

Effectiveness of the Validated Clinical Nursing Protocol for Vaccination Process Management

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Abstract Background: In Egypt, the routine training of the vaccinator nurses is not a part of ministry of health and population' continuous educational system. While, this system provides only short educational seminars for vaccinators, which are insufficiently control daily vaccinators' practice variation. Thus, the study aimed at providing a referenced protocol for vaccination process management after evaluating its effectiveness on the vaccinator nurses' knowledge and practices regarding obligatory childhood vaccination. **Aim:** This study aimed to evaluate the effectiveness of the validated clinical nursing protocol for vaccination process management. **Method:** A Quasi-experimental research design was utilized from the first of January 2020 to the end of December 2020 at Mansoura district primary health care facilities. Total sample size of 160 vaccinator nurses, as well as, 384 caregivers chosen by using convenient sampling technique. Data were collected by using three tools; self-administrated vaccinator nurses' knowledge test; observation checklist for evaluating vaccinator nurses' practice; and checklist to assess caregivers' satisfaction related to the delivered vaccination services. **Results:** Mean scores for vaccinator nurses' knowledge, and practice, as well as caregivers' satisfaction post-protocol were significantly higher than the pre-protocol mean scores. A huge effect size of the vaccination protocol on the three targeted study outcomes was also observed. **Conclusion:** the validated vaccination protocol was fundamental in the skills' acquisition of vaccinator nurses; variation reduction of vaccination practice; and enhancement of caregivers' satisfaction. **Recommendations:** More in-service training and supportive supervision are requested for vaccinator nurses to effectively manage vaccination process. Furthermore, there is a need for including of a vaccination-training curriculum in health training institutions curriculums.

Keywords: vaccination process, protocol, vaccinator nurses, knowledge, practice, caregivers' satisfaction

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1. Introduction

Vaccination represents one of the most effective and secure means public health intervention for preventing infectious diseases among children. Vaccination induces reduction in mortality and morbidity rates that profoundly changed the epidemiology of infectious diseases [1].

To comply with the Egypt's 2030 vision, which targets 100% childhood vaccination coverage. Vaccinator nurses within primary health care must deliver a variety of vaccination services either as a part of multidisciplinary team or independently. Having a skilled, confident, and competent vaccination workforce is needed to meet primary healthcare accreditation and regulation standards. One of the aims of these quality standards is to have a skilled nursing workforce to administer and educate the public about the needed immunizations. Health education would raise vaccination uptake, consequently improving children's caregivers' satisfaction and upgrading quality of vaccination services [2,3].

Literatures have emphasized on the importance of providing training curriculum for vaccinator nurses that is geared toward skill-based training on all vaccination procedures before providing vaccines to the targeted population [4,5]. Despite all these recommendations, there is still a shortage in vaccinators' knowledge and variation in daily vaccination practice [6]. It was assumed that implementing the clinical protocols that tailored to specific purposes, would standardize care by lowering unjustified variation [7].

According to the Association of Ontario Midwives [8], clinical protocol is defined as a set of predetermined criteria that defines appropriate nursing intervention that articulates or describes situations in which the nurse makes judgments relative to causes of actions for effective management of client care outcomes. In addition, Chaghari, Saffari, Ebadi, & Ameryoun [9], cited that the implementation of clinical protocols was one method that had been employed to ensure up to date educational and training interventions. Accordingly, vaccinator nurses' knowledge base and skill level would be improved, as well as guarantee consistent manner performance.

To ensure a standardized vaccination performance this study aimed to investigate the effectiveness of the validated clinical nursing protocol for vaccination process management.

2. Subjects and Methods

2.1. Research Design

The study is a two-armed, quasi experimental (intervention and control) comparative study. The study hypothesized that the implementation of a valid protocol would improve the vaccinator nurses' knowledge and practices regarding obligatory childhood vaccination process. Consequently, children's caregivers would be more satisfied with the delivered vaccination services.

