

# Data Sharing Statements and Results Reporting – requirements for clinical trials

## Section A: Individual patient data Sharing Statement

**Table: Examples of Data Sharing Statements that Fulfil ICMJE Requirements\***

<b>Example 1</b>	
Will individual participant data be available (including data dictionaries)?	Yes
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification

	Example 1	Example 2	Example 3	Example 4
What other documents will be available?		Study protocol, Statistical Analysis Plan, Analytic Code		
When will data be available (start and end date)?	Immediately following publication, No end date			
With who?	Anyone who wishes to access the data			
For what types of analyses?			For individual participant meta-analysis	
By what mechanism will data be made available	Data are available indefinitely at ( <i>Immediately after publication</i> )			

## Section B: Results Reporting

It is a mandatory requirement to report summary results of all registered clinical trials within a year from completion of the trial. The following items of results should be included:

1. Date of posting of results summaries: August 2017.
2. Date of the first journal publication of results: NOT published till now.
3. URL hyperlink(s) related to results and publications:  
[http://srv1.eulc.edu.eg/eulc\\_v5/libraries/start.aspx?ScopeID=1.&fn=ApplySearch&criteria1=1.&OrderKey=publishYear+desc&SearchText1=Effect+of+a+hemoglobinopathy+nursing+program+on+pediatric&ItemType=24.2.5](http://srv1.eulc.edu.eg/eulc_v5/libraries/start.aspx?ScopeID=1.&fn=ApplySearch&criteria1=1.&OrderKey=publishYear+desc&SearchText1=Effect+of+a+hemoglobinopathy+nursing+program+on+pediatric&ItemType=24.2.5). Till published
4. Baseline Characteristics: This randomized control trial was performed on 108 (into 2 groups) pediatric nursing students (male/female) 19 to 22 years, at the faculty of nursing, Benha University, Egypt. Pediatric nursing students' performance toward hemoglobinopathy nursing programs among study and control groups was highly statistically significant ( $P < 0.05$ ).
5. Participant flow: This randomized clinical trial was carried out during the second academic semester 2016/2017 (February - April 2017). The study was performed at teaching hall and faculty laboratory at the faculty of nursing, Benha University, Egypt.

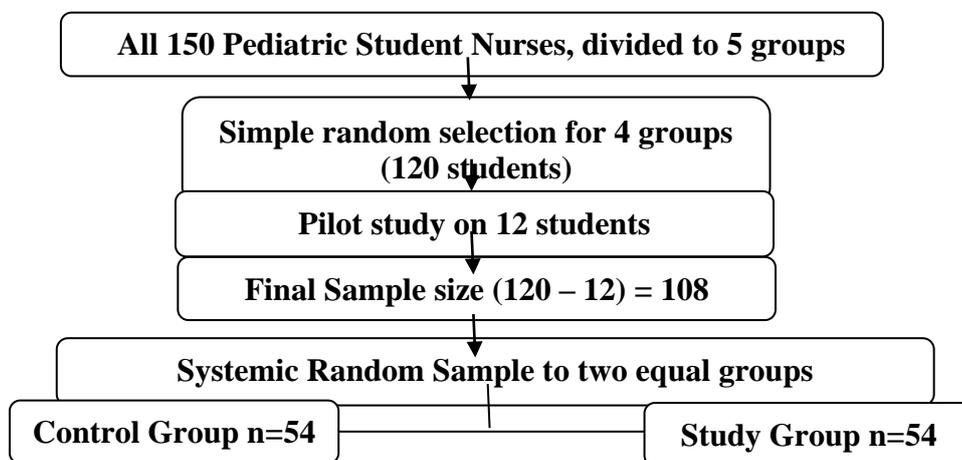


Fig. 1. Flowchart of sampling.

6. Adverse events: NA.
7. Outcome measures: Table (1) shows that, the majority (85.2% and 79.6%) of the study and control group are between 20 and 22 age group with a mean age of 21.136±1.191 for the study group and 21.032±0.959 for control group. This table reveals that, the highest percentages (79.6 % and 87%) of the students are female in both groups respectively. Table (2) reveals that there was a highly statistically significant difference (P<0.001) in the studied nursing students' total awareness, attitude, and practice score in favor of post program. Meanwhile, there was no statistically significant difference (P>0.05) in the studied students' total awareness, practice, and attitude score in the control group. (Table 3, Table 4) shows the nurse students' awareness levels in relation to their personal data among study and control group after the study. There was no statistically significant difference between the students' personal data and their level of awareness (P=>0.05). the same results regarding the students' practice and attitude. Table (5) shows that there was a positive significant correlation between students' awareness and their Practice and attitude (p= 0.001) in study group post intervention.

