

## EFFECT OF INTERVENTION PROGRAM ON NURSES' PERFORMANCE REGARDING GENE THERAPY PREPARATION AND ADMINISTRATION FOR CHILDREN

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### Abstract:

Gene therapy is a complex process usually requiring the preparation of the medicine in the clinical areas before administration to the paediatric patient to prevent harm and perform paediatric patient safety. **Aim:** This study aimed to evaluate the effect of intervention program on nurses' performance regarding gene therapy preparation and administration for children. **Research design:** A Quasi-experimental research design was utilized to fulfil the aim of this study. **Sampling:** A convenience sample of 79 nurses, working in gene therapy unit. **Tools:** Three tools were used in this study for data collection, **First tool:** A self-administered questionnaire divided into two parts: Part I demographic characteristic data for children & nurses, Part II nurses knowledge regarding gene therapy. **Second tool:** Observation checklist to assess nurses' performance regarding gene therapy preparation and administration. **Third tool:** Likert attitude scale to assess nurses' attitude regarding gene therapy preparation and administration. **Results:** Showed there was a high statistically significant difference in the total knowledge scores among studied nurses regarding gene therapy preparation and administration (pre-post program) implementation, Mean and Standard deviation of the studied nurses' total score of practice regarding gene therapy were  $14.76 \pm 3.32$  pre-program compared with  $42.03 \pm 3.68$  post program implementation, there was a high statistically significant difference in the total attitude scores among studied nurses regarding gene therapy preparation and administration (pre-post program) implementation. **Conclusion:** The intervention program about gene therapy preparation and administration had a positive effect on Nurses' performance, mean while there was increase in the level performance (knowledge, practice and attitude) post program implementation compared with pre-program implementation. **Recommendations:** An orientation program should be prepared to help the newly Nurse's to revise, acquire and develop the knowledge and Practice regarding Preparation and administration of gene therapy.

**Keywords:** gene therapy Unit, Intervention Program, Nurses Performance

### 1. INTRODUCTION

Genetic disorders are ailments brought on by one or more mutations in the genome. These diseases are good candidates for gene editing or gene therapy, which are medical interventions aimed at restoring the normal function of the defective gene. Gene editing modifies the genome at

a precise site to fix or change the genetic sequence, whereas gene therapy does this by introducing a proper copy of the gene into the genome of the target organ or tissue **(Elnegamy et al., 2021)**.

Treatment for hereditary diseases through gene therapy involves giving a patient genetic material that changes the way cells operate. Gene delivery vehicles known as vectors are essential for ensuring effective gene delivery of the therapeutic gene to the target tissue or cells. Viral and non-viral vectors are the two different categories. As follows are the four fundamental gene therapy techniques: A patient's genome can be permanently altered through gene editing, gene silencing, gene addition, overexpression of an exogenous or "foreign" gene that affects cellular function, gene replacement, or the delivery of a functional gene to replace a non-working gene **(Mendell et al., 2021)**.

Genetic disease leading to muscle atrophy and weakness. Pediatric Patients have difficulty moving, breathing, swallowing, speaking, and walking, Spinal muscle atrophy affects approximately 1 in 11, 000 live births worldwide, ~1 in 54 people carry the genetic defect, When both parents are carriers, their baby has a 25% chance of having SMA1, One disease with one root cause. Range of severity divided into three types Never achieves sitting, Sitting; never achieves walking independently, Walking; may lose ability to walk **(National Organization for Rare Disorders, 2020)**.

Medical experts, nurses, and others are involved in the safe preparation and administration of licensed gene treatments. If the institutions are planning to administer any approved gene therapy products, we advise clinical pharmacists to take the lead in creating clinical biosafety committees. Additionally, we suggest that the following roles be represented in a committee that develops appropriate safe handling procedures: waste services, biosafety officer or environmental health officer, pharmacist, physician, nurse, and occupational health officer. We also suggest that each institution hire a nurse with expertise in gene treatments as more of them are authorized and put into practice **(Aronson et al., 2019)**.

