Assessment of Nurses' Safety Practices in relation to Intravenous Iron Administration for Patients Undergoing Hemodialysis.

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Abstract

Iron deficiency is the most common cause of hypo-responsiveness to erythropoiesis-stimulating agents (ESAs) in end-stage renal disease (ESRD) patients, and is a commonly encountered reversible cause of chronic kidney disease (CKD) related anemia. In addition to the typical causes of iron deficiency, patients on hemodialysis experience routine iron loss due to the dialysis treatment (retention of blood in dialyzer and blood lines), frequent blood draws for laboratory testing, surgical procedures, accidental blood loss (vascular access), and gastrointestinal blood loss. Thus, Intravenous (IV) iron is a standard treatment for patients undergoing hemodialysis. Researches display IV iron more efficacious for restoring iron status compared to oral iron supplements. In this respect; it should be transmitted judiciously by hemodialysis nursing staff following restricted safety practices throughout the whole procedure phases: before, during and after IV iron administration due to its reported serious adverse events risk. The study aimed to assess the nurses' safety practices concerning intravenous iron administration for patients undergoing hemodialysis. Material and method: Data were collected using one tool, "The Hemodialysis Nurses' Intravenous Iron Administration Safety Practices Observational Checklist". A convenient sample of all (50) nurses who were available at the time of the study at the selected hemodialysis unit, at Alexandria Main University Hospital, Alexandria, Egypt; was included in the study. Results: the current study revealed that the studied hemodialysis nurses (100%) had unsatisfactory level of practice. Moreover, no statistical significance relation was declared between nurses' sociodemographic characteristics and their safety practices throughout IV iron administration procedure. Conclusion: The current study hemodialysis nurses' safety practices level of performance administration of intravenous iron; were noticeably unsatisfactory. Recommendations: Updating hemodialysis nurses' knowledge and practices is mandatory through providing in- service continuing evidence-based practices training programs; emphasizing on the significance of safety IV iron administration practices.

Keywords: Hemodialysis, safety, Practices, Nurse, Intravenous, Iron administration, Chronic kidney disease.

Introduction:

Iron is a vital element for sustaining numerous body functions, being the most notable ingredient of hemoglobin (Hb) synthesis. However, most healthy people can achieve a stable iron balance, managing to ingest the required amount of iron in diet to compensate daily gut's iron losses. Nevertheless, many patients with advanced chronic kidney disease (CKD) are in negative iron balance as a result of reduced dietary iron consumption, impaired gut absorption, and

increased iron loss. However, absolute iron deficiency is classified when the transferrin saturation (TSAT) is ≤20% and serum ferritin concentration is ≤200 ng/mL hemodialysis patients (National Kidnev Foundation, 2021; International Society of Nephrology, 2012). So, iron administration is considerably imperative for hemodialysis (HD) patients, to keep pace with blood loss and the erythropoiesis requirements (Gafter-Gvili, Schechter, Rozen-Zvi., 2019 & Macdougal and Bircher., 2016).

Global researches have confirmed that; iron deficiency anemia is common and treatable among patients with end stage renal disease (ESRD); yet it is frequently associated with fatigue, reduced quality of life (QoL), rapid disease progression, poor clinical outcomes, in addition to increased morbidity, mortality, and risk of re-hospitalization (NIDDK., 2021;Akel et al., 2017; Kalra and Bhandari., 2016).

In the light of this, anemia of ESRD is managed with Erythropoiesisprimarily stimulating agents (ESAs) and Intravenous (IV) iron supplements. In last few years, iron supplementation has been widely recommended and highly effective to treat iron deficiency anemia, prevent its development in ESA-treated patients, reduce the ESAs dose and raise the Hb levels (Kong & Hwang, 2020; Macdougall & White., 2018; Sarhan & Hussein., 2017). This is particularly important since ESA therapy may result in adverse clinical outcomes, most notably stroke and vascular access thrombosis (Macedo & Lima, 2019; Schiller & Bhat., 2014).

Iron supplements are administered either through oral or IV routes; oral route is relatively safe, but ineffective with severe gastric upset, minimizing HD patients' adherence to therapy (Batchelor et al., 2020; Li et al., 2017). However, IV iron has the advantages of; the administration of larger doses of iron rapidly, better tolerated, and has the capability of bypassing all issues. Intravenous iron is also superior to oral iron in achieving a sustained Hb response, reducing the need for blood transfusions and improving QOL in CKD (Auerbach, Ballard, & Glaspy, 2007).

