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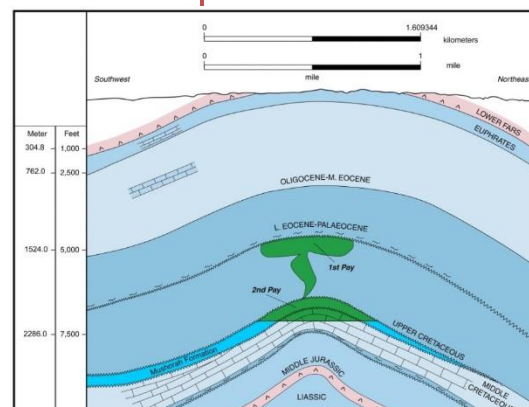
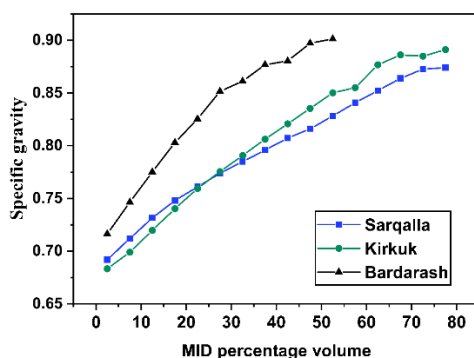
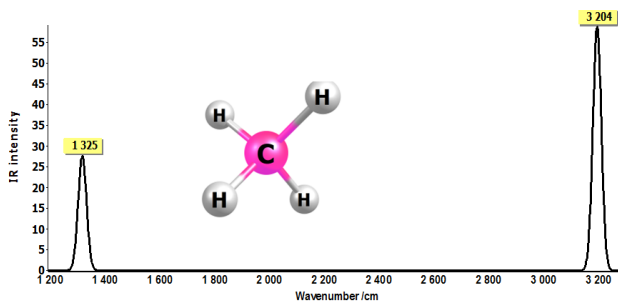
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## **Knowledge, Attitude, and Practice of Nurses About Handling Anti-Neoplastic Drugs at Hiwa Hospital in Sulaimaniyah, Iraq**

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### **Abstract**

**Background:** Anti-neoplastic drugs (ANDs) are a medical therapy utilized to fight cancer. Due to the possible health risks, safe handling and occupational exposure to anti-neoplastic agents have become significant concerns for oncology nursing staff. **Objective:** To assess the knowledge, attitude, and practice of nurses in handling ANDs at Hiwa Hematology/Oncology Hospital in Sulaimaniyah, Iraq. **Materials and methods:** A quantitative-descriptive cross-sectional design was carried out on 91 nurses working in Hiwa Hematology/Oncology Hospital from March to June 2022. A questionnaire was designed and constructed by the researcher. **Results:** The findings of this study showed that the higher percentages level of nurses' knowledge, attitude, and practice was 39.6%, 49.5%, and 51.6%, respectively, which indicated that the majority of participants in that hospital had a fair level of knowledge, attitude, and practice. A significant assertion was found between nurses' level of knowledge, attitude, and practice toward handling ANDs with age, employment status, years of experience in handling ANDs, receiving formal training, number of working hours per week, and exposure to an ANDs side effect. In addition, a highly significant association between nurses' level of knowledge, attitude, and practice toward handling ANDs ( $p=0.000$ ) were found. **Conclusion:** We concluded that most of the sample had fair knowledge, attitude, and practice about handling ANDs, with a highly significant association.

## **Introduction**

Cancer is a class of diseases defined by uncontrolled development and excessive cell proliferation, which, if not controlled, can lead to death [1]. More than 19.3 million new cancer cases were identified worldwide in 2020, which is expected to increase to 28.4 million by 2040 [2].