The nurse is the important part of the healthcare team in practicing standard precaution to protect the pediatric patient from infection. Some of the most universal precaution resulting in positive outcomes include hand hygiene, aseptic technique, optimal use of personal protective equipment, cleaning and disinfection, use of standard precautions, patient assessment and additional precautions, patient education, use of safety devices, Apply bundle strategies for infection prevention **(Chen et al., 2020)**.

Staff involved in the handling and administration of gene therapy must be trained on the handling and administration and; All administration care, including requirements for Personal Protective Equipment (PPE), should follow standard clinical care practices, unless it is nominated that additional safeguards are necessary to protect pediatric patients, staff and the environment **(Mahadeo et al., 2019)**.

**Significant of the study:**

Recently, Egypt's President spoke about the country's efforts to treat children suffering from major chronic illness as (muscle atrophy) and said 204 muscle atrophy cases had been detected in Egypt. So the role of a nurse in gene therapy is very important for patient safety, improving health standards and also for coordination of the whole study of gene therapy. In many cases, research nurses are the ones who are directly involved with pediatric patients and administration of the therapy. Hence, they need to be updated about theoretical and practical knowledge in this field (Perry et al., 2022).

Gene therapy preparation and administration should be done carefully and without any mistake, gene therapy nurse must be vigilant in avoiding disruptions to the process of administering gene therapy, which should be as error-free as possible. Errors in the administration of gene therapy are common on the unit, therefore patient safety needs to be a top priority (National Institute of Neurological Disorders and Stroke, 2020).

Therefore, the researchers found that is very important to evaluate nurses' performance about gene therapy preparation and administration to determine the gaps, errors. They need to be well educated and practically skilled in managing their pediatric patients to avoid any problems associated with gene therapy preparation and administration. So there is a prominent need to share in the improvement performance of nurses.

#### **Aim of the Study:**

This study aimed to evaluate the effect of intervention program on nurses' performance regarding gene therapy preparation and administration for children through:

- 1- Assessing nurses' knowledge, practice and attitude regarding gene therapy preparation and administration for children.
- 2- Designing and implementing intervention programs on nurses' knowledge, practice and attitude regarding gene therapy preparation and administration for children.
- 3- Evaluating the effect of intervention program on nurses' knowledge, practice and attitude regarding gene therapy preparation and administration for children.

#### **Research hypotheses**

The intervention program will improve the nurses' performance regarding gene therapy preparation and administration for children.

**Gene therapy:** Involves the transfer of genetic material into a cell, tissue, or whole organ, with the goal of curing a disease or at least improving the clinical status of a patient.

**Performance:** Knowledge, Practice and Attitude.

#### **Subjects and Methods**

**The present study was carried out through:**

- I- Technical design.
- II- Operational design.

III- Administrative design.

IV- Statistical design.

1- **Technical design:** Included Research design, Research settings, research subject and Tools of data collection

**Research design:**

A Quasi-experimental research design was utilized to fulfill the aim of this study.

**Research Setting:**

The study was conducted in Gene Therapy Unit at Ain Shams Specialized Hospital; Affiliated to Ain Shams University Hospital, Cairo Governorate.

**Research Subject:**

**Sample size and characteristics:**

A convenience sample of 79 nurses who were worked of the previously mentioned setting during the study duration and all of them agree to participate in the study.

**Tools of data collection:**

Three tools were used in this study which designed after reading related literature and taking expert's and supervisors' opinion, and written in Arabic language. It used twice (pre-post)intervention program.

**First tool:** A self-administered questionnaire: This tool contains of two parts as follow.

Part I: It was used to assess demographic characteristic data of the studied subjects

A- children: as age, sex, family number, Ranking, history of the disease.

B-Nurses characteristics as age, sex, qualification, Job and years of experience.

Part II: It was used to assess Nurses' knowledge regarding gene therapy (Definition, type, importance, complication, type of vector, uses of gene therapy, Route and Method of gene therapy administration, Store system, Prednisolone doses, best way for administration, side effect, precaution during and after administration), gene therapy preparation and administration for children. It was developed by the researcher based on **Bitettiet al. (2022) and Chand et al. (2021)** included (37) questions. This data were collected Pre & Post the program.

