

Investigation of safety precautions of healthcare workers in handling antineoplastic drugs at King Chulalongkorn Memorial Hospital

Sarunya Hengpraprom*

Nara Kulwanvijit* Wiroj Jiamjarasrangsi*

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- Background** : *Risks associated with occupational healthcare workers (HCW) who handle antineoplastic drugs are well established. Concern about moral and legal issues encourages us to examine HCW compliance with safety precautions throughout their work practices.*
- Objective** : *To examine safety precautions, especially the use of protective equipments among HCW handling antineoplastic drugs at King Chulalongkorn Memorial Hospital.*
- Research design** : *Descriptive study*
- Method** : *Self-administered questionnaires were distributed to 900 HCW in 31 patient's treatment wards and two day-care centers who were highly and daily exposed to the agents. The response rate of participation was 84.7 %.*

- Result** : *Approximately 91 percents of occupational HCW were women, aged between 22-60 years with the mean of 35 \pm 13.9 years. The majority pursued a bachelor degree. The average time of working experience with the agents was 12.7 years (SD = \pm 9.3). Types of personal protective equipments used were in the order of gloves, mask, goggle, and apron, respectively. Boot wearing was negligible in all studies. Higher awareness of primary prevention from exposure was observed in registered nurses and pharmacists than licensed practical, assistant nurses, and custodians.*
- Conclusion** : *The results indicated little attention on safety precautions among ancillary personnel, especially the custodians. Teaching and training on handling these agents should therefore be further performed.*
- Keywords** : *Antineoplastic drugs, Personal protective equipments, Safety precautions.*

Reprint request : Hengpraprom S. Department of Preventive and Social Medicine,
Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand.

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สร้อยยา เสงพระพรหม, นารา กุลวรรณวิจิตร, วิโรจน์ เจียมจรัสรังษี. การสำรวจพฤติกรรม
ความปลอดภัยต่อการสัมผัสยาเคมีบำบัดของบุคลากรทางการแพทย์ โรงพยาบาลจุฬาลงกรณ์.
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- เหตุผลของการทำวิจัย** : ผลกระทบข้างเคียงของยาเคมีบำบัด เป็นภาวะเสี่ยงที่อาจจะเกิดขึ้นได้ในบุคลากรที่ทำงานสัมผัสกับยาเคมีบำบัดมาเป็นเวลานาน พฤติกรรมด้านความปลอดภัยของบุคลากรขณะปฏิบัติงานเป็นสิ่งจำเป็นที่ควรสำรวจและติดตาม เพื่อใช้เป็นข้อมูลเบื้องต้นสำหรับการพัฒนางานทางด้านอาชีวอนามัยของโรงพยาบาล ต่อไป
- วัตถุประสงค์** : เพื่อสำรวจพฤติกรรมด้านความปลอดภัยต่อการสัมผัสยาเคมีบำบัดในบุคลากรทางการแพทย์กลุ่มเสี่ยง โรงพยาบาลจุฬาลงกรณ์
- รูปแบบการศึกษา** : การศึกษาเชิงพรรณนา
- ตัวอย่างและวิธีการศึกษา** : บุคลากรทางการแพทย์กลุ่มเสี่ยง ในแผนกที่ต้องทำงานสัมผัสยาเคมีบำบัด แบ่งตามวิชาชีพ โดยให้ตอบแบบสอบถามด้วยตนเอง มีอัตราตอบแบบสอบถามกลับร้อยละ 84.7
- ผลการศึกษา** : ประมาณร้อยละ 91 ของบุคลากรทางการแพทย์กลุ่มเสี่ยงเป็นเพศหญิงมีอายุในช่วง 22 -60 ปี (เฉลี่ย 35 ± 13.9) ระยะเวลาเฉลี่ยที่ปฏิบัติงานในแผนกที่ต้องสัมผัสกับยาเคมีบำบัดอยู่ที่ 12.7 ± 9.3 ปี เครื่องป้องกันอันตรายส่วนบุคคลที่ บุคลากรใช้ทุกครั้งขณะปฏิบัติงานเรียงลำดับจากมากไปน้อย คือ ถุงมือยาง หน้ากาก แว่นตากันกระเด็น และเสื้อกาวน์ ตามลำดับ โดยเภสัชกรและพยาบาลวิชาชีพ มีความตระหนักถึงการป้องกันตนเองจากภาวะเสี่ยงมากกว่าเจ้าหน้าที่พยาบาล ผู้ช่วยพยาบาล และพนักงานทำความสะอาด
- สรุปผลการศึกษา** : พยาบาลวิชาชีพและเภสัชกรมีความตระหนักถึงผลกระทบข้างเคียงของยาเคมีบำบัดโดยใช้เครื่องป้องกันอันตรายส่วนบุคคลขณะปฏิบัติงาน ยกเว้น ผู้ช่วย และพนักงานทำความสะอาด ดังนั้น การให้ความรู้ การสร้างความตระหนัก และการจัดฝึกอบรมแนวทางการปฏิบัติเกี่ยวกับยาเคมีบำบัด จึงเป็นสิ่งที่ จำเป็นที่ควรดำเนินการต่อไป
- คำสำคัญ** : ยาเคมีบำบัด, เครื่องป้องกันอันตรายส่วนบุคคล, พฤติกรรมความปลอดภัย