In spite the superior efficacy of IV over oral iron therapy; the improper and unsafe IV iron administration on long term use may consequence in numerous adverse events overload, namely: hypersensitivity iron reactions. cardiovascular disorders, oxidative stress. Oxidative stress or oxidantderived tissue injury results from an over production of reactive oxygen/nitrogen species or impairment in the cellular antioxidant enzymatic activities, leading to increased cardiovascular risk. This occurs as a result of increased hepcidin and serum ferritin level which subsequently lead to arterial stiffness and myocardial infarction. (Macedo & Lima, 2019; Macdougall., 2017).

Patient safety is an essential nursing skill aimed to maintaining strict aseptic technique throughout IV iron administration, to prevent infection spread in lowered HD patients' immunity. However, the IV iron administration clinical infection risk is increasing in HD patients, as it affects both bacterial growth and host immunity. Nevertheless, in iron-rich environments, bacteria accelerate its growth by acquiring iron from the blood stream directly from transferrin, via transferrin receptors. Moreover, iron overload has been linked with impaired neutrophil and T cell functions, and immune subsequent dysfunction increases Gram-positive bacteria growth in vitro (Berman and Snyder, 2021; Li et al., 2017).

Nurses are the corner stone for observing, preventing and monitoring any improper safety non-adherence practices; owing to infection, over load, hypersensitivity, and further IV iron administration complications (NICE, 2015).

Significance of the study:

As the current researchers confronted the "absence" obstacle of worldwide conducted related researches; however this research will contribute by adding a new nursing assessment safety practices insight in relation to IV iron administration especially for HD patients,. Furthermore, this safety practices assessment study; will convey worthy evidence for future medicinal benefits and further research investigations. Consequently this study is very beneficial to assess the nurses' safety practices concerning intravenous iron administration for patients undergoing hemodialysis.

Aim of the study:

Assess the nurses' safety practices concerning intravenous iron administration for patients undergoing hemodialysis.

Research question:

What are the hemodialysis nurses' safety levels of practices concerning intravenous iron administration?

Materials & Method

Materials

Research design: A descriptive research design was utilized to attain the aim of the study.

Setting: The study was carried out at the hemodialysis unit, Alexandria Main University Hospital, Alexandria, Egypt. This setting was selected because of its willingness and approval flexibility for data collection; being a university hospital. Also it incorporates suppleness access for patients' records; besides adequacy of staff, time, and patients (around 20 beds for males and females) which attain the goal of three researchers' nurses' assessment throughout the IV iron administration procedure in a short period of time.

Sample: A convenient sample of all "50" male and female nurses working in hemodialysis unit.

Tool: One tool was used for data collection in this study

It is entitled as" The Hemodialysis Nurses' Intravenous Iron Administration Safety Practices Observational Checklist". This tool was developed by the researchers after thorough reviewing of related national and international literature, to collect necessary data required for attaining the aim of the study (Li, et al., 2017; Kalra and Bhandari, 2016; NICE, 2015). It comprised four parts as follows:

- Part I: included items related to the nurses' socio-demographic data such as: age, gender, marital status, job title, educational qualifications, years of experience, and previous safe IV iron administration training for hemodialysis patients.
- Part II: Nurses' practices concerning diagnosis of anemia, which consisted of four items related to assessing the nurses for checking: the level of serum HB, the presence of anemia signs and symptoms, the level of serum ferritin and the saturation level of transferritin.
- Part III: Practices concerning safe IV iron solution preparation, it clarified eleven items as: performing hand washing,

checking the sterilization and expiry date of supplies, handling the needle without touch the sterile parts, holding syringe in dominant hand, stabilizing ampule on a flat surface, inserting the needle into the center of the ampule, inserting the needle without touching the ampule's rim, wearing gloves, disinfecting the site with alcohol swab, wiping in a circular motion for 30 seconds as well as allowing the alcohol to dry for 30 second.

