

Evaluation of Handling of Cytotoxic Drugs and Potential Occupational Risk among Health Care Workers in Pediatric Hematology/Oncology Unit

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ABSTRACT

Background: Handling of cytotoxic drugs always raises concerns particularly in preparation and administration of them. Health care workers have been handling these agents in the open areas of wards in the absence of infection control measures. **Objective:** The aim of this study is to evaluate the handling of cytotoxic drugs in pediatric Hematology/Oncology Unit at Tanta University Hospitals and potential exposure risk to cytotoxic drugs and in addition to evaluate hand flora of health care workers (HCWs). **Subjects and methods:** A performance checklist was used to assess the practices of nurses and workers; in addition, hand print was also used to assess hand flora of HCWs on blood and MacConkey agar plate (4clinical pharmacists, 11nurses and 6workers) were included. **Results:** All nurses (100%) did not follow guidelines regarding (patient care, preparation, administration, spill, waste disposal, risk behaviors and excreta management). Concerning risk exposure assessment, only (9.1%) suffered from nausea of unknown cause, (27.3%) from URTIs symptoms and (18.2%) from headache. Decontamination efficacy was evaluated by hand print technique and according to the total bacterial load detected, it was found that 54.5%, 25% and 0% of nurses, clinical pharmacists and workers respectively had excellent performance regarding hand hygiene. Moreover 50%, 25% and 9.1% of workers, clinical pharmacists and nurses had very bad performance of hand hygiene respectively. **Conclusion:** The study clarifies the need of continuous education on handling of cytotoxic drugs (CDs), give more attention to a truth that the cytotoxic agent can be critical to them.

Keywords: Pediatric Hematology/Oncology Unit, Cytotoxic Drugs, Potential Occupational Risks, Infection Control Measures During Handling Cytotoxic Drugs.

INTRODUCTION

Health care associated infections (HCAIs) are defined as those that occur during hospitalization, which weren't present or incubated during patient's admission to the hospital. The time period for identification of a hospital care associated infections is at least 2 days after hospital admission, 3 days after hospital discharge, within 30 days after an operative procedure or one year after surgical implants⁽¹⁾. The different risk factors affecting HCAI rely on the hospital environment, sensitivity of the causative agents, patient susceptibility, and lack of awareness on the presence of these infections amongst staff in a health care setting⁽²⁾.

Pediatric cancer unit (PCU) is a place that aims to gather children with cancer and excluding them from other patients to protect them. A (PCU) has a multiple forms. There is no specific definition of PCU, but generally, this term is used to supply specialized human and non-human resources to coordinate the movement of patients in the pediatric oncology unit. The purpose of PCU is decreasing death associated with cancer by providing early as possible diagnosis; efficient care, reducing death associated with treatment, and minimizing therapy give up. Once patients are diagnosed with cancer and the need to PCU is recognized, experience is built and basic needs to care like access to chemotherapy, safe handling practices are determined to improve pediatric cancer outcomes⁽³⁾.

Pediatrics with malignancy or those who are hematopoietic stem cell transplant (HSCT) recipients are at increased risk for healthcare-associated

infections (HCAI) due to their associated diseases and their protocol of treatment⁽³⁾. In limited resource countries when cancer children are transferred to tertiary hospitals, they are usually admitted with other patients, among cancer adults, or both; places may be congested and/or have low cleaning facilities (few numbers of hand washing sinks, alcohol hand rubs, personal bathrooms, etc.)⁽³⁾.

Without development of standard guidelines procedures during handling of chemotherapy, health care workers and family members will be exposed to potentially toxic substances. In spite of significant advances in health care, infection represents second only to malignancy that cause mortality in pediatric oncology patients, and infection considers a major part of budget associated with treatment⁽³⁾.

Cytotoxic drugs (CDs) are a systemic agent that can kill cancer cells as a palliative or curative. Unfortunately, CDs may also affect normal healthy cells. Frequent and close exposure to these drugs negatively affects the health of HCWs who deal with these agents. Human may be exposed to a drug in its handling stages⁽⁴⁾. Nurses, who are the first line of defense in providing care to patients, are at risk during preparation and administration of CDs. There are several ways of exposure to CDs including respiratory, skin contact and ingestive system⁽⁴⁾.

The Occupational Safety and Health Administration (OSHA) Instructive in the USA enacted rules of preventive measures to follow while the administration of CDs to ensure every one's safety⁽⁵⁾.