**Scoring system**

This tool was answered by the nurses within (30) minutes, then a scoring system were followed to obtain the outcome of nurses' knowledge. Nurse's answers were checked by using a model key answer. Related to nurses knowledge assessment a satisfactory answer scored one and unsatisfactory answer scored zero. Except for questions (No. 2, 4, 14, 17, 19, 23, 24, 26, 34 &35) give 1 mark for more than50%correct answer and less than50%scored zero. The whole knowledge questions scored37points for each area of knowledge, a total of 70% and above were considered satisfactory and less than 70% were considered unsatisfactory.

### **Second tool:** Observation checklists (Pre and Post)

Observation checklists was adopted from **WHO (2020)** and **Schwartz et al. (2021)**

It was used to assess nurses' practice regarding gene therapy preparation and administration. It contained the nurses' practices in seven procedures; hand hygiene, PPE, storage of Supplies / medications, medication preparation, medication administration, environmental safety, waste management. It was Include (42) questions. This data were collected Pre & Post the program.

#### **Scoring system**

Nurses' Practice was assessed individually by the researcher through checklist The items observed to be done were scored one and the items not done were zero within(60) minutes. For each area the scores of the item were summed-up and the total divided by the number of the items, giving a mean score for the part. These scores were converted into percent scores. The practice was considered competence if the percent score was  $\geq 95\%$  and incompetence if  $\leq 95\%$ .

### **Third tool:** Likert Attitude scale

This scale was adopted from **Elhusein et al. (2015)** and included 15 items in order to assess the attitude of the nurse toward gene therapy preparation and administration for children at Ain shams specialized hospital

#### **Scoring system**

Nurse's responses classified as "agree", "Uncertain", "disagree" and respectively scored 3, 2, and 1. The scores of the items summed up and converted into percentage scores. Then all data classified into two categories:

- Positive attitude if score  $\geq 70\%$
- Negative attitude if score  $< 70\%$

### **I-Operational Design:**

#### **Content validity**

Content validity was done for the tools by 5 experts from staff in Pediatric nursing Staff and infection control Staff at Ain Shams University to face and content validation.

#### **Reliability**

By using Cronbach Alpha coefficient test which revealed that tool consisted of relatively homogenous items as indicated by the moderate to high reliability of each tool.

#### **Pilot Study:**

It was carried out on a nurses working in gene therapy unit to test applicability and time available to collect data of the tools then the necessary modifications will be done according to the result of pilot study and will carried out on 7 nurses whom are excluded later from the study sample.

#### **Field Work:**

- The researcher revised the literature to design the tools and the tools will revise from expertise to test the content validity.

- Approval was obtained from the concerned authorities in the faculty of nursing.
- The researcher interviewed the nurses one day per week each interview will take about 30 minutes to fill it after taking Written informed consent from them

### **Program Construction:**

The present study was conducted in three phases:

#### **First, preparatory phase:**

Prior to designing the study tools, a review of recent, current, national, and international literature pertaining to various aspects of the problems was conducted. Based on the data collected on the nurses' knowledge and practice regarding the preparation and administration of gene therapy for children, a pretest was used to assess the needs of the nurse.

**Second phase:** The program was developed and implemented in this phase under the following

**Course duration:** Total hours of program for each group: 12hrs, 4 hours for total theoretical part every session was done in one hour, and 8 hours for practical part every session was done in one hour).

- **Place:** gene therapy unit.
- **Language:** The program was conducted in Arabic language.
- **Teaching methods:** lectures, demonstration-re-demonstration, role play and group discussion
- **Teaching media:** booklet, pictures, posters.
- **Resources and equipment:** Using available equipment and the material were prepared by the researcher.

#### **The program content included:**

- 1- Nurses' knowledge regarding gene therapy (mean, type, importance, complication type of vector, uses of gene therapy, Route and Method of gene therapy administration, Store system, Prednisolone doses, best way for administration, side effect, precaution during and after administration), gene therapy preparation and administration for children.
- 2- Demonstrate the practice, including, the performance of staff nurses in gene therapy unit which include: A- preparation of gene therapy; B- Administration of gene therapy; C- Care after administration of gene therapy.