• Part IV: Practices concerning safe nursing IV iron administration procedure; which was subdivided into practices before administration, it comprised six sub-item related to checking the presence of: allergy or sensitivity reaction, comorbidities, asking the female patient if pregnancy, checking the patient name, dose, route, name, time of medication from the patient chart, checking vital signs before and administration and injecting the medication undiluted into the venous port of extracorporeal circuit not in the AV access. As regards to the safe practices during administration; it constituted three subitems as: observe for the manifestations of hypersensitivity for the first 30 min after every administration, continuously monitor the heart rate during and after injection and instruct the patient to report any symptoms of anaphylaxis. as well as the safety practices after IV iron administration, it composed of three sub-items that covers: observing the injection site for inflammation or infection, reporting any complication to the physician immediately and monthly checking the serum ferritin, HB, TSAT, serum hepacidin levels. Finally, four subitems assessing safety nurses practices if anaphylactic reaction develops as: stop the iron infusion, administer Epipen, document the medication name, dose, route, patient response, and report immediately to the physician.

Scoring system: Nurses' safety practice items responses, were scored on 3 points Likert scale as follows: Done correctly =2, Done incorrectly =1, and Not done = 0. The total items score was summarized and converted to a percent score. The satisfactory levels of performance were

scored as: >75 % score satisfactory, while \leq 75 % reflected unsatisfactory safety IV iron administration nursing practices.

Method

- Faculty of nursing, Research Ethical Committee's approval was obtained. Also, approval to conduct the study was attained from the responsible authorities of the Alexandria Main University Hospital, after explaining the study aim.
- 2. The developed tool content **validity** was tested by 5 professors, experts in the field of medical surgical nursing. Accordingly, all necessary modifications were done.
- 3. The tool was tested for its **reliability** using Cronbach_ Alpha Coefficient test, where the reliability was (r=0.818).
- 4. Thereafter, **pilot study** was carried out on 5 nurses who were excluded from study sample; to ensure clarity, applicability, and feasibility of the developed tool. However, modifications and omissions of some details were done.
- 5. The researchers observed the whole procedure of intravenous iron administration to attain data related to the safety nurses' practices performed in the three procedure's phases before, during and after, at the above mentioned setting. Each nurse was observed three times, and then the mean of these observations was calculated.
- 6. However, the recommended individualized intravenous iron supplement dose for each hemodialysis patient; was administered mixed and diluted in 100 mL of sterile 0.9% sodium chloride solution forming an iron-containing infusion, to be administered through a needle placed in a peripheral vein, during the hemodialysis session.
- 7. Each nurse's safety practices observation took the same average time for intravenous iron supplement infusion; ranging from 40 90 minutes / dialysis session.
- 8. Data collection: after securing the administrative approval, the data collection was started, and continued from a period from July to September 2020. The

- researchers were available for data collection at different times on morning and afternoon shifts.
- Ethical considerations: Nurses' formal
 consent to participate in the study was
 obtained from the department head nurse.
 Confidentiality and anonymity of
 participants; as well as their right to
 withdraw from the research at any time
 were ensured.

Statistical analysis:

Data was computerized using SPSS program version 18. However, *descriptive statistics:* were presented in the form of frequencies and percentages. *Analytical statistics*: Regarding P value was considered Significant if $P \le 0.05$, Highly Significant if $P \le 0.01$.

Results:

Table (1): shows that, the most common hemodialysis nurses' age ranged between 35 < 45 years; representing two third of the studied nurses (66.0%); nevertheless, the majority of the studied nurses representing (92.6%) was Regarding nurses' position female. qualifications; less than half of the studied nurses (40.0%) were secondary education diploma nurses, followed by technical nurses (Technical Institute Diploma), and nurse supervisors (Bachelor Degree nurse) with percentage of 36.0%, and 24.0% respectively. Furthermore, less than two third of the studied nurses had 20<30 years of experience (62.0%). Likewise, more than three quarters of nurses (78.0%) did not attend programs related to safety IV iron administration practices.

Table (2): Distribution of the studied nurses according to their safety practices level throughout IV iron administration: This table clarifies that; with respect to safety practices concerning diagnosis of anemia, the majority (90%) of nurses' had unsatisfactory practices with (56.87%) mean percentage score. On the other hand, all (100%) of the nurses had unsatisfactory practice level regarding intravenous iron infusion preparation with (34.64%) mean percentage score. Also, the same table reveals that all (100%) of the nurses had satisfactory practice prior and after

procedure of intravenous iron administration, while all (100%) of them had unsatisfactory level of practice during intravenous iron administration in case of anaphylactic reaction, with mean percentage score (91.67%, 1.33%, 25.00%) respectively. Finally, all (100%) nurses had unsatisfactory total practices concerning IV iron administration with a mean percentage score (52.17%).

