11 is appropriately signed by the receiving nurse.

5.3 Guidelines for Dispensing Cytotoxic Medicines to Outpatients

Cautions

- All packages containing cytotoxic agents must have a visibly clear warning on the label.
- Tablets must be handled with powder free latex gloves on a dedicated tablet counter.
- A plastic bag shall be used if tablets need to be broken.
- Counted tablets shall be packed separately.
- Cytotoxic medicines shall be stored at the appropriate conditions.
- Safety measures must be adhered to at all times when handling cytotoxic medicines.

5.4 Dispensing oral/Injectable cytotoxic medicines to outpatients

The designated pharmacist or pharmaceutical technologist shall:

- Receive the prescription and receipt after payment and enter details in the designated cytotoxic medicine register. If the prescription requires correction, then a comment is written on the prescription for the prescriber to correct.
- Retrieve the medicines from the store, pack, label and dispense appropriately.
- For injectable cytotoxic drugs, the drugs shall be kept in the chemotherapy preparation room until the time when they shall be reconstituted for administration.
- Call the patient using all names and counsel him/her on how to use the medicine for oral medicines. For injectable medicines, the drugs shall be prepared and given to the patients in the chemotherapy administration room by the doctors and nurses.
- Confirm that new patients understand what the medicine is for and the full course of treatment. If not sure, refer to the oncology pharmacist(s) for further counseling.
- For a new prescription, if it is for more than 1 month, retain the duplicate and give the patient the original. If the prescription has been dispensed in full, then retain both the duplicate and the original prescription.

5.5 GUIDELINE FOR SAFE HANDLING OF CYTOTOXIC MEDICINES

5.6 Safe handling during reconstitution of cytotoxics

- Reconstitution shall take place in the designated rooms in the ward/ clinic (preferably in a biological safety cabinet).
- Protective gear shall be worn.
- Gloves shall be changed every 30 minutes. In case of visible contamination, gloves shall be changed immediately
- Ventilation slots shall be left uncovered
- After finishing work, the work surface shall be cleaned with water and afterwards with 70% alcohol.

- Containers for in-house transport shall be labeled.
- After completing procedure, and removing protective equipment, staff shall thoroughly wash hands and face.

5.7 **Safe handling during administration of cytotoxics and nursing of patients receiving cytotoxics**

- Liquid proof and powder-free nitrile protective gloves and liquid proof disposable gown shall be worn. The skin shall be covered completely. Facemasks shall be worn.
- Swab or cotton pad shall be used when injecting into a cytotoxic drug solution
- . After administration, the bottle and the infusion system shall be disposed as units (do not remove infusion system from the bottle and do not break it off) contaminated linen shall immediately be put into the laundry bag
- Protective clothing shall be worn when handling excreta

5.8 **Safe handling of orally administered cytotoxic drugs**

- All packages containing cytotoxic drugs shall carry clearly visible warning label
- Powder free gloves shall be worn while counting tablets
- Whenever possible, blister packed tablets / capsules shall be procured by the hospital.
- A dedicated counting tray and disposable tongue depressor shall be used when counting loose cytotoxic tablets / capsules.
- When tablets have to be broken, a plastic bag shall be used.
- Counted tablets shall be placed in a separately labeled dosage box.
- Do not touch tablets/ capsules with bare hands.

5.9 **Handling spillages**

- After spillage of cytotoxic drugs, the contaminated area shall be isolated and cleaned immediately
- Liquid proof gloves and gown, over shoes, mask and safety goggles shall be worn during the cleaning a spill kit shall be used.
- Spilled substances shall be soaked with sufficient quantities of absorbent material; avoid dust raising and aerosol production. If product is dry, cover with paper towel or similar disposable material and spray with water. Do not spray water directly or attempt to collect or sweep up the dry product as this could result in dust formation and possibility of inhalation
- For liquid or solution, the spillage shall be absorbed with paper towel or other suitable disposable material contamination of shoes and clothing shall be avoided
- The spill kit shall be replaced immediately after use

5.10 **Storage of cytotoxic medicines**

- All wards/ clinics where cytotoxic medicines are in use, pharmacies designated to stock cytotoxic medicines and the drug store shall have designated areas for storing cytotoxic medicines.
- These designated areas shall have clearly visible labels.
- The refrigerators for storing cytotoxic medicines shall be those that are easy to clean.

- Quantities stored in the user units shall be those dispensed to named patients for immediate use only.
- Medicines no longer required by patients shall be returned to the dispensing unit immediately a change of treatment plan occurs.

5.11 Disposal of cytotoxic medicines

- There shall be a separate plastic bins for disposal of used vials/ampoules/syringes, gloves and packaging material.
- The bin shall be lined with a polythene liner bag which is sealable.
- There shall be sharps container available for disposal of sharps e.g. needles.
- Each receptacle shall be labeled for the waste that it shall contain.
- The staff reconstituting the cytotoxic shall dispose each waste into the correct receptacle.
- If any of the receptacles are filled up to two thirds of the brim then the polythene bag shall be sealed, covered and relabeled and another opened.

6. References

- Guidelines on handling oral cytotoxic medicines - British pharmaceutical journal.
- Preventing occupational exposure to antineoplastic and other hazardous drugs in healthcare settings. Department of Health and Human Services – Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health (NIOSH).
- Safe Handling of Cytotoxics: Standards of Practise - ISOPP

7. Appendices

Appendix 4: Ethical approval from KNH-UON ERC

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C4 JUL 2016

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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/243

4th July 2016

Dr. Yaakub Abdulhamid Sheikh
Reg.No.U56/75024/2014
Dept.of Pharmaceutics and Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Dr. Sheikh

REVISED RESEARCH PROPOSAL: "ASSESSMENT OF KNOWLEDGE AND PRACTICE ON SAFE HANDLING OF CYTOTOXIC DRUGS AMONG HEALTHCARE WORKERS ATKENYATTA NATIONAL HOSPITAL " (P94/02/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above proposal. The approval period is from 4th July 2016 – 3rd July 2017.

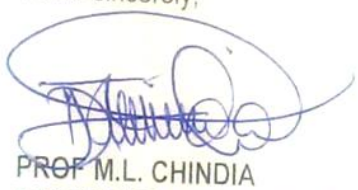
This aporoval is subject to compliance with the following requirements:

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

"Protect to discover"

Yours sincerely,



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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH- UoN ERC
The Dean, School of Pharmacy ,UoN
The Chair, Dept.of Pharmaceutics and Pharmacy Practice, UoN
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