Possible long-term health risks such as mutagenic, teratogenic, and carcinogenic effects in healthcare workers handling antineoplastic drugs have been reported by numerous epidemiological studies.⁽¹⁻⁷⁾ The long-term health risks are of particular concern since the quantities of antineoplastic drugs to treat patients associated with cancer have been dramatically increasing. Therefore, the amount of antineoplastics handled per healthcare workers (HCW) is also increasing, but mostly under unimproved working condition.⁽⁸⁾ If personal protective techniques, safety policy, and knowledge on antineoplastics are not well established, occupational HCW exposure to the hazardous drugs is potentially high.

At King Chulalongkorn Memorial Hospital, the guideline of antineoplastic drug management has been developed in 2004 and distributed to the wards responsible for cancer treatment. However, achievement on implementation of this guideline has not yet been investigated, especially in term of safety precautions. We, therefore, examined the safety precautions, focusing on the awareness of protective equipments in use among HCW handling these drugs at King Chulalongkorn Memorial Hospital.

Subjects and Methods

Self-administered questionnaires were distributed to 900 HCW, comprising of pharmacists, registered nurses, licensed practical nurses, assistant nurses, and custodians, handling antineoplastic drugs of 31 wards and two day-care centers at King Chulalongkorn Memorial Hospital. The study population was 900 HCW without sampling. Data was collected during May 9–20, 2005. Subjects' informed consents were acquired before data collection.

Data analysis

Statistical analyses were performed using the Statistical Package for Social Science (SPSS for Windows). Percentage, mean, and standard deviation were calculated to describe the demographic data and safety precautions of HCW during their work.

Results

Seven hundred and sixty three of HCW participated in this investigation with a response rate of 84.7 percent. Almost all subjects were women (~ 91 %; N = 693), aged between 22-60 years with the average of 35 ± 13.9 years. The majority pursued a bachelor degree. The subjects consisted of 40.8 % of registered nurses (N = 311), 24.4 % of assistant nurses (N = 186), 12.5 % of licensed practical nurses (N = 95), 4.9 % of pharmacists (N = 37), 4 % of custodians, and 13.5 % of other (N = 102). The average time of experience associated with antineoplastic drugs was 12.7 years (SD = ± 9.3) and the routine working hour per day was nearly 8 (SD = ± 1.6) (Table 1).

Administrators of 31 patient's treatment wards reporting antineoplastic drugs were mixed and administered at their facilities and two day-care centers were premixing the drugs and distributing to the patient's treatment wards. The guideline for antineoplastic drug management was developed by the chemotherapy committee in 2004 and regulated the use for all oncology units. The 22 out of 33 units (71 %) have implemented this guideline, whereas 5/33 units have not taken it into account. The finding results indicated that more than 70 percent of HCW have not been trained to handle the drugs before their work. Data is not shown.