This figure (1) illustrates that, the whole fifty studied hemodialysis nurses' overall safety of practice level in relation to the whole IV iron administration procedure, was unsatisfactory.

Table (3): The relationship between the studied nurses' socio-demographic characteristics and their IV iron administration safety practices mean scores: This table reveals that there was no statistically significant relation; in relating the studied nurses' safety practices throughout the IV iron administration procedure, to their socio-demographic characteristics.

Table (1): Distribution of the studied nurses according to their socio-demographic characteristics:

Nurses' socio-demographic characteristics	Total N=50				
	No.	%			
Age (years)	I	I			
- 25<35	11	22.0			
- 35<45	33	66.0			
- ≥45	6	12.0			
Gender					
- Male	4	8.0			
- Female	46	92.0			
Nurses' position & qualifications	Nurses' position & qualifications				
- Diploma (Secondary School Diploma) nurse	20	40.0			
- Technical (Technical Institute Diploma) nurse	18	36.0			
- Supervisor (Bachelor degree) nurse	12	24.0			
Years of experience since graduation					
- 10<20	13	26.0			
- 20<30	31	62.0			
- ≥30	6	12.0			
Previous training programs attendance related to safety IV iron administration practices.					
- No	39	78.0			
- Yes	11	22.0			
Frequency of training	N=11				
- Once	1	9.1			
- Twice	6	54.5			
- Three times and more	4	36.4			

Table (2): Distribution of the studied nurses according to their safety practices level throughout IV iron administration:

iron administration:							
Safety practices		Done correctly		Done incorrectly		Not done	
	No %	%	No	%	No	%	
1. Check the level of serum HB (more than 110/dl)	50	100%	0	0%	0	0%	
2. Check the presence of anemia signs and symptoms	24	48%	26	52%	0	0%	
3. Check the serum ferritin level (less than 100 microgram/L)	4	8%	46	92%	0	0%	
4. Check the level of Transferritin saturation (less than 20%)	0	0%	0	0%	50	100%	
Over score regarding diagnosis Unsatisfactory	45	90.0%	Mean Percentage score			score	
Satisfactory	5	10.0%	56.87%				
practices concerning safe preparation (to reduce infection	n):						
1. Wash hands.	18	36%	26	52%	6	12%	
2. Check sterilization and expire date of supplies.	0	0%	0	0%	50	100%	
3. Properly handle the needle without touch the sterile parts	0	0%	40	80%	10	20%	
4. Hold syringe in dominant hand.	50	100%	0	0%	0	0%	
5. Stabilize ampule on a flat surface.	0	0%	0	0%	50	100%	
6. Insert the needle into the center of the ampule.	50	100%	0	0%	0	0%	
7. Do not allow the needle to touch the rim of the ampule.	0	0%	13	26%	37	74%	
8. Wear gloves.	16	32%	0	0%	34	68%	
9. Disinfect the site with alcohol swab.	29	58%	0	0%	21	42%	
10. Wipe in a circular motion for 30 seconds.	0	0%	0	0%	50	100%	
11. Allow the alcohol to dry for 30 second.	0	0%	0	0%	50	100%	
Over score regarding practices concerning safe preparation • Unsatisfactory	50	100%	Mean Percentage score			score	
Satisfactory	0	0%	34.64%				
Practices concerning risks of iron administration (monitoring	ng of a	dverse eve	ents with iron administration):				
a- Regarding safety practices prior IV iron administration						,	
	No	%	No	%	No	%	
Check for the presence on allergy or sensitivity reaction	50	100%	0	0%	0	0%	
2. Check for presence of comorbidities	0	0%	50	100%	0	0%	
3. Ask the female patient if pregnancy is present	50	100%	0	0%	0	0%	
4. Check the patient name, dose, route, name, time of medication from the patient chart.	50	100%	0	0%	0	0%	
5. Check the vital signs before and after administration.	50	100%	0	0%	0	0%	
6. Inject the medication undiluted into the venous port of extracorporeal circuit not in the AV access	50	100%	0	0%	0	0%	
Over score Regarding safety practices prior IV iron administration • Unsatisfactory	0	0%	Mean Percentage score			score	
Satisfactory	50	100.0	91.67%				
b- Safety nurses' practices during Iv iron administration							
y	No	%	No	%	No	%	
Observe for the manifestations of hypersensitivity for the first 30 min after every	0	0%	4	8%	46	92%	
administration		00/	0	00/	50	1000/	
Continuously monitor the heart rate during and after injection	0	0%	0	0%	50	100%	