The study was conducted at 28 primary healthcare facilities affiliated to Mansoura district, El Dakahlia Governorate. The study comprised a convenience sample of two target groups, that were vaccinator nurses and children's caregivers. The sample size of vaccinator nurses was calculated MedCalc Statistical Software version 19.2.6 [10]. It was based on alpha 0.05, 95% confidence interval, power 80%, $\beta = 20\%$ and the Lost =15% (10 per group), when the hypothetical mean difference of practicing vaccination process = 3.80, the standard deviation of the interventional group before applying training intervention = 8.55, while, standard deviation of the control group before applying training intervention =7.37, the minimum required sample size per group 80 based on the study of Brown, Oluwatosin, & Ogundeji, [11]. A total of 160 nurses in two groups, the ratio of sample size in the study to control group is 1/1.

The sample size of children's caregivers was calculated based on the formula of Pourhoseingholi, Vahedi, & Rahimzadeh [12], the minimum required sample size was 384 caregivers when the population size =128690 children aged five years at Mansoura district. The desired precision =5%, expected frequency of caregivers' expectations related to ideal management process of childhood vaccination is 50% and design effect= 1 in confidence limit of 95%.

Data collection was accomplished by using three self-constructed instruments that were developed by the researcher and translated into simple Arabic to collect the necessary data for this study. The first was vaccinator nurses' knowledge assessment questionnaire included vaccinator nurses' socio-demographic and occupational data such as age, sex, qualifications, years of experience and number of attendance vaccination courses. Vaccinator nurses' knowledge regarding management process of obligatory childhood vaccination. This tool included (92) questions. With total score of 92 points. This tool was designed on the highlight of relevant literatures [13,14,15,16].

The second tool was observation checklist of vaccinator nurses' practices of vaccination management process. This checklist was concerned to nine vaccination process categories: cold chain system management; pre and post vaccination health education; confirming of child's vaccination history; health screening; vaccine

administration; management of vaccination side effects; infection control; and documentation category. All of these categories are composed of 72 steps with total scores of 72 points. This tool was formulated based on the highlight of related literatures [13,17]. The scoring system of the first and second instrument was calculated based on the study of [18].

The structured interview of children's caregivers' satisfaction assessment questionnaire was the third data collection tool. This tool included caregivers' socio-demographic data such as age, gender, education, occupation, and residence. Children's caregivers' satisfaction about the rendered vaccination services questions were organized into seven dimensions that were consisted of 52 questions. A total number of 23 questions requiring a response on 5-point Likert- rating scale with 5 continua (always, sometimes, often, never, I don't know). In addition to 21 questions requiring a response on 5-point Likert- rating scale with 5 continua (strongly agree, agree, I don't know, disagree, strongly agree), 6 questions require response on 2-point scale satisfied or not satisfied and 2 multiple choice questions. 2 questions require response on two different 4-point scale (very far, somewhat far away, somewhat close, and very close) and (very suitable, suitable to some extent, somewhat unsuitable and very unsuitable) respectively. This tool was designed based on the highlight of relevant literatures [19,20]. The categorization of total caregivers' satisfaction level was determined according to Sarkar et al. [21].

Validity of the developed tools was tested for content and face validity. The content validity was tested by ten experts of community health nursing. Pilot study was conducted for testing face validity of the designed tools on the two target groups 10% of the total sample size of vaccinator nurses (16 nurses), besides 10% of children's caregivers (38 caregivers) who were selected randomly from different Mansoura primary health care facilities and were not included into the studied sample. Accordingly, the necessary modifications of the experts, piloted vaccinator nurses and caregivers were done, some questions were added, and others were omitted. The reliability of the observation checklist, and caregivers' satisfaction scale was tested by Cronbach's α and emerged as very good (0.87 and 0.84 respectively).

2.2. Ethical Considerations

Before conducting the study, ethical approval was obtained from the research ethics committee of the faculty of Nursing, Mansoura University. An official letter from the dean of Faculty of Nursing- Mansoura University was submitted to ministry of health and population directorate to obtain approval for conducting the study at the selected primary healthcare facilities. Written consent was also assured from nurses who participated in the study for answering the questionnaire after being informed about their right to withdraw from the study at any time without giving a reason. In addition, verbal informed consents were secured from children's caregivers to participate in the study after illustrating the purpose of it. The collected data is considered confidential and kept in a closed cabinet for three years and reached only by the research team only.

2.3. Study Procedure

The actual field work of the study was conducted for 12 month's period from the first of January 2020 to the end of December 2020. The study was carried out through three phases.

