



Effect of Implementing Educational Guidelines on Nurses' Knowledge and Practices for Safe Administration of Immunoglobulin Therapy

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Abstract

Background:

Immunoglobulin is a pooled antibody, and a biological agent used to manage various immunodeficiency states, that require an advanced standardized clinical practice of well trained nurses to ensure safe administration of the therapy. **Aim:** Evaluate the effect of implementing educational guidelines on nurses' knowledge and practice for safe immunoglobulin administration. **Research Design:** Quasi-experimental design. **Setting:** Internal Medicine Hospital of Tanta University (departments: Internal Medicine ICU, Rheumatology, Hematology, and Endocrine). **Subject:** A convenient sample of 47 nurses recruited from the previous departments. **Tools:** Three tools were used; Nurses' Interview Questionnaire, an Observational Checklist for Standard Practice of Administering Immunoglobulin Therapy, and Nurses' Adherence to Safe Injection Practice of Administering Immunoglobulin Replacement Therapy. **Results:** There was a significant improvement in the mean scores of nurses' overall knowledge and practice of immunoglobulin administration with improved safe nurses' adherence to immunoglobulin therapy after implementing the educational guidelines. There was also a significant positive association between demographic characteristics and overall level of knowledge and practice in safe administration of immunoglobulin therapy. **Conclusion:** Implementation of the educational guidelines has positive effects in improving nurses' knowledge and safe practice of immunoglobulin administration. **Recommendation:** It is recommended that nurses attend continuous in-service training programs especially in complex therapies to improve their knowledge and enhance safe practice of immunoglobulin therapy considering the demographic influences of the nurses and using diverse teaching and training methods.

Key words: Educational Guidelines, Immunoglobulin Therapy, Nurses Knowledge and Practice, Safety Practices.

Introduction

The infusion therapy standards of practice provide evidence-based recommendations for infusion and access device related care in any healthcare setting. The standards have increased the frequency of the revision process from an every 5-year cycle to a 3-year cycle due to the growing base of literature and to deliver the most updated and current practice recommendations (Gorski, 2024). Immunoglobulin (Igs), or antibodies, are glycoprotein molecules produced by plasma cells, a type of white blood cells which are vital component of the immune system, playing a critical role in recognizing, binding, and neutralizing foreign substances, such as bacteria, viruses and toxins. This neutralizing ability helps protect the body from infection and disease (Abbas & Lichtman, 2022).



Immunoglobulin is classified into five main classes: IgG, IgA, IgM, IgE, and IgD. Each class has unique structural and functional properties that contribute to their diverse roles in the immune response (**Janeway et al., 2023**). IgG; the most abundant immunoglobulin class, accounts for approximately 70-80% of the total serum immunoglobulin concentration. It is the primary antibody involved in long-term immunity, providing protection against reinfection with previously encountered pathogens. IgA: The second most abundant immunoglobulin class is primarily found in mucosal secretions, such as saliva, tears, and breast milk, where it plays a crucial role in protecting the body from pathogens entering through these routes. IgM; The first immunoglobulin class produced in response to an infection, and plays a critical role in the early stages of the immune response, providing nonspecific protection until more specific antibodies are produced. IgE; is involved in allergic reactions, mediating the release of histamine and other inflammatory mediators from mast cells and basophils. It is also involved in defense against parasitic infections. IgD; The least abundant immunoglobulin class, which is primarily expressed on the surface of B cells and plays a role in B cell activation and differentiation (**Abbas & Lichtman, 2022**).

Immunoglobulin administration is a crucial medical intervention used to prevent, treat a wide range of infectious diseases and maintaining a healthy immune system. While the aim of educational guidelines should have to be developed as it enhances nurses' knowledge and performance regarding immunoglobulin administration. Their complex and diverse roles have made them valuable tools in medical diagnosis, treatment, and prevention (**El-Nabarawy et al., 2020 and Owen et al., 2022**). Also, IG is a critical aspect of patient care, particularly for individuals with immunodeficiency disorders or those requiring passive immunity. Ensuring the safe and effective administration of immunoglobulin is essential to prevent adverse reactions and optimize patient outcomes. While immunoglobulin is generally safe and effective, improper administration can lead to adverse reactions and compromise patient safety. Therefore, it is crucial for healthcare providers to adhere to strict safety practices during immunoglobulin administration (**American Society of Hematology "ASH", 2022**). While most patients tolerate IG replacement therapy well, IVIG can have side effects. With IVIG, up to half of all patients experience at least one adverse side effect such as headache, low-grade fever, aching muscles or joints and rashes. These are especially likely to occur if patients are not receiving IVIG on a regular basis and/or if they are receiving higher doses of IVIG (**Silvergleid, 2019**).

Several key safety principles should be followed when administering immunoglobulin: Patient Selection and Preparation by way of careful patient selection is essential to ensure that immunoglobulin administration is appropriate, safe and it depend on medical team physicians. Patients with a history of allergic reactions to immunoglobulin or their components should be carefully evaluated and managed. Premedication with antihistamines or corticosteroids may be necessary in some cases. Proper handling and preparation of immunoglobulin products are critical to prevent contamination and ensure product integrity. Immunoglobulins should be stored and transported according to manufacturer's instructions and prepared under aseptic conditions (**Centers for Disease Control and Prevention "CDC", 2022**).

Immunoglobulin is a biological preparation of pooled human immunoglobulin derived from a large number of human donors. In practice, administration of immunoglobulin is associated with numerous risks, including hypersensitivity reactions. Therefore, nursing care of patients subjected to immunoglobulin treatment should provide appropriate steps to enhance prevention of risk-related adverse effects. Proper preparation of medication, checking the patient, and determining the logging of the intervention and assessing vital signs prior to, during, and post-administration are crucial to guarantee safety in its administration. Many nurses depend on hospital policies for their practice of immunoglobulin administration. Educational guidelines for such nurses would fill gaps and enhance their knowledge and performance (**Guptill, et al., 2020**).

The administration technique should be tailored to the specific immunoglobulin product and patient's condition. Intravenous administration should be performed by trained personnel in a monitored setting. *Monitoring and Adverse Reaction Management*; Close monitoring of patients during and after immunoglobulin administration is essential to detect and manage any potential adverse reactions or interactions. Patients should be informed about possible side effects and instructed to report any discomfort or unusual symptoms promptly even after discharge from the hospital. *Waste Disposal*; proper disposal of used needles, syringes, and vials containing immunoglobulin residues is essential to prevent contamination and exposure risks. Adherence to these safety practices can significantly reduce the risk of adverse reactions and ensure the safe and effective administration of immunoglobulin (**World Health Organization "WHO", 2022**).