Anti-neoplastic drugs (ANDs), also known as Chemotherapeutic agents, cytotoxic drugs (CD), and hazard drugs (HD), are medicinal compounds used in the killing of abnormal cells. However, their mechanism is not selective; they do not differentiate cancerous cells from normal cells and act on healthy cells [3- 4]. Anti-neoplastic agents are essential in treating more than 12.1 million cancer patients yearly. These drugs can improve quality of life, reduce illness duration, and cure cancer; the drugs also are used to treat other diseases such as rheumatoid arthritis, nephritis, multiple sclerosis, and lupus [5].

Radiation therapy and surgery are the two most often used forms of treatment for cancer conditions. These two forms of treatment can be combined with anti-neoplastic drugs even though treatment objectives can change depending on the cancer stage, ranging from symptom reduction to medically curative treatment. Nevertheless, anti-neoplastic drugs are medicine's first line of cancer treatment [6].

The role of the oncology nurse continues to expand as the healthcare system develops. Today work in various roles and circumstances that were unheard of ten years ago but are becoming more common. oncology nurses provide long-term cancer patient follow-up care, prescreening before chemotherapy, or general symptom management. In addition, oncology nurses hold various executive positions in cancer hospitals and clinics, including chief executive officers, heads of cancer care lines, and directors of admission facilities [7].

Nurses are among the most vulnerable groups in cancer hospitals to the dangers of ANDs. The preparation and administration of cytotoxic medications and the cleanup of chemotherapy spillage are often the jobs with the highest risk of exposure. Oncology nursing is a sensitive field in which even the most minor carelessness or error can seriously affect patients, staff, and the environment [8].

Healthcare personnel who handle ANDs may be exposed to ANDs through contaminated work surfaces, drug vials and containers, contaminated clothing and hospital instruments, and patient excreta [9]. The main routes of cytotoxic drug exposure include the inhalation of aerosolized droplets, skin absorption, ingestion, and needle stick injury during the process of handling, particularly during preparing, transferring, administering, cleaning up spills, handling patients' excretions, and disposing of wastes [10-11].

Studies have shown that workplace exposure to CDs increases the chance of some potential hazards, including congenital abnormalities, infertility, and abortion [12-14] and Skin or mucus membrane irritation, abdominal pain, vomiting and jaundice, eye irritation, hair loss, sore throat [15-16], and possibly leukemia and other cancers [17].

Organizations such as the National Institute for Occupational Safety and Health (NIOSH), the American Society of Hospital Pharmacists (ASHP), the International Society of Oncology Pharmacy Practitioners (ISOPP), the Oncology Nursing Society (ONS), and the Occupational Safety and Health Administration (OSHA) were involved in developing proper safety guidelines for these drugs in response to this. Therefore, all healthcare personnel related to manufacturing, transportation, distribution, receipt, storage, preparation, administration, and even waste disposal is recommended to follow these worldwide guidelines [18].

Knowledge is necessary for good nursing practice in all healthcare settings, but it becomes even more essential when a nurse's knowledge gap endangers patient or personal safety. According to previous research, ADN's may have unintentionally affected the oncology work environment for more than thirty years. Many oncology nurses may be unaware of the health risks they face when handling ANDs in the oncology environment [19]. In addition, nurses' knowledge and attitude concerning anti-neoplastic drug exposure may impact their adherence to safety protocol, i.e., their behavior or performance when managing ANDs. According to previous research, there was a gap between nurses' knowledge, practice, and attitude while working with ANDs [20].

## **Materials and Methods**

### *Study design*

A quantitative-descriptive cross-sectional design assessed nurses' knowledge, practice, and attitude regarding handling ANDs. The study was carried out in Hiwa Hematology/Oncology Hospital in Sulaimaniyah, Kurdistan Region, Iraq, from March to June 2022.

### *Ethical consideration*

The College of Nursing and College of Medicine at the University of Sulaimani Scientific and Ethical Committees have approved this research protocol and written an official letter to the General Directorate of Health (DOH) in Sulaimaniyah to obtain permission to collect data for the current study at Hiwa Hematology/Oncology Hospital.

### *Patient consent*

After explaining the study's purpose and objectives and ensuring confidentiality, written consent was taken from the nurses. Also, the nurses were free to leave the study whenever they desired.