The preparation phase included developing the orientation training program to introduce the components of the valid vaccination protocol and its implementation principles. This protocol was developed and tested for its validity in previous work Abdallah [22] master thesis. The program sessions were designed to include four theoretical and training sessions. The two-hours sessions involved different teaching methods that covered all the vaccination protocol objectives in sequential manner with the assistance with different learning activities and aid.

During the implementation phases, a pilot study was executed on eight vaccinator nurses (10% of the intervention group) to investigate whether crucial components of the sessions plan feasibility, clarity, and applicability, in addition to provide estimate for time required for implementing these sessions. The orientation training program agenda included the date, time, topics, and duration of each session was distributed among the participated vaccinator nurses individually before the start of the program. The orientation program was scheduled at a time that was not conflicted with the facilities working hours. On the first day of the orientation program, the researcher gave an introductory PPT on the over-view of training program components, which took 20 to 30 min. The progress of PPT of each session aligned with the vaccination process phases.

Table 1. The description of data collection framework of the orientation program

Logistics of data collection	Description
Number of training sessions	2 sessions/day
Duration of data collection /day	4 hours/day (9:00 am -1:00 pm)
Assigned time for collecting one tool	15 minutes were enough for collecting the tool from each participant
Week Day	Depend on each facility predetermined vaccination days.

Each nurse of the intervention group received the Arabic version of the vaccination protocol implementation logistics' table before its implementation. The researcher was available upon application of the protocol to discuss any concerns or questions from the participant. The time of its implementation was appropriate to participated nurses' work scheduled time.

Table 2. Logistics of vaccination protocol implementation

Logistics of the protocol	Description
Duration	Two weeks.
Duration of vaccination sessions/ day	4 hours/day (9:00 am - 1:00 pm).
Numbers of vaccination process components	Nine vaccination process components
Day	Depend on each facility predetermined vaccination days.
Participants	Vaccinator nurses who accepted to participate in the study
Numbers of participants/ session	Participants

During the evaluation phase, all nurses of both groups were reassessed by using the same tools, immediately after (within 2-3 days for each studied facility), and after six months as a follow up stage of implementation of the targeted protocol.

2.4. Statistical Analysis

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 20 (SPSS Inc., Chicago, IL, USA). The descriptive analysis was done using mean and standard deviation (SD) for continuous variables and percentage for qualitative variables. Checking for normality was carried out using Kolmogorov-Smirnov test. For normally distributed variables, repeated measure ANOVA was used to indicate an actual difference between more than two related groups. While chi-square test was adopted to test homogeneity between demographic and occupational characteristics of both groups. For all above-mentioned statistical tests done, the threshold of significance is fixed at 5% level (p -value < 0.05).

3. Results

Out of 507 vaccinator nurses 160 nurses accepted to participate in the study. They were assigned either to interventional or control group as shown in Table 3. The initial assessment demonstrates homogeneity on all demographic and occupational characteristics between nurses who involved at intervention and control groups. As similarity determining "Chi square" test shows insignificant differences between two groups in terms of age, gender, qualification, work experience, and previous attendance of vaccination training program. Mean age and work experience of the participants were 49.35 (7.05) and 14.13 (5.29) years respectively, and all of them were females. Regarding qualifications, 93.1% of the participants were diploma of nursing, and 55.6% of them had attended three vaccination training courses.

Results of repeated measure ANOVA test demonstrated very highly statistically significant differences with a large effect size in intervention group mean scores throughout the three study stages. Significant improvement was observed in total knowledge mean score in the intervention group from baseline 45.00 (22.5) to immediate post-test 81.38 (4.60) and six months post-test 79.56 (6.27) at ($F=165.4$, $P \leq 0.001$) with a huge effect size ($\eta^2=0.677$) of the vaccination protocol on vaccinator nurses' knowledge. In comparison with the control group the results showed extremely minimal elevation in mean score from baseline 45.70 (22.0) to immediate post-test 46.47 (21.65), and six months post-test 47.05 (22.07), these differences were statistically significant different at ($F= 5.195$, $P \leq 0.001$) but with effect size ($\eta^2=0.074$) very smaller than intervention group as showed in Table 4.