Intravenous immunoglobulin (IVIG) therapy is a widely used treatment for various autoimmune, inflammatory, and immunodeficiency disorders. IVIG is a blood-derived product that contains a concentrated pool of immunoglobulin obtained from the plasma of healthy donors. Despite its therapeutic benefits, the administration of IVIG is associated with potential risks and adverse reactions, making it crucial for nurses to have comprehensive knowledge and adhere to safety practices during its administration. The proper handling, preparation, and administration of IVIG are essential to ensure patient safety and minimize the risk of adverse events. Nurses play a vital role in this process as they are often responsible for safe and effective administering immunoglobulin therapy. Therefore, it is crucial to assess their knowledge and performance in adhering to safety guidelines (**Smith et al., 2016 and Danieli et al., 2022**).

While all nurses learn the basics of infusions and how to start IVs, infusion nurses must acquire additional specialized knowledge through continued education and training. The basic educational requirements for registered nurses who work as infusion nurses: 1) A diploma in nursing (associate's degree, bachelor's degree or master's degree). 2) A passing grade on the National Council Licensure Examination. 3) Work experience as a registered nurse for at least one year. 4) Exposure in an infusion-related department as a registered nurse (minimum requirement is 1,600 hours or two months total). This certificate validates the knowledge and skills of these nurses who have acquired and indicate the one who is expert in the infusion field (**Cornett, 2020**).

Also prior to infusion, nurses must log the blood product, lot number(s), expiration dates and dosages in each patient's record and a central database. Nurses must be knowledgeable and able to communicate effectively to notify doctors, pharmacists and/or others involved in patients' care about real or potential risks for them (**Abbie Cornett, 2020**). These side effects could result from the lack of knowledge and compliance of the healthcare staff to the administration techniques. Nursing personnel are responsible for most functions during the administration of Igs IV, which include reading patient identification information, checking suitability, monitoring for and recording adverse reactions, and documenting vital signs. Lack of nurses' knowledge and their compliance with standards for Igs IV administration could be potential problems (**Azizi, et al., 2020**).

Nurses who infuse IG must receive training in the clinical uses for this life saving medication, as well as be familiar with the diseases treated with it. Nurses must also be knowledgeable about potential side effects, the precautions to take to prevent them and how to mitigate them if they occur. These nurses must have advanced knowledge of possible adverse reactions associated with the medication, and they must be able to immediately spot the early warning signs of adverse reactions. Untrained nurses may not recognize these signs and thus expose patients to significant risk (**Cornett, 2020**).

Educational guidelines and training programs for nurses are crucial in enhancing their understanding of immune system nature and indications of receiving immunoglobulin therapy, in addition to IVIG administration safety practices, including patient monitoring, recognizing and managing potential adverse reactions, and adhering to proper protocols and procedures (**Galeotti et al., 2017**). These educational guidelines are valuable step towards ensuring the safe and effective administration of this crucial medical intervention that can contribute to improved patient safety, satisfaction and quality of care (**Kavaklioglu et al., 2022**).

Significance of the Study

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) found that 19.7% of medication errors involved with the administration of blood and blood products, immunoglobulin, and vaccines. Immunoglobulin is an important therapeutic product and should not be administered carelessly, slowly, or in nonhospital circumstances. Inspection of hospitals across Taiwan found that nurses sometimes do not follow the correct processes for immunoglobulin administration because the educational support and supervisory focus were insufficient (**Azizi et al., 2020**). Accordingly, we aimed to enhance such instructions for nurses through this activity, to enhance the legal and secure practice of nurses.

Any specialized clinical field requires standardization to ensure best clinical practice, assure health care professional accountability, and protect patients, clinicians, and organizations. The Immunoglobulin National Society (Ig NS) has recently published the second edition of the Ig Therapy Standards of Practice, a set of guidelines that provide a framework to support multidisciplinary practices in defining and developing Ig policies, procedures, and data collection strategies.

Nurses play a vital role in this process as they are often responsible for administering immunoglobulin therapy. Therefore, it is crucial to assess their knowledge and performance in adhering to safety guidelines



(Smith et al., 2016). There are limited researches of studies had done researches in Egypt among nurses who is administering immunoglobulin therapy or observing potential interventions toward side effects of these products.

Aim of the Study

Evaluate the effect of implementing educational guidelines on nurses' knowledge and practices for safe administration of immunoglobulin therapy.

Research Hypothesis

Nurses who receive educational guidelines will exhibit significant increase in mean scores of knowledge and practices post-intervention compared to pre-intervention levels.

Operational Definition:

Safe Immunoglobulin Administration means safe administering with use of close accurate, aseptic principles and less adverse reacting during IV immunoglobulin Infusions.

Subject and Methods

Research Design:

A quasi-experimental study designed was implemented.

Setting:

The present study was conducted at Internal Medicine Hospital a branch of the Main Hospitals of Tanta University which is affiliated to Ministry of Higher Education and Scientific Research. The involved departments were Internal Medicine Intensive Care Unit that composed 18 beds one room including 2 dialysis beds. Rheumatology (2 rooms), Hematology 18 beds one room, and endocrine and immunology (3 rooms contain 21 beds).

Subjects:

A convenience sample of available nurses (47), were constituted from the previous mentioned departments. Whereas the sample were as following; Medical ICU (15 nurses), Hematology unit (15 nurses), Rheumatology (10nurses), and Endocrine (7 nurses).

Tools of data collection:

Three tools were used for data collection.

Tool (I): Nurses' Interview Questionnaire: it was developed by the researchers after reviewing related literature and composed of two main parts that were translated into Arabic language.

Part One: " Nurses' demographic Characteristics " it included nurse code, age, gender, marital status, job qualifications, job position, work experience, previous training on safe injection practice of IV Immunoglobulin administration, previous vaccination for hepatitis B and corona virus.

Part Two: "Nurses' Knowledge Assessment" It was developed by the researchers based on massive recent literatures (El-Adely, 2014, National Institute of Health Clinical Center 2016). It contained of thirty-seven multiple choice questions to assess the knowledge about four main domains; *first domain* included nurses' knowledge regarding Nature of immune system (1-5 questions); and Immunodeficiency disorders that include (Causes, Types, Laboratory investigation, Risk factors, Diagnoses and Methods of treatment immunodeficiency disorders (6-37 questions); *second domain* ; Safe administration of immunoglobulin therapy. This domain contained eighteen questions retrieved from recent guidelines and recent literature review (Nussenzweig, 2021). It includes; types of the product, storage criteria, drug indications before administration, duration of intravenous administration and duration of renal side effects follow-up, *third domain*; include Common adverse reactions after infusion, the expected complications, and the types of potential adverse reactions; and *fourth domain*; knowledge about Nursing interventions for dealing with adverse reactions to IVIG.

Scoring system for calculation of the nurse's knowledge clarified as following:

correct and complete answers scored 2, correct and incomplete answers scored 1 and incorrect and no answer scored zero.