### *Study setting*

The study was conducted in Hiwa Hematology/Oncology Hospital, the only hospital for handling ANDs, located in the southeastern district of Qrga in Sulaimaniyah, Iraq. The hospital was constructed in 2007 and received patients with cancer and hematological disorders of all ages. It has 142 beds and consists of three floors with 12 departments; Hematology, Oncology, Pediatric, Outpatient, Palliative, Isolation, Emergency, MRI-CT-U/S and X-ray, Chemotherapy preparation, Pharmacy, Laboratory, and Echocardiography. The present study used Hematology, Oncology, Pediatric, and outpatient departments for data collection. All services offered in the hospital are free of charge for every patient. The hospital is receiving patients in whole cities of Iraq, and it has about 2500 to 3500 newly registered cancer cases annually. Moreover, about 500 to 600 patients visit the hospital daily, and about 200 patients receive chemotherapy.

### *Study sample*

A non-probability, convenience sample technique was used for 91 nurses who had regularly linked with their duties at Hiwa Hematology/Oncology Hospital.

### *Inclusion criteria*

All nurses who handle ANDs regardless of gender with work experience of >6 months were enrolled.

### *Exclusion criteria*

Nurses who could not participate in the study.

### *Data collection*

After permission was granted from the hospital managers, the researcher interviewed the nurses before data collection, explaining to them the study's objectives and cooperation to be involved. Consequently, data has been collected through nurse administration by direct interview to fill the structured questionnaire and observation of the nurses to fill the checklist during handling ANDs.

### *Study instrument*

To achieve the study's objective, the researcher developed a questionnaire through an extensive review of international literature and guidelines. The questionnaire is a proper and more convenient technique for data collection, and the data process consists of 4 parts. Part one includes socio-demographic data and professional characteristics (14 items), such as age, gender, residency, economic status, level of education, years of employment, employment status, type of work, and years of experience handling ANDs. Moreover, the place of work received any formal training regarding handling ANDs, many days' work in the department per week, exposed to any side effects of AND's toxicity, while part 2 covers the nurses' knowledge regarding handling ANDs, using personal protective equipment (PPE), and spill management (20 items). Then, part 3 outlines the nurses' attitudes toward handling ANDs, their concerns, and the feelings that they contain (6 items), and part 4 observes nurses' practice before, during, and after handling ANDs in their setting, such as using PPE, handwashing, eating, drinking, in the medication handling areas, and following waste disposal protocol (22 items).

### *Pilot study*

A pilot study was carried out for 10 hospital nurses who worked in Hiwa Cancer Hospital from 3<sup>rd</sup> to 13<sup>th</sup> March 2022. The sample of the pilot study was excluded from the present study sample. Furthermore, the study attempted

to ensure that the instrument's structure is apparent throughout the subject's understanding to, identify the necessary modifications, and determine the average time spent gathering data for each respondent. Also, to improve the validity and reliability of the questionnaire and to identify any obstacles that may occur during data gathering.

*Reliability of the questionnaire*

The reliability of the questionnaire was determined through the Alpha Cronbach. The outcome was 0.919, which indicates that the questionnaire was highly reliable as a tool for data collection.

*Rating scales and scores*

Twenty questions assessed nurses' knowledge, and each response was scored as False and True. The scoring range of the questionnaire was 20 (maximum) to zero (minimum). The scale of knowledge of nurses was classified as good knowledge ( $\geq 75\%$ ) with a score of 15-20, fair knowledge ( $50\% < 75\%$ ) with a score of 10– 14, and poor knowledge ( $< 50\%$ ) with score 0–9.