Consistently with the total observed vaccinator nurses' practice, repeated measure ANOVA test results indicated significant improvement in total practice mean score in the intervention group from baseline 37.3 (11.24) to immediate post-test 64.05 (5.27), and six months post-test 63.07 (5.41) at ($F=367$, $P \leq 0.001$) with a large effect size ($\eta^2=0.823$). Compared with the control group results that showed reduction in total practice mean score from

baseline 35.08(15.59) to immediate post-test 34.85 (15.49)-, were statistically significant different at ($F= 4.482$, and six-months post-test 33.38 (14.68), these differences $P=0.013$), but with smaller effect size ($\eta^2=0.054$).

Table 3. Distribution of the studied vaccinator nurses according to their demographic and occupational characteristics

Demographic and occupational characteristics	Total number of nurses =160						P- value
	Interventional N=(80)		Control N= (80)		Total N= (160)		
	No.	%	No.	%	No.	%	
Age							0.239
≤39	9	11.3	32	40	41	25.6	
-49	18	22.5	36	45	54	33.8	
-50 and More	53	66.3	12	15	65	40.6	
Mean ±SD	49.90±7.2		48.8±6.88		49.35 ±7.05		
Gender							NA
Female	80	100	80	100	160	100	
Qualification							0.958
Diploma of nursing	72	90	77	96.3	149	93.1	
Diploma of Technical Institute	7	8.8	3	3.8	11	6.9	
Experience years							0.752
<10	23	28.8	43	53.8	66	41.2	
-20 and more	57	71.3	37	46.2	94	58.8	
Mean ±SD	14.65±5.46		13.61±5.10		14.13± 5.29		
Number of attendance vaccination training programs							0.107
Twice	23	28.8	48	60	71	44.4	
Three times or more	57	71.3	32	40	89	55.6	

P-value of Chi-square test.

Table 4. Comparison between both vaccinator nurses' groups related to their total knowledge and practice score of vaccination process management throughout the three study phases

Items	Nurses No=160											
	Interventional N= (80)						Control N= (80)					
	Pre		Immediate Post		After 6 months		Pre		Immediate Post		After 6 months	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total vaccinator nurses' knowledge (score =92)												
Poor (<50%)	39	48.8	0.0	0.0	0.0	0.0	40	50	35	43.8	38	47.5
Fair (50%-80%)	30	37.5	4	5	13	16.3	29	36.3	35	43.8	31	38.8
Good (>80%)	11	13.8	76	95	67	83.8	11	13.8	10	12.5	11	13.8
\bar{X} (SD)	45.00 (22.5)		81.38 (4.60)		79.56 (6.27)		45.70(22.00)		46.47(21.65)		47.05(22.07)	
(Repeated measure ANOVA within group)	F=165.4, P-value (within group) = 0.000, $\eta^2=0.677$						F= 5.195, P-value (within group) =0.00, $\eta^2=0.062$					
Total observed vaccinator nurses' practice (score =72)												
Unsatisfactory (<80%)	76	95	9	11.3	12	15	72	90	74	92.5	75	93.8
Satisfactory (≥80%)	2	5	71	88.8	68	85	8	10	6	7.5	5	6.3
\bar{X} (SD)	37.3 (11.24)		64.05 (5.27)		63.07 (5.41)		35.08(15.59)		34.85(15.49)		33.38(14.68)	
(Repeated measure ANOVA within group)	F=367, P-value (within group) = 0.000, $\eta^2=0.823$						F=4.482, P-value (within group) = 0.013, $\eta^2=0.054$					

F: RM- ANOVA, \bar{X} : Mean, SD: Standard deviation

η^2 : Partial Eta Squared (the effect size of RM-ANOVA), P: Significance. * Significant ($p \leq 0.05$)

Table 5. Comparison between both caregivers groups related to their total satisfaction score throughout the three study phases:

Items	Total parents No=384											
	Interventional N=(192)						Control N=(192)					
	Collected from PHC facilities N=(14)						Collected from PHC facilities N=(14)					
	Pre		Immediate Post		After 6 months		Pre		Immediate Post		After 6 months	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total satisfaction score= (188)												
Low satisfactory = <75%	179	93.2	18	9.2	31	16.1	190	99	191	99.5	192	100
High Satisfactory = ≥75%	13	6.8	174	90.6	161	83.9	2	1	1	0.5	---	----
\bar{X} (SD)	76.98(21.40)		146.61(25.27)		145.15(22.2)		77.43(14.98)		75.52(13.96)		76.12(14.63)	
(repeated measure ANOVA within group)	F= 705.81, P-value (within group)=0.000 $\eta^2=0.787$						F= 11.33, P-value (within group)=0.000 $\eta^2=0.056$					

F: RM- ANOVA, \bar{X} : Mean, SD: Standard deviation

η^2 : Partial Eta Squared (the effect size of RM-ANOVA), P: Significance. * Significant ($p \leq 0.05$).