The aim of this study is to evaluate the handling of CDs in pediatric hematology/ oncology unit and potential exposure risk to CDs.

SUBJECTS AND METHODS

Study design: This is an observational study

Study setting This study was carried out in governmental Pediatric Hematology Oncology Unit in Tanta University. This study was conducted within time period of 3 months (January, February, and March 2022). In this study 4 clinical pharmacists, 11 nurses and 6 workers were included.

Study tools:

- A performance checklist was used to assess the practices of nurses and workers (6-8), regarding general guidelines in the hospital for handling of cytotoxic drugs, sociodemographic data (age, marital status, education, working duration, training status, and duration of working with CDs), PPEs, drug preparation using aseptic technique, drug administration (apparel, available cytotoxic agent kit, biosafety cabinet, risk behaviors, spill management, patient care, patient excreta handling, waste management and exposure risk including (rash, allergic reaction, abdominal pain, hair loss, nausea, dizziness, skin- or eye-injury, reproductive harm (abortion), upper respiratory tract infection symptoms, headache, sore throat, loss of weight, diarrhea, cough and bronchospasm).
- Hand print of HCWs on blood agar and MacConkey agar plates (for 4 clinical pharmacists, 11 registered nurses, 6 workers) were taken after preparation, administration, and cleaning of CDs(9). The plates were incubated aerobically for 24 hrs. (Blood and MacConkey) at 37°C and estimated for bacterial growth. Colonies were counted and results of cultures were presented as colony forming units (CFUs)/cm². The bacterial colonies were stained by gram stain and examined under the microscope to distinguish Gram positive and Gram negative bacteria. Gram positive cocci were then tested using catalase test to differentiate between bacteria that produce catalase enzyme as staphylococci species and bacteria that does not produce catalase enzyme as streptococcus. Catalase positive Gram positive cocci were isolated and inoculated on mannitol salts agar to further differentiate Staphylococcus aureus (Mannitol fermenting grow as golden yellow colonies) and other coagulase negative staphylococcus (Mannitol non-fermenting grow as pink colonies).

Ethical consent: An approval of the study was obtained from Tanta University Academic and Ethical Committee. Every Nurse signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics

of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

The Statistical Package for Social Science (SPSS) version 24 computer programme and Microsoft Excel were used to conduct the statistical analysis of the data. Qualitative data were presented as frequencies (n) and percentages (%). Reliability of the questionnaire was assessed using Cronbach’s alpha reliability was used to determine correlations between different variables.

RESULTS

Results of the first part (observational checklist):

Sociodemographic data illustrated that out of the eleven nurses participated in this study, 72.7% were in the age between (40-50yrs). All (100%) were married. Regarding educational level 72.7% had secondary school nursing and 27.3% technical institute of nursing. The working duration for all nurses was (10+yrs) and 27.3% of them handled cytotoxic drugs for less than 10 yrs and 72.7% for more than 20 yrs (Table 1).

Table (1) Demographic characteristics of nurses

Characteristics	Sample (N=11)	
	No	%
-Age (years):		
* 20-30	1	9.1%
* 30-40	2	18.2%
* 40-50	8	72.7%
-Marital status:		
* Single	0	0%
* Married	11	100%
-Education:		
*Secondary school of nursing	8	72.7%
*Technical institute of nursing	3	27.3%
*Faculty of nursing	0	0%
-Working duration(years):		
* 1-4	0	0%
* 5-9	0	0%
* 10+yrs	11	100%
-Training program:		
* Received	0	0%
* Not received	11	100%
-Duration in the profession		
* Less than 10yrs	3	27.3%
* 10-20yrs	0	0%
*More than 20yrs	8	72.7%
Total	11	100%

Patient care results showed that all nurses (100%) did not protect the patient skin from their excreta by cleaning with soap; water and applying barrier cream to the perineal area.

Observation for prior administration practices showed that there was no special place for preparation/administration cytotoxic drugs (engineering controls), all nurses did not follow up administration and waste disposal guidelines (100%) except for gathering of equipment required for drug

administration, which was followed by all nurses (100%) (Table 2).

Table (2) Prior administration guidelines steps

Prior to administration	Yes N %	No N %
1. Presence special place for preparation and administration cytotoxic drugs (engineering controls)	0%	11=100%
2. Gather equipment required for drug administration.	11=100%	0%
3. Select appropriate gloves for hazardous drug administration.	0%	11=100%
4. Select appropriate gown for hazardous drug administration.	0%	11=100%
5. Identify conditions when face shield/eye protection is required.	0%	11=100%
6. Locate spill kit and mask.	0%	11=100%
7. Obtain hazardous waste container.	0%	11=100%

Observing administration practices showed that all nurses (100%) did not follow infection control guidelines during administration of different types of cytotoxic drugs administration.