The total level of nurses' knowledge (pre and post) scored as following based on cutoff point:

- Low for less than 70 %.
- Moderate from 70 to 80 %.
- High knowledge more than 80 %

Tool II: An Observation Checklist for Standard Practice of an immunoglobulin Therapy: it is validated checklist in care of a patient receiving Intravenous Gamma Globulin (IVIG). The checklist developed by the



National Institute of Health, Clinical Center (2016), and adopted by the researchers, aimed to evaluate the nurses' practice of IV immunoglobulin therapy administration. The checklist involved the main steps of the nursing process with ten subtitled steps:

- I. Assessment (for patient and for order).
- II. Interventions:
 - a. Prior to immunoglobulin administration
 - b. During immunoglobulin administration
 - c. Post immunoglobulin administration
- III. Evaluation:
 - a. Documentation Quality

The checklist scored in three levels Likert scale given (2) for done completely or (1) partially done, and (0) for not done steps. The cutoff point was computed at $\geq 70\%$ and less than 70% of the total score of the checklist was indicated to satisfactory practice or unsatisfactory respectively.

Tool (III): "Nurses' Adherence to Safe Injection Practice for administering Immunoglobulin Replacement Therapy"

Injection Safety practice Checklist adopted from the **Center of Disease Control and Prevention (CDC; 2024)** and modified by the researcher according to the policy of the Internal Medicine Hospital. It is used systematically to assess' adherence of nurses to safe injection practice through direct observations by the trained two nurse observers. It contained nine steps considered the minimum expectation for safe care.

Scoring system for performance of practice

Done adhered for yes (1) and (0) for no adherence in practice.

Scoring system for total level of practice based on cut of point

Satisfied $\geq 70\%$

Unsatisfied $< 70\%$

Research Methods

An official letter explaining the study purpose was addressed to the dean of the Faculty of Nursing, Vice Dean of postgraduate studies and researches and head of Medical Departments and director of Nursing Department to get permission for data collection.

Ethical considerations:

- Ethical approval letter (Code. no. **104-9-2022**) was obtained from ethical committee of the Faculty of Nursing, Tanta University.
- Nature of the study was not causing any harm or pain to the entire sample.
- Written consent was obtained from every nurse after meeting the head nurses of each department for conducting the workflow of the study including assessment, observations and training.
- Anonymity was assured to participated nurses with full detailed explanation.
- Nurses' right was granted to call off during the workflow of the study.

Content Validity:

A panel of 5experts from the professors of Medical Surgical Nursing (3professors), Nursing Administration (one professor) and professor of Hematology (one professor) from the Faculty of Medicine were consulted to evaluate the content validity of each tool.

Pilot study:

The pilot study was carried out on 10% of nurses to test the feasibility of the study questionnaire and needed modifications were done. The knowledge questionnaire was converted into Arabic language with estimation of not more than 30 minutes to answer all the questions. Content validity was done for the Arabic version by the panel and the pilot test was repeated for the same nurses who were accepted from the authentic study sample.

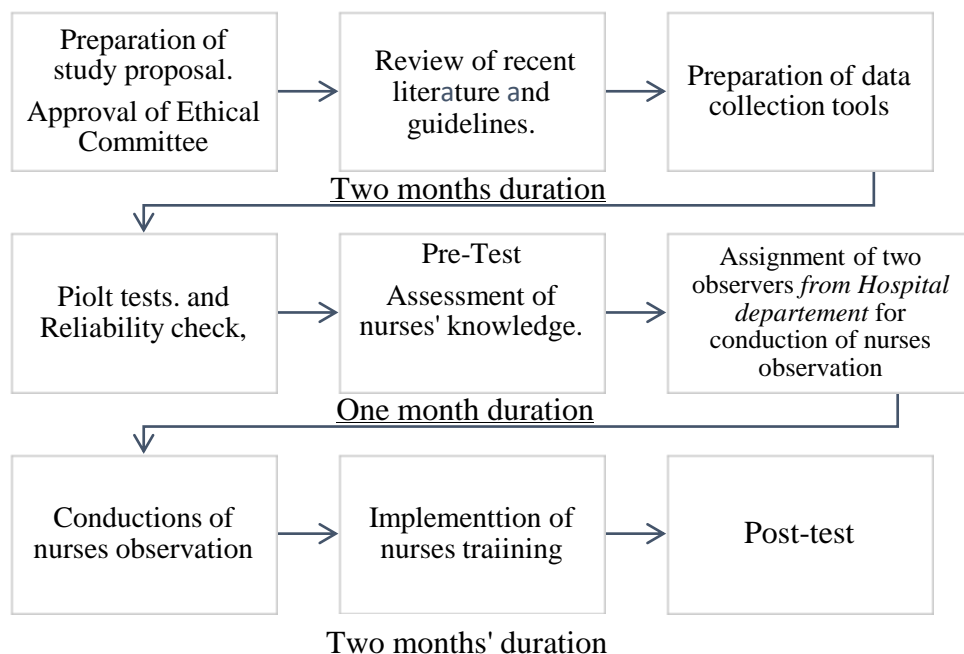
Reliability:

Reliability of tool (I) tool II and tool III was tested by using Cronbach's alpha factor test in total is 0.854 applied on 5 nurses.

Field Work:

- Data were collected over a period of 3 months started from 15 Feb. 2024 to 15 April 2024.

- Every 5- 8 nurses were interviewed at morning shift whereas the researcher asked them to meet from the night and morning shift nurses during the period of the study 3 days per week. The study was done on three phases: preparatory phase, assessment phase, planning phase, implementation phase and evaluation phase.



Assessment and preparatory phase:

- Initial interview was done for the head nurses and explain the aim of the study
- Obtain basic data through pretest questionnaire using tool I part A.
- The head nurse selected two nurses for observation of nurses' performance for practice using tool II and Tool III.
- The studied nurses were assessed using tool I Part one to collect demographic data and part two to collect knowledge regarding all domains.
- Nurse's performance was assessed before educational guidelines using tool II and tool III to assess nurses safe practice of administration of IG IV therapy and tool III was used to assess nurses' adherence to the safe practice of IG IV administration.

Planning phase:

- The researcher developed an educational guidelines based on assessment of nurses' learning needs, goal, priorities and expected outcome criteria which was formulated based on literature review to improve nurses' knowledge, nurses' safe practice and increase the safety practice adherence to the procedure steps of administering immunoglobulin therapy.
- In this phase development of teaching sessions as part of educational guidelines were given for two days.
- The educational guidelines included two main parts; one theoretical and other one for practical. The education was applied in about 10 sessions , each session was taken duration 30-45 minutes.
- Teaching method was included group discussions, demonstration and re-demonstration.
- Also teaching media was including video tape, PowerPoint and colored booklet which were designed by the researchers in Arabic language and planned to be given to them, its content related to immune system, immune-deficiency diseases, types of immunoglobulin therapy, adverse reactions that may occur. The nursing interventions for every type of potential adverse reactions. The instructions needed toward safety practice of administering, infection control measures, documentation during and after administering, for follow up of cases immediately, 7 days follow up for renal adverse reactions and documenting the duration needed for the patient to receive the therapy every 3-4 weeks. After doing the needed investigations for IG factors, CBC, ESR etc,... were taught.