Table 5 demonstrates repeated measure ANOVA test results that indicated very highly significant differences in intervention group mean score from baseline 76.98 (21.40) to immediate post-test 146.61(25.27)-, and 6-months post-test 145.15 (22.20) at ($F=705.81, P \leq 0.001$) with an enormous effect size ($\eta^2=0.787$) of the application of vaccination protocol on targeted caregivers' satisfaction score. In comparing with the control group results which indicated minimal change in mean score from baseline 77.43(14.98) to immediate post-test 75.52(13.96), and 6 months post-test 76.12(14.63) at ($F=11.33, P \leq 0.001$) with effect size ($\eta^2=0.056$) noticeably lower than intervention group.

4. Discussion

High-quality vaccination competencies are crucial for effective controlling morbidity and mortality rates of vaccine-preventable disease, among under-five years children. However, vaccinator nurses are responsible for task of vaccination management process, who often have insufficient skills and competencies to effectively function in this role [23]. Capacity building of vaccinator nurses on this task is a key for ending vaccine-preventable diseases and optimizing vaccination coverage. Thus, the current study aimed at examining the effectiveness of the validated clinical nursing protocol for vaccination process management.

The baseline assessment indicates similarity on all demographic and occupational characteristics of vaccinator nurses in both intervention and control group. As, Chi square test shows insignificant differences in terms of age, qualification, experience years, and previous attendance of training program about vaccination.

Regarding the total vaccinator nurses' knowledge score of management process of obligatory childhood vaccination, results demonstrated very highly statistical improvements throughout the three study phases with a huge effect size on intervention group mean scores ($F=165.4, P \leq 0.001, ES=0.677$), compared to a minimal changes in mean score and effect size of the control group results. The findings of the current study were supported by two reviews, the first is qualitative systematic review conducted by Leung, Akinwunmi, Elias, & Feldman [24] that concluded that provider-specific education significantly indicates improvement in knowledge score in post assessment test. While the second review concluded that the provider-oriented interventions had improved the coverage of childhood immunization in low and middle-income countries [25]. Furthermore, it is consistent with many study findings that aimed at assessing the effectiveness of structured training intervention on knowledge toward vaccination [6,26,27,28].

The effective practice of vaccinator nurses is essential tool for success of both community-based and primary facilities-based programs [29]. Therefore, it was crucial to emphasis on the effect of the current study intervention on overcoming practice among vaccinator nurses. The current study demonstrated significant improvements with a massive effect size in the intervention group mean scores throughout three evaluation tests at ($F=367, P \leq 0.001, ES=0.823$). In contrast, the control group presented weak

improvements with less than one point improve. This finding is an indication to generalize the study findings, nationally. This high improving results was compatible with the results of Resnick et al [30] who reported that, "the majority of the target group (88%) made changes related to immunization processes within their setting, and all reported that immunization practices improved" after using practice standardization materials. Additionally, there are worthy harmonious studies that demonstrated statistically significant higher total knowledge and practice scores in the post-intervention phase as were reported by [11,26].

In Egypt, the evaluation of caregivers' satisfaction level toward the delivered vaccination services in the primary health care facilities is a relatively new research area. At the same time, it is one of the priority recommendations for healthcare providers and a major determinant for increasing the immunization coverage [31]. The present study presented higher significant results regarding the caregivers' satisfaction score toward the provided vaccination services from baseline survey to post implementation stages in the intervention group. These findings are matched with the results of [32,33] who reported considerable effect of the vaccinators' communication and performance on raising vaccination services acceptability and reducing vaccine hesitancy among caregivers.

5. Conclusion

The application of vaccination process management protocol had a significant effect on improving knowledge, and practice of the vaccinator nurses in relation to vaccination process management.

6. Recommendations

Continuous efforts for increasing the awareness and raising skill level among vaccinator nurses toward various phases of vaccination process and other primary health care areas should be prioritized by implementing different strategies, education modules, and the provision of appropriate training programs at regular intervals.

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