The attitude of nurses was assessed by six questions focusing on nurses' attitudes regarding handling ANDs. Each response was scored as 'agree, neutral, and disagree; then participants' attitudes scores were calculated. The scoring range of the questionnaire was 12 (maximum) to 0 (minimum). Positive attitudes were marked as 2, while those answered as neutral were marked as 1, and the negative attitudes were marked as 0. The scale of the attitude of nurses was classified as good attitude ( $\geq 75\%$ ) with a score of 9-12, fair attitude ( $50\% < 75\%$ ) with a score of 6–8, and poor attitude ( $< 50\%$ ) with a score of 0–5. Moreover, 22 questions assessed nurses' practice, and each response was scored as Yes or No. The scoring range of the questionnaire was 22 (maximum) to zero (minimum). The scale of the practice of nurses was classified as good practice ( $\geq 75\%$ ) with a score of 17-22, fair practice ( $50\% < 75\%$ ) with a score of 11–16, and poor practice ( $< 50\%$ ) with score 0–10.

**Table 1.** Classification of questions, range, scores, and levels of knowledge, attitude, and practices during handling anti-neoplastic.

Item	Knowledge	Attitude	Practice
Number of questions	20	6	22
Total scores	20	12	22
Range	0 – 20	0-12	0 – 22
Min	0	0	0
Max	20	12	22
Poor ( < 50%)	0-9	0-5	0-10
Fair ( $\leq 50\% - < 75\%$ )	10-14	6-8	11-16
Good ( $\geq 75\%$ )	15-20	9-12	17-22

*Statistical analysis*

SPSS (Version 24.0) was used to analyze the data. The information had been coded, analyzed, and presented descriptively. The questionnaire's reliability was tested using Alpha-alpha Cronbach's test, while inferential data analysis was done using the Chi-square test. P value is considered highly significant ( $P < 0.001$ ), significant ( $P < 0.05$ ), non-significant ( $P > 0.05$ ), and very high significant ( $P < 0.000$ ).

**Results**

Table 2 shows the nurse's socio-demographic characteristics. Most participants were aged between 26–35 years (59.3%), and only 17.6% were >35 years old. Most participants in the study (60.4%) were females, and only 39.6% were males. Among the study participants, 68.1% were from urban and 31.9 % were from suburban residences, 56% were from barely sufficient economic backgrounds, while the sufficient rate was 28.6%, and 15.4% were from insufficient economic backgrounds. Regarding education, most nurses graduated from institutes (54.9%), while 40.7% graduated from Universities. The majority of the years of employment were between 5–10 years (49.5%), while 29.7% were < 5 years, and the minority of the years of employment was more than 20.9%.

**Table 2.** Distribution of the nurses according to their socio-demographic characteristics.

Variable	Frequency	Percentage
<b>Age (Year)</b>		
≤25	21	23.1
26–35	54	59.3
>35	16	17.6
<b>Mean ±SD</b>	30.44 ~ 30 ±6.64	
<b>Gender</b>		
Male	36	39.6
Female	55	60.4
<b>Residency</b>		
Urban	62	68.1
Suburban	29	31.9
<b>Economic status</b>		
Sufficient	26	28.6
Barely sufficient	51	56.0
Insufficient	14	15.4
<b>Level of education</b>		
Preparatory nursing school	4	4.4
Technical diploma	50	54.9
Bachelor	37	40.7
Post-graduate	0	0.0
<b>Years of employment</b>		
<5	27	29.7
5–10	45	49.5
>10	19	20.9
<b>Mean ±SD</b>	7.63 ~ 8 ±5.33	
<b>Total</b>	<b>91</b>	<b>100</b>

In Table 3, most employment statuses were volunteers (49.5%), and only 35.1% were permanent. Most participants (56.0%) had day shift work, and 44.0% were night shift, while 46.2% had 3–6 years of experience in handling ANDs, and also 27.4% of the participants were less than three years of experience in handling ANDs. Moreover, 69.2% of the nurses worked in the inpatient ward, and the rest worked in outpatients. About 50.5% of the participants had received training regarding handling ANDs, and their training course duration was 1-2 days. Moreover, 84.78% attended training courses, 86.96% of their training was done inside the country, and 13.04% were outside. Furthermore, 57.1% of participants worked 30-39 hours in their department each week, and 27.5% worked 20-29 hours. Additionally, most nurses (52.7%) handle ANDs 10-30 times daily, and 25.3% handle ANDs >30 times daily in their setting. Then, 71.4% had been exposed to side effects of AND's toxicity; 32.39 % of the symptoms were redness, itching, and a headache.