#### **Third phase:**

- **Evaluation phase:** This phase was done to evaluate the effect of intervention program on nurses' performance regarding gene therapy preparation and administration for children at previously mentioned setting. A post –test was done to the nurses after accomplished the intervention of the program.
- program based on conducting session plan using different educational methods and media in addition to the use of guiding booklet specially designed and developed based on nurses

assessment needs implementation of the program took six months through visited the pre mentioned setting one days /week, one hours /day (8:30-9:30) and sometimes from (1.30pm-2.30pm) number of hours different from one session to another to accomplish program session and practices training, session was conducted in gene therapy unit.

### **Ethical Considerations:**

Approval was taken from the Ethical Research committee of faculty of nursing, Ain Shams University before starting the study. Agreement of nurses to participate in the study after explaining the aim of the study. Anonymity and confidentiality & freedom to withdraw from the study at any time were assured. Then oral and written approval obtained from nurses to apply the study.

**II. Administration Design:** An official approval letter was taken from the faculty of Nursing – Ain Shams University to the general manager of previously mentioned setting to facilitate in conducting the study.

**III. Statistical Analysis:** The obtained finding was analyzed by appropriate statistical methods and tests of significance and then will be presented in tables

### **Results**

**Table (1):** shows the distribution of the nurses according to their demographic data for nurses age highest percent was (38%) for the age group (30 < 40) years and lowest percent (7.6%) for age group ( $\geq 50$ ), the mean age was  $37.41 \pm 6.36$  In relation to the majority of the nurses gender was female (88.6%). The level of education analysis of data pointed out that highly percentage (94.9%) for Nursing Institute graduate. As for experiences (77.2%) of nurses had expert  $\geq 10$  years in providing care for children. (77.2%) of the nurses did not have training sessions about gene therapy.

**Table (2):** This table shows that 45.5% of studied children were in the age group **9 < 12 months** and 18.2% were in the age group **1 year < 2 years** while 59.1% of them are male, 59.1% of them were arranged as 2nd child in their family.

**Table (3):** Showed there was a high statistically significant difference in the total knowledge scores among studied nurses regarding gene therapy preparation and administration pre – post program

**Table (4)** Showed there was a high statistically significant difference in the total practice scores among studied nurses regarding gene therapy preparation and administration pre – post program

**Table (5):** This table shows that there is a statistical significant relation between age, years of experience, training course of studied nurses regarding gene therapy and their demographic data. While there is no statistical significant difference with other else of nurses' characteristics.

**Table (1):** Distribution of the studied nurses regarding their demographic data (n=79).

<b>Demographic data</b>	<b>No.</b>	<b>%</b>
<b>Age (years)</b>		
<20 years	0	0.0
20 < 30years	18	22.8
30 < 40years	30	38.0
40 < 50years	25	31.6
≥50 years	6	7.6
<b><math>\bar{X} \pm SD</math></b> 37.41±6.36		
<b>Gender:</b>		
Male	9	11.4
Female	70	88.6
<b>Qualifications:</b>		
Technical nursing Institute	75	94.9
Bachelor of nursing	4	5.1
Postgraduate	0	0.0
<b>Job</b>		
Nurse	75	94.9
Head nurse	4	5.1
<b>Years of experience:</b>		
1-<5 years	0	0.0
5-<10 years	18	22.8
≥10 years	61	77.2
<b>Training course of sessions on Gene therapy</b>		
Yes	18	22.8
No	61	77.2

**Table (2):** Distribution of the studied children regarding their characteristics (n=22).

<b>Children's Characteristics</b>	<b>No</b>	<b>%</b>
<b>Age (years)</b>		
At 6 months	2	9.1
6 < 9 months	3	13.6
9 < 12 months	10	45.5
1 1 year < 2 years	4	18.2
≥ 2 years	3	13.6
<b><math>\bar{X} \pm SD</math></b>		1.10±0.30
<b>Gender:</b>		
Male	13	59.1
Female	9	40.9



**Family member**

2-<4	22	100.0
4-<6	0	0.0
6-<8	0	0.0

**Ranking**

1 <sup>st</sup>	5	22.7
2 <sup>nd</sup>	13	59.1
3 <sup>r</sup> 3 <sup>th</sup>	4	18.2

**Table (3):** Percentagedistribution of the studied nurses' total score of knowledge regarding gene therapy for children (pre & post Nursing Intervention) (n=79).