Table 1. Background Characteristics Data of among Occupational Exposure Dealing with Antineoplastic drugs in King Chulalongkorn Memorial Hospital.

Characteristics	Mean (\pm SD)	No. (%)
Gender		
Female		693 (90.8)
Male		70 (9.2)
Age (yr)	35 (\pm 13.9)	
Education		
Below undergraduate		334 (43.83)
Undergraduate		380 (49.8)
Graduate		49 (6.42)
Job Description		
Pharmacists		37 (4.9)
Registered nurses		311 (40.8)
Licensed practical nurses		95 (12.5)
Assistant nurses		186 (24.4)
Custodians		31 (4.0)
Others		102 (13.5)
Duration of work in present ward (yr)	12.7 (\pm 9.3)	
Having shift works		566 (74.14)
Working hours per day	7.83 (\pm 1.58)	
Working days per week	5	

Few wards restrict the location of drug preparation and many preparation sites were equipped with the effective Biological Safety Cabinet (BSC). Four of the available BSC were a ventilated glovebox/isolator constructed at two day-care centers and 2 out of 31 wards of patient's treatment. The glovebox/isolator is classified as a class III cabinet which is totally enclosed with gas-tight construction under negative pressure. The operations are performed through the attached gloves and all air is filtered by high efficiency particulate air filter (HEPA).⁽⁹⁾ The class

III cabinet provides both operators and product protections.⁽⁹⁾ The rest of the preparation sites (29/31 wards) were equipped with a Class II BSC type A which recalculates approximately 70 % of cabinet air through HEPA filters back into the cabinet and 30 % are discharged through a HEPA filter into the preparation room.⁽⁹⁾ Although the class II type A provides both operator and product protection, its contaminated duct is under positive pressure. Consequently, the risk of HCW to be exposed to the drug's aerosol and/or vapor relatively exists.⁽⁹⁾ Data is not shown.

Pharmacists and registered nurses were responsible for preparing administrations. Their awareness of safety precautions was investigated regarding to care of protective equipments and techniques. The results found that absolutely 100 % of the HCW used gloves and mask whereas greater than 75 % wore goggle and apron. Boot wearing was negligible (Figure 1a).

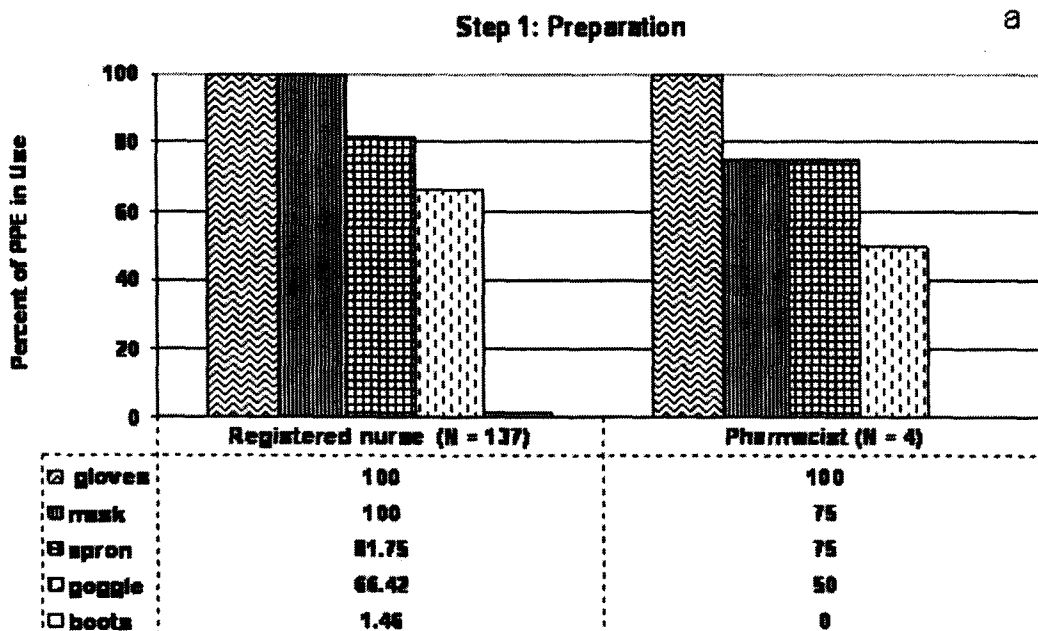
Registered nurses were not only prepared the drugs for administration but also responsible for administering the drugs to the patients via iv line. Therefore, their awareness of safety precautions was investigated. Figure 1b shows that over 60 % of nurses cared of gloves and mask and approximately 25 % of goggle and coat were treated. Boot wearing was also neglect. Except for the boots, the percentage of the PPE in use apparently dropped in comparison with the preparation process.