Implementation Phase

The educational guidelines were presented by the researcher and finally hard copy of a colored booklet was given to each nurse. Nurses were divided into 5 groups; each group was consisted of 8-10 nurses and the researcher was attending the sessions that was scheduled in the morning. The sessions were given as following: four sessions were given; two theoretical and two practical sessions.

Evaluation phase:

Nurses were evaluated 2 times; 1st time pre-implementing the educational guidelines immediately for patients perceiving IV. immunoglobulin therapy and 2nd time was post implementing of educational guidelines about knowledge and practice of safe immunoglobulin administration.

Statistical Analysis:

The collected data were organized, tabulated and statistically analyzed using SPSS software statistical computer package version 26. For quantitative data, the range, mean and standard deviation were calculated. For qualitative data, comparison was done using Chi-square test (χ^2). For comparison between means for variables pre and post intervention in a group, paired samples T-test was used. For comparison between means for variables during two periods of intervention (pre-post) educational guidelines sessions in a group, or for more than two variables, the F-value of analysis of variance (ANOVA) was calculated.

Correlation between variables was evaluated using Pearson and Spearman's correlation coefficient r. A significance was adopted at $P < 0.05$ for interpretation of results of tests of significance. Also, a highly significance was adopted at $P < 0.01$ for interpretation of results of tests of significance (Praktiknjo et al., 2020).

Results

Table (1): Distribution of the studied nurses' demographic characteristics

Characteristics		Studied Nurses (n=47)	
		N	%
Department	▪ Internal Medicine ICU	17	36.2
	▪ Rheumatology & immunology	2	4.3
	▪ Hematology	23	48.9
	▪ Endocrine and immunology	5	10.6
Age (in years)	▪ (<25)	15	31.9
	▪ (25-<30)	15	31.9
	▪ (30-<35)	8	17.0
	▪ (35-<40)	1	2.1
	▪ ≥40	8	17.0
Gender	▪ Male	15	31.9
	▪ Female	32	68.1
Marital status	▪ Married	32	68.1
	▪ Single	15	31.9
Qualifications	▪ Diploma	25	53.2
	▪ Bachelor	22	46.8
Job position	▪ Nursing Technician	25	53.2
	▪ Staff nurse	13	27.6
	▪ Head nurse	3	6.4
	▪ Supervisor	6	12.8
Work experience (in years)	▪ (<6)	22	46.8
	▪ (6-<11)	9	19.1
	▪ (11-<16)	7	14.9
	▪ (16-20)	9	19.1
Previous training on injection safety	▪ No	5	10.6
	▪ Yes	42	89.4
Vaccination for hepatitis virus HBs Ag	▪ No	19	40.4
	▪ Yes	28	59.6
Vaccination against Corona	▪ No	15	31.9
	▪ Yes	32	68.1

Table 1: This table reveals that near half (49.9%) of nurses were from Hematology Department followed by nurses who is working in Internal Medicine ICU (36.2 %). Most of nurses age from < 25 - <30 years are representing (63.8%). The majority of studied nurses (68.1 %, 68.1 %) was females and married respectively. Regarding to qualifications, more than half of the studied nurses (53.2%, 53.2%) had Diploma and employed as a Nursing Technician respectively. Also, near half of studied nurses 46.8% has less than 6 years' experience in their work in the internal medicine department (Hematology Department) and 89.4 % of them had previous training courses in injection safety.

Table (2) Studied Nurses' total knowledge domains about immunoglobulin therapy

Total nurses' knowledge domains	The studied nurses (n=47) Range Mean ± SD		t	P
	Before	After		
First: Nature of immune system and immunodeficiency disorders	(0-74) 57.00±17.721	(29-74) 66.91±12.229	9.966	0.002*
Second: Safe administration of immunoglobulin therapy	(0-11) 6.55±2.518	(5-14) 12.40±2.517	126.97	0.000*
Third: Immunoglobulin therapy adverse effects and interactions	(0 – 8) 5.23 ± 3.20	(2 – 8) 7.30 ± 1.55	3.984	0.001*
Fourth: Nursing interventions for IVIG adverse reactions therapy	(0-20) 13.28±5.144	(13-22) 19.11±2.899	45.81	0.000*

* Significant at level P<0.05.

Table 2: compares pre- and post-intervention knowledge levels of nurses on four main domains of knowledge, which demonstrate improvement in the mean scores of all domains after the intervention. Statistical significance was confirmed across all domains, with P-values below 0.05, indicating that the intervention likely had a positive impact on the nurses' knowledge. The highest domain was in the theoretical knowledge about the nature of the immune system and immunodeficiency disorders 66.91±12.229, while the lowest domain was in the understanding of the immunoglobulin therapy adverse effects and interactions 7.30 ± 1.55.

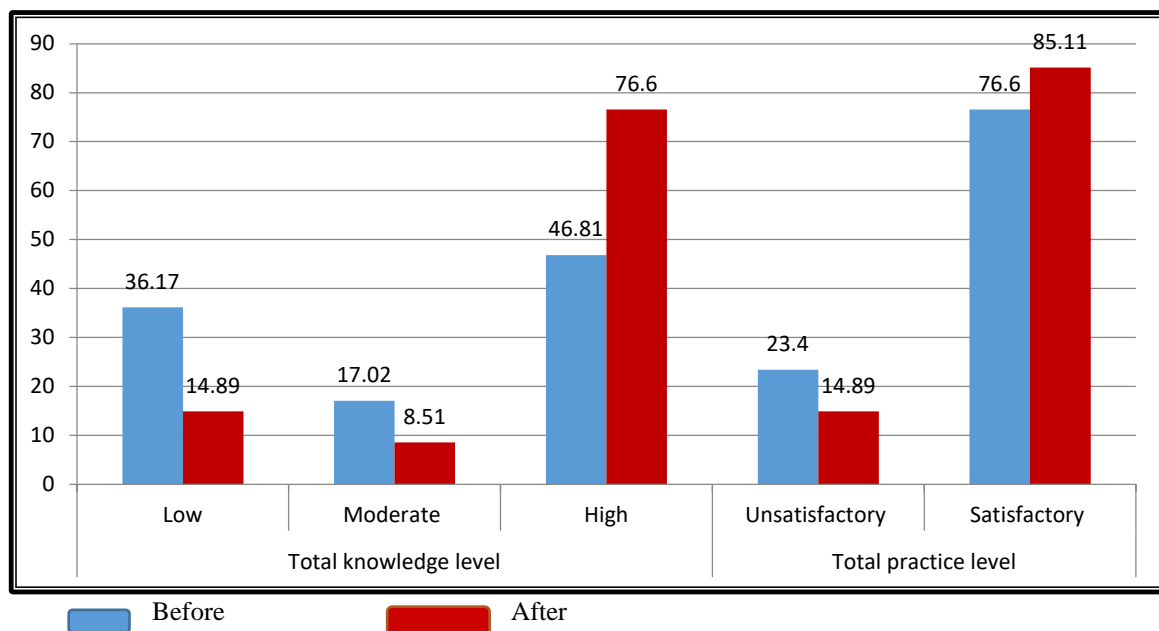


Figure 1: Assessment of studied nurses according to total knowledge, and practice levels about immunoglobulin treatment.