On the other hand, during administration of **IV infusion** all administration guidelines were followed except for placing absorbent pad to protect patient from droplet. While for **IV push** medication all (100%) of the administration guidelines were followed except for wrapping absorbent pad around connection to catch drug splashes (0%).

While for **oral drugs** administration, all administration guidelines were not followed except for avoiding direct handling of oral cytotoxic drugs, nurses use paper or tissue. Lastly for **IM/SC** injection, it was not available in the Department (Table 3).

Table (3) Administration guidelines steps

Administration	Yes (N %)	No (N %)
1. Wash hands and wear gown and gloves before opening delivery bag.	0%	11=100%
2. For IV infusions:	0%	11=100%
• Place absorbent pad to protect patient from droplets.		
• Detach cap from IV tube and attach to patient delivery site.	11=100%	0%
• Firmly locking connections.	11=100%	0%
• When finish, detach IV bag/bottle/tubing intact and recap patient delivery site.	11=100%	0%
3. For IV push medications:	0%	11=100%
• Wrap absorbent pad around connection site to contain drug droplets.		
• Firmly locking connection.	11=100%	0%
• When finish, remove syringe from needleless connection.	11=100%	0%
• Discard syringe and waste in puncture proof safety box.	11=100%	0%
4. For oral drugs:	0%	11=100%
• Don gloves.		
• Avoid direct handling of oral cytotoxic drugs and using paper or tissue	11=100%	0%
• Categorize all oral cytotoxic drug containers with cytotoxic labels and do not smash or break oral cytotoxic drugs for any cause outside of the pharmacy or CDSC	0%	11=100%
• Communicate with the pharmacy if it is necessary to prepare a cytotoxic drug mixture, or if tablets or capsules need to be smashed or broken to deliver the correct dose	0%	11=100%
• Transport tablets and capsules from their main containers directly into a disposable medication cup	0%	11=100%
• Inform the patient to take the tablet or capsule directly from the medication cup, with no handling	0%	11=100%
5. For intramuscular/subcutaneous injections:	Not available	
• Tighten needle to syringe.	Not available	
• Tighten locking connection site.	Not available	
• When finish do not recap needle.	Not available	
• Dispose syringe needle unit in puncture proof safety box.	Not available	
6. Training on different types of cytotoxic drugs administration at safe level.	0%	11=100%

Observation of post administration standards results showed that all guidelines were not followed by all nurses (100%).

In addition, **risk behaviors** observation found that all nurses (100%) performed risk behaviors in the area of handling of cytotoxic drugs as eating, drinking and storing food and beverages.

Also nurses primed the I.V tubing after adding the cytotoxic drugs on the ground and not into absorbent pad or basket, wrote patient and drug name on the container but did not label it as cytotoxic drug, expelled air from syringes filled with cytotoxic drugs, regarding oral route cytotoxic drugs, they put the dose on paper sheet or tissue and not into medication cup, and received medication from pharmacy in plastic sac and not in closed container.

For **excreta management**, it was observed that all guidelines for excreta management were not followed (100%) by all workers.

Results showed that all **waste disposal management** guidelines were not followed by all workers (100%).

Spill management practices observation revealed that all nurses (100%) did not follow up any of guidelines.

For assessing **risk exposure effects**, it was observed that one nurse (9.1%) suffered from nausea, (27.3%) suffered from frequent upper respiratory tract infection symptoms and (18.2%) suffered from headache (Table 4).

Table (4) Risk exposure assessment

Exposure risk assessment	Yes NO%	NO NO%
Rash	0%	11=100%
Allergic reaction	0%	11=100%
Abdominal pain	0%	11=100%
Hair loss	0%	11=100%
Nausea	1=9.1%	10=90.9%
Dizziness	0%	11=100%
Skin-eye injury	0%	11=100%
Reproductive harm(abortion)	0%	11=100%
Upper respiratory tract infection symptoms	3=27.3%	8=72.7%
Headache	2=18.2%	9=81.8%
Sore throat	0=100%	0=100%
Loss of weight	0=100%	0=100%
Diarrhea	0=100%	0=100%
Cough and bronchospasm	0=100%	0=100%

All HCWs (nurses and workers) reported that no training was received on CDs handling preparation, administration, excreta, waste, spill, patient care management.