Safety practices	Done correctly		Done incorrectly		Not done	
	No	%	No	%	No	%
Instruct the patient to report any symptoms of anaphylaxis	0	0%	0	0%	50	100%
Over score Regarding Safety nurses' practices during Iv iron administration • Unsatisfactory	50	100%	Mean Percentage score			
• Satisfactory	0	0%	1.33%			
c- Regarding safety practices after IV iron administration	n					
Observe the injection site for inflammation or infection	50	100%	0	0%	0	0%
Report any complication to the physician immediately.	0	0%	50	100%	0	0%
Monthly check the serum ferritin level, HB, TSAT, serum hepacidin	50	100%	0	0%	0	0%
Over score Regarding safety practices after IV iron administration • Unsatisfactory	0	0%	Mean Percentage score			
Satisfactory	50	100%	87.50%			
d- Regarding safety practices during IV iron administrat	ion an	aphylacti	c reacti	on (if oc	cur):	
Stop the iron infusion	0	0%	50	100%	0	0%
2. Administration of Epipen	0	0%	0	0%	50	100%
Document the medication name, dose, route, patient response	0	0%	50	100%	0	0%
4. Report immediately to the physician.	0	0%	50	100%	0	0%
Over score Regarding safety practices during IV iron administration anaphylactic reaction • Unsatisfactory	50	100%	Mean Percentage score			
Satisfactory	0	0%		52.	17%	
Total Nurses' Safety Practice concerning IV Iron Administration Procedure • Unsatisfactory	50	100%	Mean Percentage score			
Satisfactory	0	0%		52.	17%	

Figure (1) overall nurses' safety practices level regarding IV iron administration procedure:

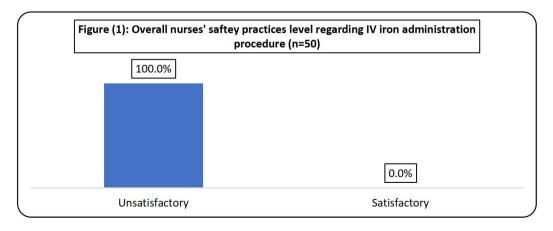


Table (3): The relationship between the studied nurses' socio-demographic characteristics and their IV iron administration safety practices mean scores:

Nurses' Socio-demographic data (n=50)	Safety IV iron administration practices Mean ± S. D	Test of significance			
Age					
- 25<35	31.45±1.916	F=1.562			
- 35<45	31.45±1.583	P=0.220			
- ≥45	30.17±1.722				
Gender					
- Male	32.25±1.500	t= 1.379			
- Female	31.22±1.698	P=0.246			
Nurses' position & qualifications					
- Diploma (Secondary School Diploma) nurse	30.75±2.340	F= 1.057			
- Technical (Technical Institute Diploma) nurse	31.30±1.328	P=0.355			
- Professional (Bachelor) nurse	31.67±1.325				
Years of experience since graduation					
- 10<20	31.46±2.025	F= 1.562			
- 20<30	31.45±1.502	P=0.220			
- ≥30	30.17±1.722				
Previous training programs attendance related to safety IV iron administration practices.					
- No	30.64±1.963	t= 2.220			
- Yes	31.49±1.587	P=0.143			
Frequency of training					
- Once	30.00±1.788	F= 1.400			
- Twice	31.00±1.693	P=0.255			
- Three times and more	31.50±2.380				

F= ANOVA TestT= Student T Test * statistically significant at ≤0.05

Discussion:

Considering the lack of theoretical framework, guidelines and comparative results in this area of specified hemodialysis nursing safety practice; thus this research is considered an innovative and a pioneer building block of nursing science. Likewise, the current study researchers found it a crucial opportunity to explore new gaps in the existing literature and to convey the need for further study in the area. So, the present study meant to assess the safety nurses' practices toward intravenous iron administration procedure for patient undergoing hemodialysis.

However, patients undergoing maintenance hemodialysis (HD) usually have a negative iron balance owing to reduced absorption and increased blood loss. In addition, several studies showed that; 12% of CKD patients develop anemia, as well out of 13,249 studied patients; 1627 (12%) had one or more related infection during the 4-month follow-up during hemodialysis IV iron administration. In this respect, safety during its administration is mandatory in HD patients

(Xiaojuan et al., 2019; Akel et al., 2017; Del Vecchio & Locatelli., 2017).