Figure 1: Illustrate that there were about one third (36.17 %) of total studied nurses' knowledge had low level, 17.02% had moderate knowledge and 46.81 % of studied nurses had high knowledge level about immunoglobulin therapy before implementing educational guidelines sessions compared to after implementations of educational guidelines; they had high knowledge level (76.6%), 8.51 % of studied nurses had moderate level and 14.89% had low level of knowledge. On other hand, the total practice level were satisfactory (76.6%) in administering immunoglobulin therapy before giving educational guidelines compared to (85.11%) after guideline sessions, that could be explained due to their previous training on safe practice injection and IVIG administrations.

Table (3) Observation of Nurses' Standard Practice in administration of Immunoglobulin therapy.

Observed Practice domains			Studied nurses (n=47)			
			Before	After	T	P
I) Assessment	Range		(0-14)	(1-14)	0.279	0.599
	Mean ± SD		11.55±2.403	11.89±3.708		
II) Interventions						
1. Prior to immunoglobulin administration	Range		(0-24)	(1-24)	3.815	0.054
	Mean ± SD		18.47±4.881	20.62±5.750		
2. During immunoglobulin administration	Range		(0-30)	(2-30)	0.819	0.368
	Mean ± SD		23.96±4.978	25.15±7.527		
3. After immunoglobulin administration	Range		(0-2)	(0-2)	5.576	0.020*
	Mean ± SD		1.60±0.614	1.85±0.416		
III) Documentation and its quality.	Range		(0-14)	(4-14)	7.775	0.006*
	Mean ± SD		11.15±3.155	12.72±2.243		
Total Practice Score	Range		(0-82)	(14-82)	2.681	0.105
	Mean ± SD		65.13±13.058	70.38±17.712		

* Significant at level P<0.05.

Table 3: shows that there are near one third of mean score of studied nurses' practice interventions during immunoglobulin administration (23.96±4.978) before giving educational guidelines while after giving sessions the mean score of nurses' practice were 25.15±7.527. as regard to practice after immunoglobulin administration, the mean score was minor 1.60±0.614 before sessions compared to 1.85±0.416 with high significant difference (P= 0.020). On other hand the documentation steps after administration of immunoglobulin therapy mean score was 11.15±3.155 before the educational guidelines compared to the mean score 12.72±2.243 after giving sessions of educational guidelines about immunoglobulin therapy. There was high significant difference related to documentation steps in practice of administration p= 0.006.

Table (4) Nurses' adherence to safety practices for immunoglobulin replacement therapy.

Nurses' adherence to safety practices	The studied nurses (n=47)												χ ² P
	Before						After						
	No		Some Extent		Yes		No		Some Extent		Yes		
	N	%	N	%	N	%	N	%	N	%	N	%	
1. Perform proper hand hygiene	0	0.00	6	12.77	41	87.23	1	2.13	2	4.26	44	93.62	3.585 0.167
2. Prepare injections using aseptic technique in a clean area	1	2.13	10	21.28	36	76.60	2	4.26	5	10.64	40	85.11	2.249 0.325
3. Using needles and syringes are used for only one patient.	4	8.51	9	19.15	34	72.34	1	2.13	5	10.64	41	87.23	3.741 0.154
4. Disinfecting of the rubber septum on a vial is with alcohol prior to piercing.	1	2.13	13	27.66	33	70.21	2	4.26	3	6.38	42	89.36	8.161 0.017*
5. Entering with a new needle and a new syringe to vials.	3	6.38	9	19.15	35	74.47	0	0.00	10	21.28	37	78.72	4.267 0.118

6. Using single-use product vials or ampules for only one patient.	0	0.00	8	17.02	39	82.98	1	2.13	6	12.77	40	85.11	1.686 0.430
7. Using product administration tubing for only one patient.	3	6.38	12	25.53	32	68.09	4	8.51	7	14.89	36	76.60	1.710 0.425
8. Disposing all used needles in sharps containers.	1	2.13	11	23.40	35	74.47	1	2.13	7	14.89	39	82.98	1.113 0.573
9. Disposing filled Sharps containers according to biohazards wastes disposal policy.	1	2.13	12	25.53	34	72.34	3	6.38	2	4.26	42	89.36	9.815 0.007*
Range					(0-18)				(9-18)				t=3.018
Mean ± SD					16.15±3.219				17.23±2.153				P=0.552

* Significant at level $P < 0.05$.

Table 4: illustrates that more than three fourth and more than half of total sample (87%, 70. %, 72%) respectively adhere to safety practice of immunoglobulin administration before implementing educational guidelines regarding proper hand hygiene, disinfection of the rubber septum on a product vial with alcohol prior to piercing and disposing filled sharp container, compared to the majority of total sample (93.62 %, 89.36%, 89.36%) adhered to the performing hand hygiene properly, Disinfecting of the rubber septum on a product vial with alcohol prior to piercing and disposing filled sharp containers according to biohazards wastes disposal policy respectively.

There was a high significant difference in mean score of nurses' adherence to safety practice related to disposing full filled sharps containers according to biohazards wastes disposal management policy of the hospital ($P=0.007$), and disinfected with alcohol prior to piercing for the rubber septum of vial ($P=0.017$).

Table (5) Correlation between studied nurses' knowledge and practice level about immunoglobulin therapy

Total knowledge level	The studied nurses (n=47)							
	Total practice level							
	Before				After			
	Unsatisfactory		Satisfactory		Unsatisfactory		Satisfactory	
	N	%	N	%	N	%	N	%
▪ Low	8	17.02	9	19.15	4	8.51	3	6.38
▪ Moderate	2	4.26	6	12.77	2	4.26	2	4.26
▪ High	1	2.13	21	44.68	1	2.13	35	74.47
χ^2	10.505				15.316			
P	0.005*				0.000*			
r	0.706				0.815			
P	0.000**				0.000**			

r: Pearson' correlation coefficient * Significant at level $P < 0.05$.

Table 5: shows a high and positive correlation between total knowledge level and total level of safe practice of administering an immunoglobulin therapy with high significance ($p < 0.05$).