Table 4 indicates 20 questions about the nurses' knowledge of handling ANDs, the attitude of nurses (6 questions) on handling ANDs, and the practice of nurses (22 questions) during handling ANDs. Regarding the participants' knowledge about handling ANDs, 39.6% had fair knowledge, 38.4% had good knowledge, and 22% had poor knowledge. Moreover, regarding the participants' attitudes about handling ANDs, 15.4% had a poor attitude,

49.5% had a fair attitude and 35.1% had a good attitude, in addition, regarding the participants' practice, while handling ANDs, 19.8% had poor practice, 51.6% had fair practice, and 28.6% had a good practice.

**Table 3.** Distribution of the sample according to their professional background.

<b>Variable</b>	<b>Frequency</b>	<b>Percentage</b>
<b>Employment status</b>		
Permanent/formal employment	32	35.1
Contract	14	15.4
Volunteer	45	49.5
<b>Type of work</b>		
Day shift	51	56.0
Nightshift	40	44.0
<b>Years of experience in handling ANDs</b>		
<3	25	27.4
3 – 6	42	46.2
7 – 9	12	13.1
>9	12	13.2
<b>Mean ±SD</b>		5.14 ~ 5 ±3.56
<b>Place of work</b>		
Outpatient ward	28	30.8
Inpatient ward	63	69.2
<b>Have you ever received any formal training regarding handling ANDs?</b>		
No	45	49.5
Yes	46	50.5
<b>If yes, duration of the training?</b>		
1-2 days	39	84.78
>2 days	7	15.22
<b>Total</b>	46	100.0
<b>Location</b>		
Inside country	40	86.96
Outside the country	6	13.04
<b>Total</b>	46	100.0
<b>How many hours of work in your department per week?</b>		
20 – 29	25	27.5
30 – 39	52	57.1
> 39	14	15.4
<b>How many ANDs do you handle each day?</b>		
< 10	20	22.0
10 – 30	48	52.7
> 30	23	25.3
<b>Have you ever been exposed to any side effects of AND's toxicity?</b>		
No	26	28.6
Yes	65	71.4
<b>If yes, mention the side effects.</b>		
Abortion	2	2.82
Dermatitis	4	5.63
Respiratory distress	6	8.45
Hair loss	4	5.63
Redness of skin and itching	23	32.40
Dizziness and eyes irritation	8	11.27
Skin rash	4	5.63
Decreased libido	4	5.63
Headache	11	15.50
Nausea and vomiting	5	7.05
<b>Total</b>	71	100.00

**Table 4.** Levels of knowledge, attitude, and practices during handling anti-neoplastic drugs.

Items	Knowledge		Attitude		Practice	
	Fr.	%	Fr.	%	Fr.	%
Levels						
Poor	20	22.0	14	15.4	18	19.8
Fair	36	39.6	45	49.5	47	51.6
Good	35	38.4	32	35.1	26	28.6
Total	91	100.0	91	100.0	91	100.0

Table 5 represents the relationship between nurses' knowledge with their attitude and practice. there is a significant association between nursing knowledge with their attitude (p=0.000) and practice (p=0.000).