Nurses' Knowledge	Pre Intervention				Post Intervention				Chi-square test	
	Satisfactory >70%		Unsatisfactory <70%		Satisfactory >70%		Unsatisfactory <70%		$\chi^2$	P-Value
	No.	%	No.	%	No.	%	No.	%		
Definition of gene therapy	13	16.5	66	83.5	66	83.5	13	16.5	52.215	<0.001**
Preparation of gene therapy	14	17.7	65	82.3	72	91.1	7	8.9	62.413	<0.001**
Administration of gene therapy	11	13.9	68	86.1	72	91.1	7	8.9	55.314	<0.001**
Care after administration of gene therapy	7	8.9	72	91.1	72	91.1	7	8.9	83.613	<0.001**
Level of Total knowledge	11	13.9	68	86.1	71	89.9	8	10.1	49.386	<0.001**

**Table (4):** Percentagedistribution of the studied nurses' total practice regarding gene therapy preparation and administration (Pre & Post Nursing Intervention) (n=79).

Practice	Pre Intervention				Post Intervention				Chi-square test	
	Correct $\geq 60\%$		Incorrect <60%		Correct >60%		Incorrect <60%		$\chi^2$	P-Value
	No.	%	No.	%	No.	%	No.	%		
Hand hygiene	33	41.8	46	58.2	77	97.5	2	2.5	38.295	<0.001**
PPE	19	24.1	60	75.9	75	94.9	4	5.1	72.193	<0.001**
Storage of supplies / medications	30	38	49	62	77	97.5	2	2.5	45.235	<0.001**
Medication preparation inside Laminar Flow	27	34.2	52	65.8	77	97.5	2	2.5	62.683	<0.001**

Medication administration	20	25.3	59	74.7	79	100	0	0	73.261	<0.001**
Environmental safety	23	29.1	56	70.9	77	97.5	2	2.5	65.296	<0.001**
Waste Management	28	35.4	51	64.6	79	100	0	0	75.261	<0.001**
Total	26	32.9	53	67.1	77	97.5	2	2.5	61.746	<0.001**

**Table (5):** Relation between nurses knowledge regarding gene therapy according to their demographic data (N=79).

Demographic data	Pre Intervention (n=79)				Post Intervention (n=79)				
	Satisfactory (n=11)		Unsatisfactory (n=68)		Satisfactory (n=71)		Unsatisfactory (n=8)		
	No.	%	No.	%	No.	%	No.	%	
<b>Age (years)</b>									
20-29 years	4	36.4	14	20.6	10	14.1	8	100.0	
30-39 years	3	27.3	27	39.7	30	42.3	0	0.0	
40-49 years	4	36.4	21	30.9	25	35.2	0	0.0	
≥50 years	0	0.0	6	8.8	6	8.5	0	0.0	
<b>Chi-square test (x<sup>2</sup>)</b>	2.480				30.166				
<b>p-value</b>	0.479				<0.001**				
<b>Gender:</b>									
Male	0	0.0	9	13.2	8	11.3	1	12.5	
Female	11	100.0	59	86.8	63	88.7	7	87.5	
<b>Chi-square test (x<sup>2</sup>)</b>	1.643				0.011				
<b>p-value</b>	0.200				0.917				
<b>Qualifications:</b>									
Nursing Diploma	8	72.7	51	75.0	53	74.6%	6	75.0	
Technician nursing Institute	3	27.3	13	19.1	14	19.7%	2	25.0	
Bachelor of nursing	0	0.0	4	5.9	4	5.6%	0	0.0	
<b>Chi-square test (x<sup>2</sup>)</b>	0.965				0.550				
<b>p-value</b>	0.617				0.760				
<b>Job</b>									
Nurse	11	100.0	64	94.1	67	94.4	8	100.0	
Head nurse	0	0.0	4	5.9	4	5.6	0	0.0	
<b>Chi-square test (x<sup>2</sup>)</b>	0.682				0.475				
<b>p-value</b>	0.409				0.491				
<b>Years of experience:</b>									
5-<10 years	4	36.4	14	20.6	10	14.1	8	100.0	
>10 years	7	63.6	54	79.4	61	85.9	0	0.0	