Table (6): Relations between Demographic characteristics, total nurses' knowledge and total Practice Scores

Demographic Characteristics	The studied nurses (n=47)			
	Mean ± SD			
	Total Knowledge Score		Total Practice Score	
	Before	After	Before	After

Department				
▪ Internal Medicine ICU	88.94±19.69	124.29±8.33	64.29±12.36	75.65±9.05
▪ Rheumatology & immunology	114.00±5.66	122.78±18.52	70.00±5.66	70.22±21.22
▪ Hematology	98.83±27.27	131.50±2.12	63.87±15.13	77.50±6.36
▪ Endocrine & immunology	116.40±1.52	84.80±6.57	71.80±2.05	50.40±12.26
F, P	2.539, 0.069	11.271, 0.000*	0.606, 0.615	3.105, 0.036*
Age (in years)				
▪ (<25)	104.53±18.78	118.07±17.91	65.27±6.34	63.67±22.97
▪ (25-<30)	99.40±20.54	116.40±23.29	67.87±9.98	70.40±18.06
▪ (30-<35)	98.75±20.95	124.00±18.04	70.38±5.15	78.50±8.35
▪ (35-<40)	116.00±0.00	126.00±0.00	72.00±0.00	82.00±0.00
▪ ≥40	79.50±35.45	123.63±11.36	53.63±24.68	73.38±9.12
F, P	1.801, 0.147	0.354, 0.84	2.359, 0.069	1.137, 0.352
Gender				
▪ Male	89.00±15.26	130.13±4.64	66.73±8.42	78.93±5.42
▪ Female	102.19±26.38	114.75±20.53	64.38±14.80	66.38±20.01
t, P	3.219, 0.081	8.139, 0.007*	0.328, 0.571	5.653, 0.022*
Marital status				
▪ Married	98.00±26.28	119.06±17.14	66.28±14.84	71.03±15.81
▪ Single	97.93±19.27	120.93±21.078	62.67±7.93	69.00±21.78
t, P	0.000, 0.993	0.102, 0.751	0.779, 0.382	0.132, 0.718
Qualifications				
▪ Diploma	95.82±21.85	122.00±22.28	67.50±8.66	76.64±8.87
▪ Bachelor	104.40±13.53	124.50±13.19	65.20±7.97	71.30±21.04
t, P	0.450, 0.640	2.648, 0.082	0.907, 0.411	4.180, 0.023*
Job position				
▪ Nursing Technician	101.07±27.32	118.15±21.09	75.33±3.51	81.00±1.73
▪ Staff nurse	83.73±16.56	122.55±14.01	59.09±11.36	74.18±10.49
▪ Head nurse	101.67±19.86	125.00±3.00	55.33±14.58	66.67±21.40
▪ Supervisor	108.33±9.95	118.50±19.95	70.17±5.23	74.83±9.28
F, P	1.943, 0.137	0.228, 0.876	1.781, 0.165	1.054, 0.378
Work experience (in years)				
▪ (<6)	107.09±16.81	117.87±20.82	65.83±8.17	65.96±22.61
▪ (6-<11)	96.78±20.57	111.67±21.11	70.22±8.42	70.11±12.04
▪ (11-<16)	79.67±14.26	131.17±4.58	69.67±5.16	81.83±0.41
▪ (16-20)	88.11±37.38	124.56±10.71	55.22±23.51	74.33±9.00
F, P	3.162, 0.034*	1.684, 0.185	2.721, 0.056	1.514, 0.225
Previous training on injection safety				
▪ Yes	107.20±14.99	126.80±5.36	71.40±4.22	80.00±2.74
▪ No	96.88±24.81	118.81±19.37	64.38±13.57	69.24±18.40
t, P	0.819, 0.370	0.829, 0.368	1.299, 0.260	1.674, 0.202

* Significant at level P<0.05.

Table 6: illustrate relations between demographic characteristics, total knowledge and total practice mean scores before giving educational guidelines sessions and after sessions. As regard to the Departments; it was noticed that there is a high mean score (116.40±1.52) of total knowledge of endocrine department staff nurses' before sessions compared to hematology department staff nurses knowledge mean score (131.50±2.12) after educational guidelines, while there were high total level of practice mean score of endocrine staff nurses' department (71.80±2.05) before sessions compared to after educational guidelines mean score of total practice (77.50±6.36) was among hematology Department nurses.

As for gender, it was noticed that females have a high mean score (102.19±26.38) of knowledge before educational guidelines compared to after sessions (130.13±4.64) male were improved in their knowledge while total level of practice mean scores (66.73±8.42) were high in males' pre-educational guidelines and improved with them the mean scores of total levels of practice (78.93±5.42) after sessions.

On other hand, the qualifications of the staff nurses were observed high mean scores of total levels of knowledge (104.40 ± 13.53 , 124.50 ± 13.19) had Bachelor degree compared to the total level of nurses' practice mean scores (67.50 ± 8.66 , 76.64 ± 8.87) had diploma degree pre-educational guidelines implementation and after sessions with high significance difference after implementations of guidelines regarding practice.

As, regard to *work experience*, there was a high statistical significance in total mean score of knowledge had < 6 years of experience before giving educational guidelines about safety practice of administering immunoglobulin therapy compared to after sessions mean scores were (131.17 ± 4.58) with nurses had (11-< 16 years) experience while total level practice mean score before (70.22 ± 8.42) with nurses who had 6-<11 years of experience compared to after the mean score of total practice (81.83 ± 0.41) had 11 -< 16 yrs. of experience. Finally, there was no statistically significant difference relation between total mean score of knowledge and total mean score of practice in relation to safety injections before giving educational guidelines sessions and after about immunoglobulin therapy.

Discussion:

Intravenous immunoglobulin (IVIG) therapy is a widely used treatment for various autoimmune, inflammatory, and immunodeficiency disorders. IVIG is a blood-derived product that contains a concentrated pool of immunoglobulin obtained from the plasma of healthy donors. As highlighted in a recent review article by **Danieli et al., (2022)**, IVIG therapy has proven to be effective in treating a wide range of conditions, including autoimmune and inflammatory diseases, neurological disorders, and primary immunodeficiency. Despite its therapeutic benefits, the administration of IVIG is associated with potential risks and adverse reactions, making it crucial for nurses to have comprehensive knowledge and adhere to safety practices during its administration.

The findings of the present study revealed that near half of the studied nurses were from hematology department followed by Internal Medicine Intensive care unit staff then Endocrine nurses' then Rheumatology Department. This can be explained by the Hematology Department physicians usually prescribe IV Immunoglobulin and refer most cases to the Internal Medicine ICU to receive the therapy under close observations and the needed emergency equipment available in this unit as Cardiac Monitor, Crush Cart, Suctions and Defibrillator. This result was consistent with findings from **Perez et al., (2017)** who noted the prevalence of immunoglobulin use in hematology units.

In relation to age of studied nurses more than half of nurses were (<25 - <30 yrs.). The predominance of younger nurses reflects trends observed by **Smith and Johnson (2019)**, who reported a growing influx of younger nurses in specialized care unit, and it could be explained in our settings due to those patients in need to be cared with fresh educated and recently graduated nurses. In contrary to the opinion of **Browne et al., (2018)** who argued that a mix experienced and novice nurses provides optimal patient care in complex therapies, suggesting this age distribution might not be ideal.