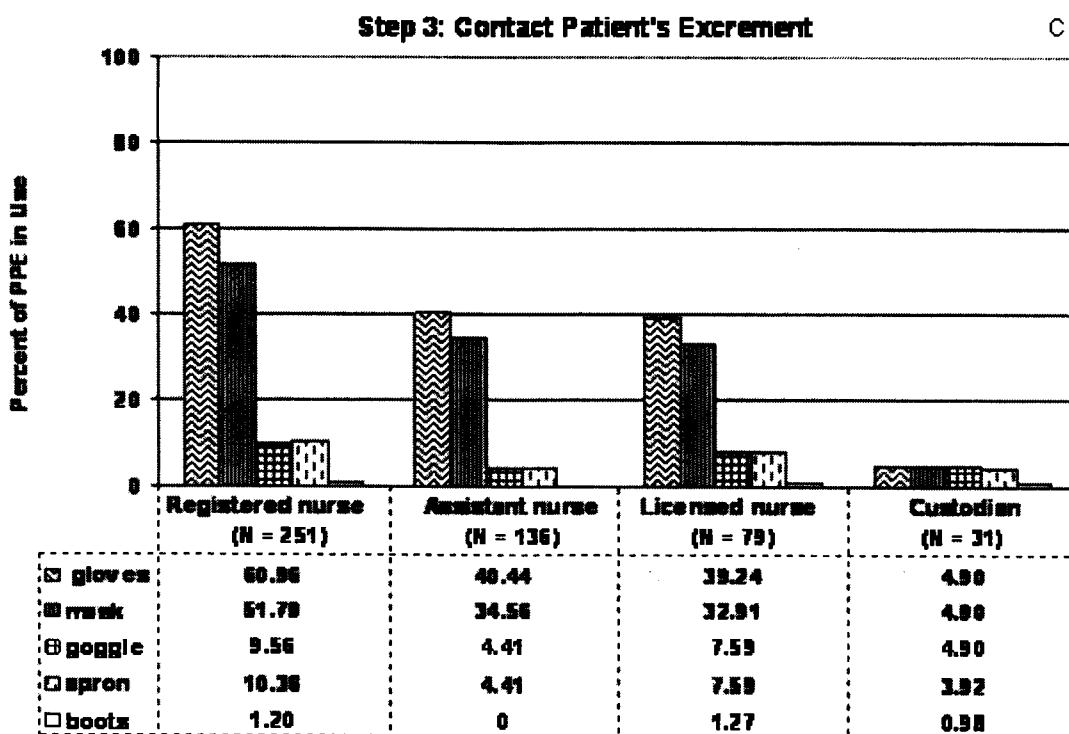
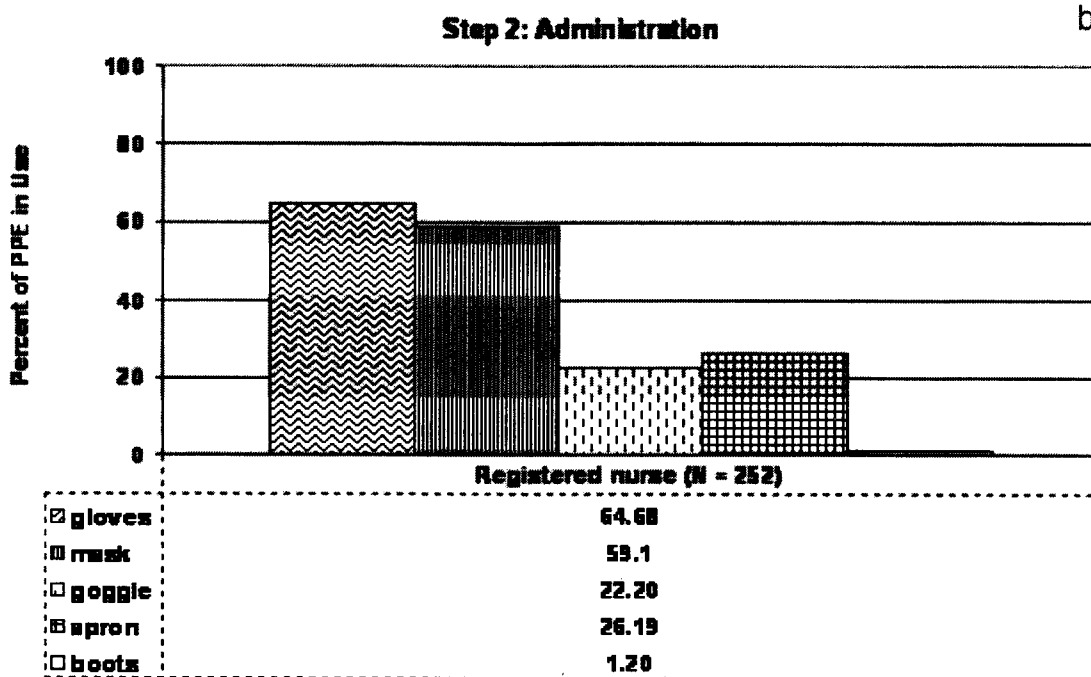
Not only giving the drugs, but nurses also contact with contaminated excrement (urine, feces,