**Table 5.** Association between nurses' knowledge, nurses' attitude, and nursing practice.

Items	Nursing knowledge							Significant Test	
	Poor	Fair	Good	Total					
	Fr.	%	Fr.	%	Fr.	%	Fr. (%)		
Nurses' attitude	Poor	10	11.0	3	3.3	1	1.1	14(15.4)	$\chi^2 = 41.779$ P = 0.000
	Fair	9	9.9	25	27.5	11	12.1	45(49.4)	
	Good	1	1.1	8	8.8	23	25.3	32(35.2)	
	Total	20	22.0	36	39.6	35	38.4	91(100.0)	
Nursing Practice	Poor	15	16.5	2	2.2	1	1.1	18(19.8)	$\chi^2 = 87.595$ P = 0.000
	Fair	5	5.5	32	35.2	10	11.0	47(51.6)	
	Good	0	0.0	2	2.2	24	26.4	26(28.6)	
	Total	20	22.0	36	39.6	35	38.5	91(100.0)	

Table 6 shows the correlation between nurses' knowledge, attitudes, and practice. There is a significant positive correlation between nursing knowledge and attitude/practice (p=0.000).

**Table 6.** Correlation between nurses' knowledge and nurses' attitude and nursing practice.

Variables		Nursing attitude	Nursing Practice
Nursing knowledge	Correlation	0.619	0.641
	Sample	91	91
	P-value	0.000	0.000

\*\* Correlation is significant at the 0.05 level (2-tailed); correlation: Spearman rank correlation

## Discussion

The present study's analysis indicates that the highest percentage of nurses' age ranged between 26-35 years, followed by <25 years old groups, which account for nearly one-quarter of the sample. The lowest percentage of the sample ages were >35 years, with a mean of 30.44 ~ 30 ±6.64. These results are consistent with the finding of [21], who found that the mean age was 30.71 years. However, our results disagreed with this study [22] which found that the mean age was 43.39 years. The proportion of females accounts for more than half of the sample,

aligned with [23], who discovered that almost two-thirds of their sample were female. The researchers' perspective is that nursing employment is more acceptable to women.

As Hiwa hospital is located inside Sulaimaniyah city, most of the sample was from urban, and the rest were from suburban. This result disagrees with this study [24], which found that the majority of the sample was rural (51.7%). Furthermore, more than half of the sample was in an intermediate economic state, and approximately one-quarter had a good financial status. The researcher's view regarding the economic level is that about half of the sample were volunteers and received a minimal salary.

Nearly one-third of the sample had a bachelor's degree, and more than half graduated from nursing institutes. It is worth mentioning that only 4.4% of the sample graduated from preparatory nursing. Recently, in Sulaimaniyah city, all primary and preparatory nursing schools were closed, and only the institute and College of Nursing remain. This present study agrees with [25] in that most of their sample had institute degrees (diploma education).

Most of the years of employment were between 5-10 years, and the lowest percentage of the sample was employed for more than 10 years. These findings contradicted [26], who revealed that the average number of years of work was 1–4 years. because the authorities have not hired any new staff in >10 years, many participants were volunteers, with only one-third being permanent. Because most nurses who handle ANDs work day shifts and most patients get chemotherapy during the day, more than half of the nurse's work day shifts. This result agrees with [27] regarding the type of work.

Concerning participants' years of experience, the highest percentage of the sample had experience in handling ANDs ranging from 3-6 years. On the other hand, only one-quarter of the sample had <3 years of experience. This result disagrees with [28] in Egypt. They found that the majority of nurses had an experience of >10 years in oncology. However, this result is consistent with [29] regarding years of experience handling chemotherapeutic agents.

Regarding nurses' workplace, more than one-quarter of the nurses were working in outpatient (male and female), and the rest were inpatients such as the oncology unit, hematology unit, and pediatric ward. This result agrees with [30] in Taiwan that most of their sample worked in inpatient settings. Furthermore, half the sample participated in training courses mainly inside the country. However, this result disagrees with [31], who revealed that only 38.53% of the sample had received some training regarding handling ANDs. This could be due to differences in hospitals' setup and rules and regulations or safety policies on the safe handling of ANDs. Moreover, workshops and other training forums are essential for oncology nurses regarding the safe handling of ANDs in hospitals.

Regarding the number of hours worked per week, most participants worked 30-39 hours per week, and nearly one-third of the sample worked 20-29 hours in their department. However, controversial findings were found by [32], who illustrated that most of the sample worked 39-43 hours per week.