As regard to sex; more than half of studied nurses were females and married respectively. This study was similar to the global nursing demographic reported by the **World Health Organization (2020)** which found that approximately 70% of the nursing workforce worldwide is female. In other hand these study findings were disagreed to the equal percentage of gender and marital status both (68.1%) are statistically unlikely and warrant further investigations as highlighted in research methodology guidelines by **Thompson, (2021)**.

In relation to nurses' qualifications, the present study revealed more than half of the studied nurses (53.2%, 53.2%) had diploma and employed as a nursing technician (bedside nurse) respectively. This result was in align to their younger age and graduated with immediate recruitment has obtained. It can be aligned with findings of **Rodriguez et al., (2018)** who observed similar patterns in specialized nursing units in developing countries. This study is disagree with **Lee and Park (2022)** who argue that advanced nursing degrees are increasingly important in specialized care, suggesting a potential need for higher qualifications in these departments.

Moreover, in the current study, near half of studied nurses has less than 6 years in their work. This study could be agreed with the high percentage of nurses less than 6 years' experience corresponds with the younger age demographic, a trend also noted by **Wilson et al., (2020)** in their study of nursing workforce dynamics. This study is disagreeing with **Kang et al., (2019)** who found that patient outcomes in complex therapies improved with nurse experience, suggesting that this experience level might not be optimal for immunoglobulin therapy administration.



Furthermore, the present study showed that majority of studied nurses 89.4% had previous training courses in injection safety it means that they are aligned to the recommendations of (CDC, 2021) to reduce injection related infections; the nurses must be encouraged to have an outlined best practice regarding infusions. Whereas it is disagreed with WHO, (2019) recommended that 100% compliance with injection safety training for all health care workers administering injections, indicating that the 10.6% gap in training could be a potential safety concern.

Concerning the studied nurses' total knowledge domains about immunoglobulin therapy at pre-and post-intervention of educational guidelines for safe administration of immunoglobulin therapy, nurses' understanding of the immune system and immunodeficiency diseases significantly improved following the implementation of educational guidelines. Pre-intervention mean scores were 57.0 ± 17.72 , which increased to 66.91 ± 12.229 post-intervention ($P < 0.05$). This suggests the educational sessions, incorporating active learning methods like group discussions and interactive lectures were effective in enhancing nurses' knowledge. These methods have been shown to enhance knowledge retention and understanding among health care professionals as reported by Brown et al., (2017) and Nejati et al., (2019). Additionally, Weurlander et al., (2019) and Cant et al., (2020) emphasized that interactive teaching methods, such as case studies, group discussions, and hands-on practice, are essential for promoting active learning and critical thinking, which are crucial for knowledge application in clinical practice. The present finding was congruent with Li et al. (2019) as showed that structured educational interventions significantly improved nurses' knowledge of specialized therapies, with a notable increase in mean scores, reinforcing the effectiveness of targeted educational programs. Also aligns with Naji et al., (2021), nurses' knowledge about immunodeficiency disorders after implementing educational programs was significantly improved.

The findings of the present study find out that, nurses had basic knowledge about the indications and severity of immunoglobulin therapy before the educational sessions. After the sessions, their understanding expanded to include details on different immunoglobulin products, storage requirements, and inspection procedures. This aligns with previous studies that reported similar improvements in knowledge scores (e.g., Youssef et al., 2019; Dash et al., 2021). A gap was identified in nurses' knowledge about monitoring renal side effects post-discharge. Many nurses do not make follow up adequately on these adverse effects, focusing instead on general follow-up appointments. This gap indicates a need for more emphasis on long-term monitoring and follow-up procedures in educational programs. This explanation was supported by Gershon et al. (2018) as observed that certain complex aspects of patient care, such as post-discharge follow-up for renal side effects, often require more intensive or repeated educational interventions for sustained improvement.

The finding aligns with Chen et al., (2020), found variable retention of knowledge across different care aspects of specialized care, indicating that some areas may show minimal improvement despite educational efforts. Also, Galeotti et al., (2017) asserted that implementation of educational guidelines and training programs can significantly enhance nurses' knowledge and performance related to safety practices in IVIG administration. This can minimize risks and adverse reactions, thereby improving patient outcomes. Other studies such from Egypt such as El-Shabrawi et al., (2019), emphasized that well-trained nurses can minimize risks and adverse reactions associated with IVIG, leading to better patient outcomes. Also, Shawky et al., (2021) reinforces the importance of nurse education for ensuring proper IVIG administration and monitoring, particularly in pediatric patients.

There was significant improvement in nurses' knowledge about the potential adverse effects and nursing interventions for immunoglobulin therapy, with mean scores rising from 13.28 ± 5.144 to 19.11 ± 2.899 ($p = 0.000$). This indicates that the educational guidelines effectively enhanced nurses' understanding of interventions for reactions such as chills, headache, flu-like symptoms, and more and attributed to the teaching methods used, which involved a structured approach to assessing and planning interventions based on specific adverse reactions. The improvement aligns with previous research showing that structured educational programs can significantly boost nurses' knowledge and skills in managing adverse reactions (Kim et al., 2019; Sousa et al., 2019). The high statistical significance ($p = 0.000$) underscores the effectiveness of the educational intervention.

Despite overall improvements, some areas of knowledge domain showed low progress in the understanding of the immunoglobulin therapy adverse effects and interactions 7.30 ± 1.55 , the finding reflect that not all the nurses exposed to patients with adverse effects from the product and mixing signs of adverse effect with the interactions of the product. This variability highlights the need for targeted educational strategies to address

more challenging aspects of immunoglobulin therapy and ensure comprehensive knowledge retention among nurses.

As regard the assessment of total nurses' knowledge and practice level regarding immunoglobulin therapy, both before and after the implementation of educational guidelines, reveals several important findings: Before the educational interventions, about one-third of the nurses had low knowledge of immunoglobulin therapy. Post-intervention, over three-fourths of the nurses demonstrated high knowledge, reflecting a significant improvement. This suggests that the educational guidelines effectively enhanced nurses' understanding of the therapy. In terms of practice, before the educational sessions, more than three-fourths of the nurses had satisfactory level of practices. Compared to, the majority of them maintained increased practice after the sessions. The researcher explained this finding as the staff had previous practice training on safe injections and increased after intervention of educational guidelines about safe administering of IVIG therapy. Also, This indicates that while knowledge improved, the overall level of practice was markedly improved. In this perspective **Cotrell-Gibbons and Brown, (2020)** suggested that knowledge improvements should reach at least 80% post-intervention to be considered clinically meaningful in specialized nursing areas, indicating that more substantial improvements are sometimes necessary for clinical significance. Also, Aligns with **Dash et al., (2021)** reported significant increases in nurses' knowledge of complex therapies after educational programs, demonstrating the broad benefits of education in various clinical domains.