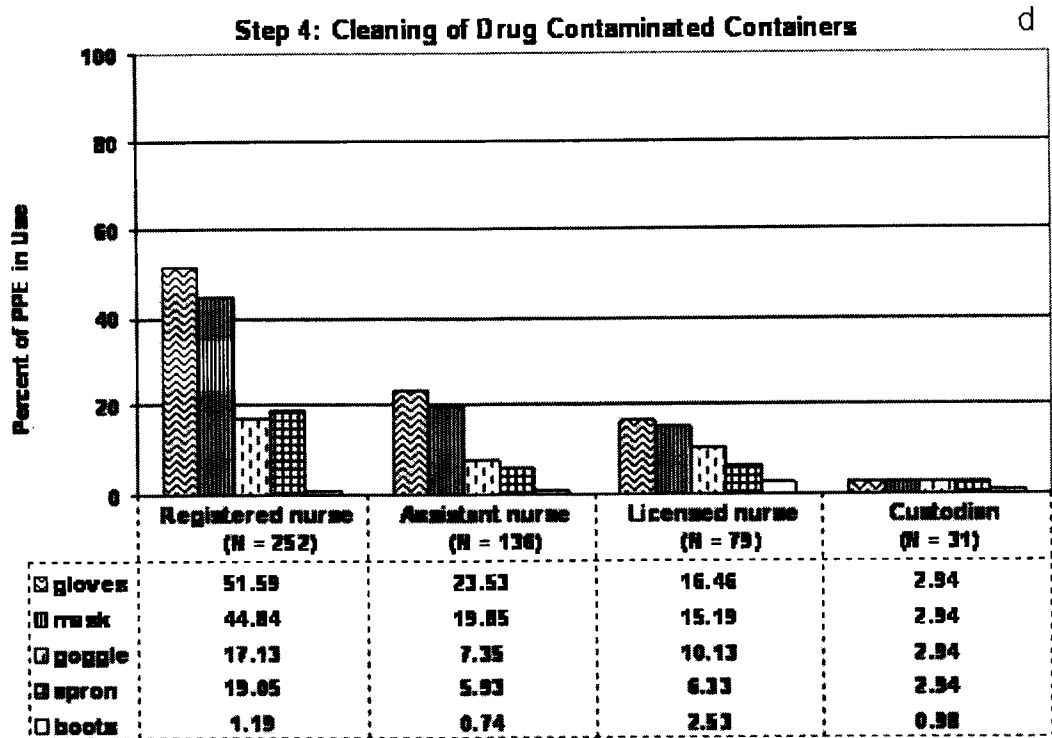
or vomitus) of the treated patients. From figure 1c, we can see that the percentage of registered nurses using PPE was greater than assistant nurses, licensed practical nurses, and custodians, respectively. For registered nurses, application of gloves and mask were relatively consistent with the administration process but apparently lower comparing to the preparation process. It is interesting to note that only 5 % of the custodians (N = 31) were aware of safety precautions while they were on duty.