- ☒ **Results of the second part (Hand print):** All isolated bacteria were either coagulase negative staphylococcus or bacillus spp (100%) with different numbers and neither staph aureus nor Gram negative bacteria were detected. Decontamination efficacy was evaluated by hand print technique and according to the total bacterial load detected, it was found that 54.5%, 25% and 0% of nurses, clinical pharmacists and workers had excellent performance regarding hand hygiene. Moreover 50%, 25% and 9.1% of workers, clinical pharmacists and nurses had very bad performance of hand hygiene respectively (Table 5).

Table (5): Results of hand print of HCWs

HCW No	Evaluation					Total
	Very bad >100cfu No %	Bad (75-100)cfu No %	Good (50-75)cfu No %	Very good (25-50) cfu No %	Excellent (0-25)cfu No %	
Clinical Pharmacists (4)	1 25%	1 25%	0%	1 25%	1 25%	4=19%
Nurses(11)	1 9.1%	3 27.3%	0%	1 9.1%	6 54.5%	11=52.4%
Workers(6)	3 50%	1 16.7%	0%	2 33.3%	0%	6=28.6%
Total	5 23.8%	5 23.8%	0%	4 19%	7 33.4%	21=100%

cfu: Colony forming unit

DISCUSSION

The present study was conducted in pediatric hematology/oncology unit at Tanta University hospitals and aimed to evaluate the handling of cytotoxic drugs, potential exposure risk to cytotoxic drugs and in addition to evaluate hand flora of HCWs. **Regarding training**, all participants did not receive any specific training in oncology unit on handling of CDs. This study was in line with **Zayed et al.**⁽¹⁰⁾, in Tanta Oncology Hospitals, **Mahdy et al.**⁽¹¹⁾, in Ain Shams University, **Bolbol et al.**⁽¹²⁾, in Zagazig University and **Waheida et al.**⁽⁸⁾, in Menoufia Oncology Department who reported that the majority of nurses did not receive any training in Oncology Department on cytotoxic drugs handling and related basic information.

All nurses had satisfactory levels of knowledge but practices score was generally inconvenient and were not adhering the universal standards. Similarly to **Zayed et al.**⁽¹⁰⁾ in Tanta Oncology Hospitals, their study did not find any considerable relation between knowledge and practice or between situation and practice.

This highlights the discrepancy between questionnaire, knowledge and observational study and that knowledge is not a true indicator among HCWs about safety practices within the oncology unit.

Gambrell and Moore⁽¹³⁾, in Greenville Hospital in South Carolina recommended in their study that work team should plan to spend enough time observing work practices in the place and events that may need to follow up. In addition, there were not any **standard guidelines** available in the hospital for handling of cytotoxic drugs. According to the study of **Mahdy et al.**⁽¹¹⁾, all of their nurses (100%) declared that the guidebook is not available in the work place. Despite the presence of these guidelines, several studies found that guidelines are not being universally followed as found by **Boiano et al.**⁽¹⁴⁾, in Ohio. The findings of the present work were contradicted with **Bolbol et al.**⁽¹²⁾, in Oncology Unit in Zagazig University who reported that small number of nurses said that there were rules for procedures for treatment with cancer patients who receive CDs in addition to participation in training during service.

The results of the current study highlight the necessity for giving importance for training of nurses in dealing with CDs to protect them from toxic effects of CDs as all nurses (100%) had bad performance in all CDs **handling stages**. This study observation was in accordance with **Zayed et al.**⁽¹⁰⁾ and **Khan et al.**⁽¹⁵⁾, in tertiary hospital in Pakistan who reported that major number of the nurses had weak performances and not following the international standards for chemotherapy in the three phases including prior administration, administration and after administration before implementation of educational sessions. While, they reported that post accomplishment of educational meetings, the awareness and practices of nurses was

perfect in their study. In accordance with **Burgaz**⁽¹⁶⁾ in Turkey the present study found that all nurses have no knowledge about the risk of contamination of CDs vials or ampoules during preparation of cytotoxic agents.