The study evaluated the effect of educational guidelines on nurses' standard practice related to administration of immunoglobulin (IVIG) therapy at an Internal Medicine Hospital. Before the educational interventions, the improvement in practice mean scores (11.55 and 11.89 pre- and post-intervention, respectively) was not as pronounced in the domains of practice assessment but showed significant gains in practice related to intervention stages ($p < 0.020$) and documentation (mean scores of 11.15 and 12.72 pre- and post-intervention, respectively, $p < 0.006$). This could be interpreted related to the increase awareness from the educational guidelines related to interventions toward side effects that may occur with patients and its different signs in addition to the item of documentation related to follow up were not activated by the staff nurses due to pressured patients admissions and shortage of staff numbers in different departments. The findings are consistent with other comparative studies, such as those by **El-Nabarawy et al. (2020)** and **Kavaklioglu et al. (2022)**, which reported significant improvements in nurses' knowledge and practices following educational programs. Similarly, a research by **Galeotti et al. (2017)** underscores the importance of thorough training in ensuring safe IVIG administration and reducing risks. This finding is consistent with **Arumugham and Rayi, (2023)**, who highlighted the critical role of nurses in managing IVIG infusion and promptly reporting adverse reactions. Also, emphasized the importance of nurses in monitoring and managing adverse reactions during IVIG infusion.

Nurses' adherence to safety practices for immunoglobulin replacement therapy; Focusing on the nurses adherence to safety practices, a significant improvements were observed in adherence to safety practices, before the educational sessions mean score 16.15 ± 3.219 compared to 17.23 ± 2.153 after educational sessions which indicated that the general nurses adherence to safety practice of the infusion therapy were high and maintained higher progress post training. As seen in the reduction of standard deviations scores, not all nurses get benefit equally from education programs, this variability is consistent with the studies of **Zhang et al., (2018)** and **Chen et al. (2020)**, who suggested that some topics may require more intensive or repeated education for sustained improvement. Despite improvements in specific practices, the overall adherence to safety practices did not show a significant change. This suggests that while targeted educational interventions can enhance specific behaviors, broader changes in practice may be more challenging (**Bingham et al., 2018**).

Statistical significance illustrated in particular safety practice adherences including proper disposal of sharps ($p = 0.007$) and disinfecting vial septum's ($p = 0.017$). These results were consistent with other studies highlighting the positive effects of educational interventions on specific safety practices (**Alshehari et al., 2018**; **Mahmood et al., 2019**). In the same line, other studies by **Smith et al., (2016)** demonstrated that educational programs significantly improved nurses' knowledge of infection control protocols, supporting the broader findings of educational interventions on healthcare professionals' knowledge. **Youssef et al., (2019)** found significant improvements in nurses' knowledge scores on infection control practices following educational interventions, this highlights the effectiveness of educational programs in enhancing nursing knowledge.

Effective IVIG therapy requires adherence to a nursing policy for the treatment and management of adverse reactions (**Hošnjak et al., 2018**). Nurses need thorough training in both IVIG and Subcutaneous Immune



Globulin (SCIG) therapies, including understanding different product preparations and stabilizers. While, the educational guidelines significantly improved nurses' knowledge of immunoglobulin therapy, there is a need for further efforts to ensure that this knowledge translates into practical changes in clinical behavior and enhanced practical training and continuous support could help bridge this gap.

As regard to Correlation between total knowledge level and practice level about immunoglobulin therapy; the study found positive significant knowledge improvements, but the translation of this knowledge into consistent clinical practice remains uncertain. Some nurses may not have experienced as much improvement, highlighting the need for tailored approaches (**Lam et al., 2020; Fernandez et al., 2020**). The study did not address the sustainability of improvements as it have to be ongoing receiving in-service training and support to the hospital agency to sustain the improvement in knowledge and practice of IV IG administration. Without ongoing reinforcement, gains from educational interventions can diminish over time (**Lydon et al., 2017**).

Whereas, the relations between the nurses' demographic influences on their knowledge and practice; as resulted in the present study significant improvements in knowledge and practice across various inpatient units were notably in hematology unit and endocrine unit. This improvement was statistically significant, with the highest gains seen in specialized departments (**Sharma & Patel, 2022**). Also, Nurses aged 35-40 years demonstrated stronger knowledge and practice before training compared to other age groups. Female nurses showed greater knowledge, while male nurses excellent in practical application. This highlights the varying impacts of age and gender on training outcomes. In addition to Tanta female nurses staff hospitals were noticed and eager to read more than male as a point of view from the researcher different from male staff who were interest more in practice especially in complex therapies.

In relation to Bachelor's degree nurses retained knowledge and skills better than diploma nurses, especially in practical applications. Supervisors and head nurses, due to their experience and administrative roles, exhibited higher knowledge and better practice compared to other job positions. Nurses with less than six years of experience performed better in knowledge, while those with six to eleven years of experience excelled in practice before training. However, those with 11-16 years of experience showed better retention of knowledge and practice post-training. The lack of prior training was identified as a challenge in acquiring the new knowledge and practices.

The study emphasized that while certified infusion nurses offer the highest quality of care, experienced non-certified nurses can also provide excellent care. Specialized training and certification are crucial for ensuring safe and effective IVIG administration. **Cornett (2020)** underscores the need for infusion nurses to be well-trained in critical thinking, emergency response, and infusion techniques. Overall, the study highlights the significant improvements in nurses' knowledge and practices following educational interventions. It underscores the importance of specialized training in enhancing the quality of IVIG infusion therapy and the need for ongoing education to maintain high standards of patient care. **Hong et al., (2018) and Yu et al., (2020)** supported the importance of educational interventions in improving nurses' competencies and knowledge in various clinical areas, reinforcing the positive impact of continuous professional development on patient care quality.

Conclusion

The present study induced positive effect of implementing educational guidelines and training programs on nurses' knowledge and practice for the safe administration of intravenous immunoglobulin (IVIG) therapy. This significance is going with wide-ranging implications for patient safety and outcomes. Interactive and well-structured educational programs are essential for ensuring sustained improvements in nursing knowledge and clinical competence. Immunoglobulin therapy requires a high degree of specialized education and advanced, standardized clinical practice to ensure safety and good clinical outcomes. Adherence to the Ig therapy standards of practice is critical, as it guides all major aspects of practice, including appropriate product selection and dosing, route and method of administration, mitigation of risks, management of adverse events administration protocols, and other aspects. The standards facilitate collaboration of care, serve as a foundation to organizational policies, support clinicians, and most importantly add value to patients' safety.

Recommendation:

In the light of the current study, recommendations focus on the following points;



- Nurses must maintain and update the IG IV infusion therapy standards of knowledge and practice every three years through comprehensive educational programs.
- Implement ongoing training sessions and refresher courses to keep nurses updated .
- Develop targeted strategies to address the specific learning needs and preferences of different age groups and genders to enhance overall effectiveness.

Further researches

- Encourage and support nurses in obtaining certification in IVIG administration.
- Provide opportunities for professional development and career advancement to motivate nurses to pursue further education and specialization in infusion therapy.

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