For cleaning process (Figure 1d), the obtained results were similar to the previous process: 1) the awareness of registered nurses on safety precautions was greater than assistant nurses, licensed practical nurses, and custodians, respectively, and 2) a small number of custodians (3 %) was conscious of safety precautions. Surprisingly, the number of HCW using safety equipments in the process of cleaning contaminated containers was lower than the first three processes mentioned above (Figure 1d).

Figure 1. Use of personal protective equipment.







Discussion

With today's rapid expansion of ambulatory chemotherapy services, the need for specialized instruction in the safe handling of antineoplastic drugs has become increasingly apparent. In the course of their duties, oncology nurses and pharmacists endure daily exposure to toxic agents, which poses a concern for occupational safety. An established procedure manual standardizes work practices for use in the workplaces.

At King Chulalongkorn Memorial Hospital, a guideline for antineoplastic drug management has been developed and implemented in 2004. The implementation existed in the 22/33 of oncology units whereas 5/33 units have not taken into account. The guideline provides medical policies, list of antineoplastic agents currently in use, order sheet for chemotherapy, storage, drug preparation and technique of administration, waste disposals and

cleaning, maintenance and decontamination of hoods, medical surveillance, and prevention of employee exposure. However, this guideline facility was not fully in compliance with the Occupational Safety and Health Administration (OSHA) guideline⁽¹⁰⁾ since the number of exclusion existed. The exclusion such as categorization of drugs as hazardous and evidence supporting the management of antineoplastic drugs as an occupational risk should have been in the document to reflect the scientific knowledge and increase awareness of safety precautions to HCW. Revised and expanded work-practice guidelines are beneficial to limit the exposure of workers to the hazardous drugs.

Although the hospital limited the preparation of antineoplastic drugs only to pharmacists and registered nurses who have been trained in handling of the hazardous drugs, some wards allowed assistants, licensed practical nurses, and physicians

to mix the drugs themselves. Pharmacists had access to the effective ventilation hood and personal protective equipment (PPE), whereas physicians and nurses were least likely to have hood and access to proper equipments. Consequently, they have a relatively high chance of exposure to the hazardous drugs. In contrast to pharmacy personnel, registered nurses frequently prepared the drugs for administration, and in addition, were responsible for administering the drugs to the patients via iv line. As a result, external contamination exposure by nurses was potentially high. Additionally, internal exposure such as skin penetration was another of particular concern.