**Table (1): Personal data of the pediatric nursing students in study and control groups (n= 108)**

Personal data	Study group (n=54)		Control group (n=54)	
	n	%	n	%
<b>Age</b>				
< 20 years	2	3.7	7	12.9
20: <22 years	46	85.2	43	79.6
>22 years	6	11.1	4	7.4
$\bar{X} \pm SD$	21.136±1.191		21.032±0.959	
	20.64±0.988 years			
<b>Gender</b>				
Male	11	20.4	7	12.9
Female	43	79.6	47	87
<b>Residence</b>				
Urban	46	85.2	41	75.9
Rural	8	14.8	13	24.1
<b>Marital status</b>				
Single	44	81.5	46	85.2
Married	10	18.5	8	14.8
<b>Family history</b>				
Yes	4	7.4	5	9.3
No	50	92.6	49	90.7

**Table (2): Total awareness, practice, and attitude scores of the PNSs (n=108)**

topic	Study group (n=54)				t	P	Control group (n=54)				t	P
	Pre		Post				Pre		Post			
	No	%	No	%			No	%	No	%		
<b>Total awareness score</b>												
Good	4	7.5	38	70.4	-19.335	<.001*	5	9.2	6	11.1	0.220	.826
Average	3	5.5	13	24			4	7.5	5	9.2		
Poor	47	87	3	5.6			45	83.3	43	79.7		
$\bar{x} \pm SD$	19.68±13.34		48.65±6.94				20.26±13.75		23.96±11.54			
<b>Total practice score</b>												
Competent	16	29.7	54	100	-29.351	<.001*	18	33.3	21	38.9	0.273	.786
Incompetent	38	70.3	-	-			36	66.7	33	61.1		
$\bar{x} \pm SD$	50.96±5.1		74.52±4.47				50.85±5.43		51.24±5.47			
<b>Total attitude score</b>												
Positive	27	50	54	100	-32.419	<.001*	24	44.4	26	48.1	1.863	.065

Negative	27	50	-	-			30	55.6	28	51.9		
$\bar{x} \pm SD$	17.56±2.4		28.61±2.1				16.67±2.56		19.67±2.31			

\* Significant at  $p < 0.01$

<b>Table (3): PNSs' awareness levels in relation to their personal data after program implementation (n=108).</b>																
Personal data	Study group (n=54)							Control group (n=54)								
	Good		Average		Poor		X <sup>2</sup>	P	Good		Average		Poor		X <sup>2</sup>	P
	n	%	n	%	n	%			n	%	n	%	n	%		
<b>Age</b>																
<20 years	1	1.85	1	1.85	—	—	1.540	0.820	1	1.85	—	—	6	11.1	2.818	0.589
20:22 years	33	61.1	10	18.5	3	5.6			3	5.6	5	9.3	35	64.8		
>22 years	4	7.4	2	3.7	—	—			1	1.85	—	—	3	5.6		
<b>Gender</b>																
Male	7	12.9	2	3.7	2	3.7	6.252	0.042	—	—	—	—	7	12.9	1.828	0.401
Female	31	57.4	11	20.4	1	1.85			5	9.3	5	9.3	37	68.5		
<b>Residence</b>																
Urban	33	61.1	10	18.5	3	3.6	1.308	0.520	4	7.4	4	7.4	33	61.2	0.111	0.946
Rural	5	9.3	3	5.6	—	—			1	1.85	1	1.85	11	20.4		
<b>Marital status</b>																
Married	5	9.3	5	9.3	—	—	4.832	0.089	—	—	1	1.85	7	12.9	1.018	0.601
Single	33	61.1	8	14.8	3	5.6			5	9.3	4	7.4	37	68.5		
<b>Family history</b>																
Yes	4	7.4	—	—	—	—	1.819	0.403	2	3.7	—	—	3	5.6	6.446	0.040
No	34	63	13	24.1	3	5.6			3	5.6	5	9.3	41	75.9		

\* Significant at  $p < 0.01$

**Table (4) PNSs' practice levels in relation to their personal data after program implementation (n=108).**

Personal	Study group (n=54)						Control group (n=54)					
	Competent		Incompetent		X <sup>2</sup>	P	Competent		Incompetent		X <sup>2</sup>	P
	N	%	N	%			N	%	N	%		
<b>Age</b>												
<20 years	2	3.7	—	—	—	—	6	11.1	1	1.85	4.801	.091
20:22 years	46	85.2	—	—			31	57.4	12	22.2		
>22 years	6	11.1	—	—			1	1.85	3	5.6		
<b>Gender</b>												
Male	11	20.4	—	—	—	—	3	5.6	4	7.4	2.920	.177*
Female	43	79.6	—	—			35	64.8	12	22.2		
<b>Residence</b>												
Urban	46	85.2	—	—	—	—	27	50	14	25.9	1.666	.301*
Rural	8	14.8	—	—			11	20.4	2	3.7		
<b>Marital status</b>												
Married	10	18.5	—	—	—	—	4	7.4	4	7.4	1.869	.217*
Single	44	81.5	—	—			34	63	12	22.2		
<b>Family history</b>												
Yes	4	7.4	—	—	—	—	4	7.4	1	1.85	.245	.621*
No	50	92.6	—	—			34	63	15	27.8		