In addition, more than half of the sample handle ANDs daily, ranging 10-30 times per day, mostly during administration, and nearly one-quarter of the sample handle ANDs <10 times. These findings disagree with [33], who revealed that most nurses administer ANDs between 1-10 times per day. The number of handlings ANDs by nurses depends on the unit; the majority of patients at Hiwa Hospital get chemotherapy in female and male outpatient settings, and handling in those departments more often occurs than in other departments.

More than half of the sample got side effects of ANDs toxicity, such as skin rash, eyes irritation, redness and itching skin, respiratory distress, nausea, vomiting, alopecia, decreased libido, headache, dizziness, dermatitis, and abortion were the most commonly experienced symptoms in the current study. In addition, nurses have reported the side effects of ANDs in different studies. This result agrees with three previous studies by [15,34-35], who found the same side effects in their respondents. According to the researcher's opinion, the frequency of symptoms

in the nurses who handle ANDs may be the result of applying insufficient safety precautions. Exposure of health professionals to this thesis type of these drugs depends not only on the number of preparations performed each day but also on individual work practice and the precautions taken in handling these agents [36].

Regarding the nurse's knowledge, 38.4% had good knowledge, 39.5% had fair knowledge, and only 22.0% had poor knowledge. The statements with the correct answers were items 1 (100%), 9(87.1%), 18(96.70%), and 20 (100%), which indicate a good level of knowledge. The statements with the most incorrect answers were items 6(63.74),7(65.93), and item 11(64.84), which indicate a poor level of knowledge. This lack of knowledge on preventive measures is of concern as it increases the health workers' risky behavior. These results contradict this study [37] which found that most respondents had good knowledge of handling ANDs. On the other hand, this study [38] indicated that most respondents had good knowledge about handling ANDs. In contrast, a study done by [39] agreed with our study and found that most of the sample (59.3%) had fair knowledge.

Generally, the analysis revealed that 15.4% of the sample had a poor attitude, 49.5% had a fair attitude, and 35.1% had a good attitude. This study [3] supported these findings; they divided their sample's attitude into low, medium, and high levels and showed that 63.3% had a medium attitude.

Regarding the nurse's practice, 28.6% had good practice, 51.6% had fair practice, and only 19.8% had poor practice. These results disagreed with [31] who found that most of the sample had a good practice (49.54%) and only 16.52% had fair practice. These could be related to the nurses-to-patient ratio and hospital pressure as a result of more cancer patients in recent years,

The nursing society recommends that to provide quality care and maintain safety standards; nurses must be competent in oncology nursing practices and aware of workplace risks. A significant facet of this competency is that nurses must remain educated and regularly engage in standard practical safety guidelines [40].

The study's result showed a significant association between nurses' knowledge level, attitude, and practice toward handling ANDs ( $p < 0.05$ ), and the correlations between them were strong and positive. This means nurses with a good level of knowledge have a positive attitude and good practice; in contrast, nurses with a poor level of knowledge have a negative attitude and poor practice. These results are consistent with [41] who showed a strong positive correlation between knowledge and attitude regarding the safe handling of ANDs ( $p < 0.001$ ). Also, this study [42] demonstrated that the nurse's knowledge about the handling of cytotoxic drugs affects their attitudes and practices of handling cytotoxic drugs in their daily practices.

## **Conclusions**

Most healthcare workers are vulnerable to AND toxicity in health facilities, and the occupational tasks that pose the highest risk of exposure occur during AND handling. Most of the participants were 26-35 years old, male, had diploma degrees, permanent employment, 3-6 years of experience in handling ANDs, lived inside the city, were exposed to side effects, received training regarding handling ANDs, had a fair level knowledge, attitude, and practice and minority had poor level. Significant associations were found between nurses' level of knowledge, attitude, and practice toward handling ANDs with age and employment status.

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## Conflict of interest

The authors declare that there is no conflict of interest in this study.

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