Thus. intravenous iron replacement therapy has become standard care in CKD patients' anemia management for many years (Macdougall et al., 2020; Batchelor et al., 2020; Kalra & Bhandari, 2016). Hence, several studies reported the adverse effects and reactions accompanies IV iron administration, therefore the current study researchers found it is necessary to highlight and emphasize the role of nurse in maintaining and monitoring safety practices; to prevent IV iron administration complications thru the management for patients with CKD anemia. (George & McCann., 2020; Agarwal., 2017; Bailie et al, 2013).

Mitka (2010) clarified that; when nurses administer IV irons infusion must be knowledgeable about way of assessment and monitoring its side effect to ensure patients' safety. Moreover, Fadili et al., (2016) assessed the shortcomings in the clinical practice of nurses working in different Moroccan dialysis centers. They clarified that; renal IV iron replacement therapy is considered a routine procedure, but nevertheless remains at high-

risk of technical errors and complications that requires skillful and a decision maker nursing staff.

In this respect the result of the current study declared that, the overall nursing practices regarding IV iron administration were not correctly done by the majority of nurses; also, the overall safety IV administration practices level were un-satisfactory. This might be due to that the shortage of nursing staff in the hemodialysis unit with multiple task role, as well this may be related to; the higher percentage of nursing educational qualifications was diploma and technical nurse; with 20<30 years of experience. Likewise, about two thirds of nurses age ranged from 35> 45 years, declaring that a majority of them did not attended patients' safety training program regarding IV iron administration.

In spite the difficulties confronted the researchers in finding related articles for comparing their present study result; a study by **Elkattan**, (2013), **Shafik and Abd Allah**, (2015) was contradicting the present study results declaring that; more than two thirds of their total study sample, had <10 years of experience. This might be due to that, the most common age of the studied nurses is in the age group ranging between 18 < 30 years. On the other hand it is in line with **Elewa and Elkattan.**, (2017) who stated that, 73.3% of their hematology nurses had nursing diploma with <5 years of experiences.

Moreover this IV iron administration unsatisfactory nursing safety practices agreed with Alomar, (2012); and Deborah and Corcoran, (2011) who stated; near two thirds of the study nurses had unsatisfactory practice regarding management of patients' blood transfusion, also with Shafik & Abd Allah, (2015) who reported that; the majority of nurses didn't perform blood transfusion procedure accurately.

Furthermore Fadili et al., (2016), and George & McCann, (2020) concluded that; renal IV iron replacement therapy is currently considered a routine procedure, nevertheless it remains at high-risk of technical errors and complications that requires skillful and a decision maker nursing staff. This goes with the result of the current study, where the majority of nurses were in-correctly monitoring and managing patients 'anaphylactic reactions. As well the

entire nurses were incorrectly documenting data concerning IV iron administration.

safetv These unsatisfactory nursing practices may be also owed to; the lack of training programs concerning safe IV iron administration during hemodialysis, defining and managing its adverse events. However it was challenging to cite studies comparing similar results; however a study by Elewa and Elkattan, (2017) in the field of blood transfusion supported the presented study rational and declared that, 70.0% of nurses didn't receive training related to transfusion. However their study affirmed that; educational program had a positive effect on nurses' knowledge and practice related to thalassemia and blood transfusion, which improved quality of nursing care, and increased patients' satisfaction. They also recommended the development of a specialized orientation program for newly appointed nurses in such highly sensitive departments.

Conclusion and recommendation:

It was noted that the level of hemodialysis nurses' practices concerning safe administration of intravenous iron were unsatisfactory in various procedure administration aspects of assessment.

Through this research signifies the importance of academic institutions and administrators to collaborate for developing educational programs and nursing standard concerning safe intravenous iron administration.

Moreover, the research results highlights the urgent need for encouraging the hemodialysis nurses to attend in-service training programs; in order to improve the quality of patient care, which in turn affects positively health outcomes. However, future researchers need to be conducted to revise this specific study tool utilized for data collection.

Limitation of the study:

Lacking of research resources discussing comparable study results conducted in the field of hemodialysis nurses' IV iron administration safety practices; being a new area of research practice; in addition to the small size of the sample.

Conflict of interest:

None declared.

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