X<sup>2</sup>= Chi Square test, \* F = Fisher Exact te

**Table (5): Correlation between total awareness, practice and attitude scores after intervention for study group (n=54)**

Items	Awareness score		Practice score	
	r	P	r	P
Attitude score	0.568	<0.001*	0.357	<0.001*
practice score	0.661	<0.001*	-	-

\* Significant at  $p < 0.01$

8. URL link to protocol file(s) with version and date: Attached.
9. Brief summary:

Hemoglobinopathies (a collective term for severe inherited blood disorders) are the most common life threatening, monogenic disorders in the world, with approximately 5% of the world's populations are carriers for hemoglobinopathies. The most common causes of inherited hemolytic anemia are sickle cell disease and thalassemia. SCD and thalassemia are inherited blood disorders, passed from parents to children through altered hemoglobin genes.

The role of the hemoglobinopathy nurse is critical to the management of chronic disorders such as thalassemia or SCD. One of the most important aspects of that role is to support patients in playing an active part in their own care. "Pre-service" refers to activities which take place before a person takes up a job which requires specific training, i.e. before a person 'enters service'. Also, the public awareness about hemoglobinopathies in need to more improvement and the future health workers also need that. So, the aim of the current study was to evaluate the effect of a hemoglobinopathy nursing program on pediatric student nurses' awareness and performance.

#### **The study hypothesis**

The pediatric student nurses' awareness and performance level is improved after implementing hemoglobinopathy nursing program.

A quasi experimental research design was used for the current study. Systematic random sample of 108 pediatric student nurses from third year at pediatric nursing department at the faculty of nursing, Benha University. The used tools in the current study was; a structured questionnaire sheet used to evaluate students' awareness, and observational checklist sheets for performance and pediatric student nurses' attitude scale for attitude. The process of data collection carried out from the 2nd week to the 10th week of the second academic semester 2016/2017 (February till end of April 2017).

#### **The main findings of the present study were:**

☐ more than three quarters (85.2% and 79.6%) of the study and control group are between 20 and 22 age group with a mean age of  $21.136 \pm 1.191$  for the studied group and  $21.032 \pm 0.959$  for control group.

☐ more than three-quarters (79.6 % and 87%) of the students are female in study group and control group.

☐ three-quarters (74%) of the students at the study group aware to the blood role in transporting the oxygen to cells, which changed post the program intervention to the vast majority (90.7%).

☐ As regarding blood groups, half of the studied students (50%) didn't aware to all types of blood groups and changed post program intervention to more than three quarters (85.2%).

☐ the majority (87%) of the students had a poor level of awareness toward hemoglobinopathies at pre-intervention phase. However, more than two-thirds (70.4%) of the students had a good level and

nearly one-quarter (24%) of them had a moderate level of awareness toward hemoglobinopathies at evaluation phase.

☐ more than quarter (29.7%) of the students had a competent performance level regarding hemoglobinopathies pre-intervention, that turned to all students had a positive competent performance level toward hemoglobinopathies.

☐ the half (50%) of the students had a negative attitude regarding hemoglobinopathies pre-intervention, that turned to all students had a positive attitude toward hemoglobinopathies.

☐ there were highly statistical significant differences between the study and control group regarding pediatric nursing students' awareness, performance, and attitude ( $P < 0.05$ ).

☐ there were highly statistical significant differences between pediatric nursing students' awareness, performance, and attitude pre and post implementing the program in the study group ( $P < 0.001$ ).

☐ there was a positive significant correlation between students' awareness and their performance and attitude ( $p = 0.001$ ) in study group.

**The study conclusion:**

Based on the results of the current study, it can be concluded that, the research hypothesis is accepted while it was found that the educational program was effective in improving pediatric student nurses' awareness, performance, and attitude after program implementation as compared to preprogram. The results of this study reflect the importance of health education as a keystone in improving students' awareness, performance, and attitude towards hemoglobinopathies.

**The study recommendations were to**

Hemoglobinopathies training and educational programs should be made available to all pediatric nursing students as a way of increasing their awareness and performance.

College campuses could serve as an effective outlet for health education and research studies to address hemoglobinopathies .

3. Guideline program for all student nurses about premarital screening and common genetic disorder.