<i>Chi-square test (<math>\chi^2</math>)</i>	1.339	30.166
<i>p-value</i>	0.247	<0.001**
<b>Training course</b>		
Yes	5    45.5    13    19.1	18    25.4    0    0.0
No	6    54.5    55    80.9	53    74.6    8    100.0
<i>Chi-square test (<math>\chi^2</math>)</i>	1.771	7.627
<i>p-value</i>	0.152	<0.001**

#### 4. DISCUSSION

Our study showed that most of the studied nurses (77.2%) had  $\geq 10$  years of experience compared to **Fathy et al. (2020)** study which demonstrated the highest percentage of nurses constituted (96.7%) had from (1-3) years of experience working. Also **Zyoud et al. (2019)** reported that most nurses had only 5–10 years of total experience.

Regarding the nurse's qualification, most of study nurses (94.9%) graduated from the technical institute which is similar to **Fathy et al. (2020)** results which showed that more than half of included nurses had graduated from a technical institute degree in nursing. This may be explained by the little number of faculty graduates employed in the university hospital and other work in schools or the ministry of Health hospitals.

The a recent study, it was found that more than half of the study subjects (77.2%) didn't have any training or education programs before, other studies have indicated medication errors to be the result of lack of in-service training and inadequate knowledge of nursing graduates, and that a lack of pharmacological knowledge other important cause of medication errors (**Cheragi et al. 2013; Cloete 2015**).

The current study revealed that 45.5% of studied children were in the age group 9<12 months and 18.2% were in the age group 1 year < 2 years which is similar to **Waldrop et al. (2020)** results which showed that In children  $\leq 6$  months, gene transfer was well tolerated. In this young group and Food and Drug Administration approved given zolgenezma on May 24, 2019, for any patient age <2 years without end-stage disease.

In our study, the nurse's knowledge regarding gene therapy administration and use of medication showed significantly high un satisfaction results before the intervention program compared to high satisfaction results after the intervention program. A similar result was shown in **Fathy et al. (2020)** study as the knowledge level regarding medication administration errors was unsatisfactory. This may be due to inadequate training in the area and the new era of this type of medication. In line with these results, a study conducted at Helwan University Hospital reported that greater than half of the studied sample had incomplete satisfactory information regarding the knowledge of the preparation of medication (**Abdel-Fattah et al., 2019**).

The current study contraindicated with **Kaur and Charan (2018)** who reported that almost two thirds of nurses were on average knowledge followed by less than one-third of them having poor score levels. **Liu et al. (2011)** study found that the knowledge regarding gene therapy in

medical staff was related to cancer therapy only. In previous studies, we found that the stage of cancer had an impact on the attitude of medical staff to the utility of gene therapy (**Jiang et al. 2007; 2006; Li et al. 2008**).

This could be explained by that in Egypt, gene therapy is still in its early stages of development. There are a few clinical trials underway to assess the safety and efficacy of gene therapy for various pediatric conditions. However, gene therapy is not yet widely available in Egypt (**Temtamy and Hussien, 2017**).

## 5. CONCLUSION

Based on the findings of the current study it was concluded that the intervention program about gene therapy preparation and administration had a positive effect on Nurses' performance, meanwhile there was increase in the level performance (knowledge, practice and attitude) post program implementation compared with pre-program implementation.

## 6. RECOMMENDATIONS

The findings of this study highlight the following recommendations:

1. Continuous evaluation of nurses 'knowledge and practice is essential to identify their needs in gene therapy unit about caring pediatric patient with spinal Muscle atrophy.
2. An orientation program should be prepared to help the newly graduated Nurse's to revise, acquire and develop the knowledge and Practice regarding Preparation and administration of gene therapy.
3. Availability of all facilities, materials and of written guidelines required for applying standard precautions of infection control.
4. Replications of the study on larger subjects selected from different Geographical areas of Egypt are recommended.

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