The present study revealed that all nurses did not use any PPEs as (gown, mask, eye glasses and gloves) due to lack of awareness of protective measures and according to their actual practices they thought that use of gloves will act as a barrier to feel the vein of the patient and also, they supposed that the CDs are not infective agent and not hazardous. This was in accordance to the results study of **Creedon**⁽¹⁷⁾ in Ireland, **Boiano et al.**⁽¹⁴⁾ in Ohio, **Bolbol et al.**⁽¹²⁾, and **Zayed et al.**⁽¹⁰⁾. Similarly to **Mahdy et al.**⁽¹¹⁾ who reported that 78.5% of the surveyed nurses mentioned that they were ignorant of the secure practices for handling of cytotoxic drugs and 60.0% of them considered using of the personal protective equipment unprofitable and disturbs their work, 86.2% of nurses stated that work overload impact their compliance of safe handling behaviors. This study was contrary to **Shahrashi et al.**⁽¹⁸⁾, in Iran who reported that all nurses were utilizing some protective PPE necessary during handling of CDs.

All nurses (100%) were eating, drinking and storing food and drinking beverages in handling area of CDs. All risk behaviors observed in this study were similarly reported by **Mahdy et al.**⁽¹¹⁾, **Elshamy et al.**⁽¹⁹⁾, in Mansoura University, **Bolbol et al.**⁽¹²⁾, and **Turk et al.**⁽²⁰⁾ in Turkey.

The present study detected that during spills related to CDs administration none of the nurses (100%) follow up any of guidelines and all nurses delt with CDs spill as any ordinary spill as they cleaned the surface with chlorine only and sometimes spills were not cleaned up. This may be explained by that there was neither spill kit nor training on spill management. This study was in accordance with **Boiano et al.**⁽¹⁴⁾, and **Polovich and Clark**⁽⁶⁾ in US who reported that spills during administration were not uncommon.

Regarding risk effects, according to the study of **Mahdy et al.**⁽¹¹⁾ (83.1%) of their HCWs complained of hair loss, (76.9%) headache, (63.1%) eye injury, and (61.5%) sore throat, while only (13.8%) complained of miscarriage and (7.7%) congenital anomalies and early birth. The present study showed that low self-esteem, inadequate equipment, work overload, inappropriate place, no sufficient time, crowdedness and dirty unit, and deficiency of knowledge were the main reason for unsafe handling of CDs. Regarding waste handling, this was in accordance with that of **Boiano et al.**⁽¹⁴⁾, in Ohio, who stated that recommended practices regarding waste handling were not followed. As well, **VerStrate**⁽²¹⁾, in Michigan reported that the participants in the study reported a low comprehensive use of safety measures when handling wastes. Furthermore, the present study showed that all guidelines for excreta management were not followed

(100%) by all nurses. Similarly **Waheida et al.** ⁽⁸⁾, reported there was bad use of PPEs among studied nurses when handling patient excreta without using of safety measures. Regarding the findings of hand print of health care workers after (preparation, administration, and cleaning), all isolated bacteria were either coagulase negative staphylococcus or bacillus spp (100%) with different numbers and neither staph aureus nor Gram negative bacteria were detected. Decontamination efficacy was evaluated according to the total bacterial load detected. It was found that 54.5%, 25% and 0% of nurses, clinical pharmacists and workers respectively had excellent performance regarding hand hygiene. Moreover 50%, 25% and 9.1% of workers, clinical pharmacists and nurses had very bad performance of hand hygiene respectively. **Mandel et al.** ⁽⁹⁾ conducted a study in the Hematology Oncology Units in Chandigarh for analyzing the hand hygiene practices in terminology of decontamination efficacy among the care providers (physians, nurses, and their parents or closed relatives) of leukemia children. A total 60 care providers, were chosen to study the priority and adherence to hand hygiene and 316 of fingerprints were sampled from the study participant's hands before and after hand hygiene. Concerning to the decontamination effectiveness it was revealed that, between nurses only 60 % of hand washing led to effective decontamination, Percent less among relatives (37.0%) and physicians (41.2%) were recorded.

CONCLUSION

The present study found that in spite of the knowledge of importance of safe handling of CDs, HCWs practices related to CDs handling preparation, administration, post administration, waste disposal, spill, excreta management and patient care were not according to standard guidelines. Furthermore, this work emphasizes the need for training on all stages of CDs handling in order to improve attitudes of nurses regarding handling of CDs with safe manner. All staff should be fully informed of the potential exposure hazards of CDs.

DECLARATIONS

- **Consent for Publication:** I confirm that the authors accept to submit the manuscript.
- **Availability of data and materials:** All data are available.
- **Competing interests:** None is declared.
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- **Conflict of interests:** No conflict of interest.

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