The potential risks to pharmacists, nurses and physicians from repeated contact with the antineoplastics can be effectively controlled by using a combination of specific containment equipments and certain work techniques. The protective equipments and adequate handling technique protect the skin, respiratory system, and conjunctival of HCW from any contact with the drugs. The use of personal protective equipment at the workplace in the present study was apparent. The common types of PPE used were in the order of gloves, mask, apron, goggle, and boots, respectively. Boot wearing was neglected in all studies. During drug preparation, a variety of manipulations are performed which may result in aerosol generation, spraying, and splattering. Examples of these manipulations include: withdrawal of needles from drug vials; use of syringes and needles or filter straws for drug transfer; opening of ampules; and the expulsion of air from the syringe when measuring the precise volume of the drug. Although the preparation sites at the Oncology Unit, King Chulalongkorn Memorial Hospital, were

constructed with effective BSC, the operators were relatively aware of the safety precautions. Their awareness of safety precautions obtained in this study was satisfied: 100 % in their use of gloves, and roughly 88 % in their use of masks.

During administration, plume of aerosol may be generated while clearing air from a syringe or infusion line and leakage at tubing. The disposal of cytotoxic drugs and trace contaminated vials presents a possible source of exposure to the pharmacists, nurses and physicians as well as to ancillary personnel, especially the custodians. Excreta from patients receiving the antineoplastic therapy may contain high concentrations of the drugs. Every HCW should be aware of this source of potential exposure and should take appropriate precautions to reduce the hazardous uptake and to avoid accidental contact.

The finding results revealed that assistants and licensed practical nurses, when compared with registered nurses, did not differ in their relative frequency of exposure to the antineoplastic drugs. Registered nurses were generally considered to have a higher risk than assistants and thus they were aware of protective measures. Assistants and licensed practical nurses may also have contact with the agents as well, for example by touching patient's excrement and cleaning contaminated vials or laboratory containers. Unfortunately, they applied less protective measures. Custodians were the most vulnerable group who were of particular concern since data in this study showed the smallest percentage of PPE in use (less than 5 %) among them. Little attention to the risk of hazardous exposure among "the vulnerable group" may be attributed to the lack of knowledge and/or training before starting their work.

Our results indicated that more than 70 % of HCW have not been trained to handle antineoplastic drugs. This is in accordance with a study of Ben-Ami et al.⁽³⁾ who reported that HCW's knowledge was significantly correlated with their actual behavior concerning the potential risks of cytotoxic drugs and their use of protective measures ($p < .005$).

Our finding results suggest that awareness of the potential hazards and willingness to address the issue on education and training on dealing with the drugs should be promoted. Improvement may reflect both in increased awareness of potential hazards of staff exposure and reduction of their health problems. Despite the development of guidelines for handling of hazardous drugs, the guidelines at the hospital facilities was not fully in compliance with those of OSHA. Therefore, having a revised and expanded the guidelines at the workplace, and subsequently, submitting the guidelines for professional analysis will improve its efficiency and the quality of life of the HCW.

Various studies reported a remarkable uptake of drugs by pharmacists and nurses, although they had been working under standard safety precautions.⁽¹¹⁻¹⁵⁾ Ensslin et al.⁽¹⁶⁾ found cyclophosphamide (CP) excretion rates ($5.9 \mu\text{g/L}$) in two urine samples out of 13 pharmacists and technicians. All subjects had applied standard safety precautions in that study. Burgaz et al.⁽¹⁷⁾ found CP excretions with a mean of $1.22 (\pm 2.11) \mu\text{g}/24$ hour in urine samples of 20 out of 25 exposed nurses with less application of safety precautions. These accumulated researches on biological uptake of antineoplastics among HCW would be sufficiently convincing to the hospital facility to warrant issuing handling guidelines. It seems

prudent for HCW to follow the guidelines as a minimum standard for protection of themselves. In addition, to improve the hygiene during work, the source of contaminated (environmental monitoring) should be investigated in parallel to biological monitoring. Biomarkers can be used to monitor the benefits of regulations and other policies aimed at reducing exposure of workers.

In summary, appropriate training, utilization of effective equipment and supplies, and strict compliance with detailed policies and procedures provide the best approach to reducing the potential health risks of occupational exposure to hazardous drugs. Our data showed high awareness of pharmacists and registered nurses on their safety precautions but not among the ancillary personnel, especially the custodians. Therefore, education and encouragement on safety behavior among them are of essential for their well-being.

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