

Chapter 4

Results

This chapter includes analysis and interpretation of data obtained from the primary caregivers done according to study objectives. The results are presented in a phased manner under the following headings.

1. Results of qualitative part
2. Results of quantitative part

Results of Phase I – qualitative part

- The needs assessed through FGDs.

Research objective 1: To explore the existing gaps between awareness and practices of primary caregivers related to vaccine related problems and their management.

The needs assessed through focus group discussions

The following information needs were identified after content analysis of the verbatim as stated by the primary caregivers during focus group discussions. The major theme was identified was information need of primary caregivers.

Parent them (information needs) had the following sub themes.

- Vaccine related information
- Management of vaccination related problems

Vaccination related information-

1. Importance of vaccination
2. Vaccine specific information
3. Minor and serious problems after vaccination.
4. Balanced information after every vaccination.

Management of vaccination related problems

1. Actions to reduce pain during vaccinations
2. Poor management of local reactions.

Table 2: Parent theme and sub themes of focus group discussions.

Parent theme	Sub themes	Codes
Information need	1.Vaccine related information	a. Importance of vaccination
		b. Vaccine specific information
		c. Minor and serious problems after vaccination.
		d. Adequate information after every vaccination.
	2.Management of vaccination related problems	a. Actions to reduce pain during vaccinations
		b. Poor management of local reactions.

1. Vaccine related information

a. Importance of vaccination

Verbatim 1- it is important for children in every manner, protects them from all diseases, government has started a good policy, names of diseases like polio, TB etc ,don't know much"

Verbatim 2 -" I don't know how but it protects"

Verbatim 3.-" I only know about one disease ,there must be more"-

It was observed that most caregivers were not aware of the importance of vaccinations. Most acknowledged that immunization program is beneficial for children but were unaware of protection it provides. Some caregivers stated that vaccines protect children from various diseases however the name of the diseases were not known to them. Only a few could name polio, hepatitis and measles. Few mothers related vaccination to jaundice and diabetes.

b. Vaccine specific information

Verbatim 1- -"The child shouldn't have fever before vaccination, not even diarrhoea. They should tell more about vaccination but don't have time, they tell more when there are camps"

Verbatim 2- "what to expect after BCG wasn't told."

All the caregivers have indicated the need for more information about the vaccination and the related details about the diseases and protection the child gets. They wanted to know more about vaccines at every vaccination event. At the same time the reason stated for inadequate information as they felt, was overcrowding and overburdened staff at the day of immunization.

c. Minor and serious problems after vaccination.

Verbatim 1- “we are told only about fever, nothing else”

Verbatim 2- “fever usually occurs, the child is very restless for 10-12 hrs, sleep is also disturbed, the child keeps waking time and again. It’s difficult to manage the child during this time”.

Verbatim 3- it is said that fever should happen else the injection is useless.

Verbatim 4--“ fever happens, there is nodule formation on the leg, the child remains restless for 1-2 days”

Minor problems that happen after vaccination (pain, fever, nodule formation, feeding and irritation) were experienced by most of the caregivers. Fever should happen after vaccination no fever means the vaccine will not have effect. Many didn’t know whether fever should happen or not. They also needed to know what was expected after each immunization especially their side effects/adverse effects. None knew about any serious side effect or allergic reactions.

d. Adequate information after every vaccination.

Verbatim 1--“they only inform about fever nothing else.”

Verbatim 2 –“they should tell more about vaccination but don’t have time, they tell more when there are camps”.

Verbatim3 - “the information is same every time. Nothing is told about any other problem or side effect”

All the caregivers have indicated the need for more information about the vaccination and the related details about the diseases and protection the child gets. At the same time the reason stated for inadequate information was overcrowding and overburdened staff at the day of immunization. They also needed to know what was expected after each immunization especially their side effects/adverse effects.

2. Management of vaccination related problems

a. Actions to reduce pain during vaccinations

Verbatim 1 – “pain is intense every time. It happens what can be done.”

Verbatim 2 – “there is no specific method to hold the baby for injection just as it is, the area is massaged after injection.”

Verbatim 3 – “the child gets very painful, doesn’t let touching the leg”.

All the caregivers acknowledged painful condition of child during and after vaccination. The caregivers used to hold the baby according to their convenience. They were not aware of any specific position or method of holding the baby during vaccination. They also expressed their desire to learn pain reduction methods after vaccination.

b. Poor management of local reactions.

Verbatim 1- Fever remains for 1-2 days; it didn’t happen during day but occurred at night. We get drops from the hospital that you give up to the marked area.”

Verbatim 2- “we massage the area and apply vicks. We can give hot fomentation also. More warm water can be poured at the time of bath.”

Verbatim 3- “I don’t know what is to be done if there is pus in the arm.”

Verbatim 4- “Nothing is done usually for pain or hard skin, only at bathing time warm massage can be done on the area.”

Verbatim 5- “The child feeds well but cries a lot during feeds, what can be done.”

Most were unaware of management of immunization reactions. The caregivers had knowledge deficit related to staged healing of BCG site. Pus formation at BCG site was a matter of concern among some of the caregivers. A practice of vicks application was also found among many of them. Application of hot fomentation and massage at vaccination site was also a common practice.

Results of phase II (quantitative part)

The quantitative part was conducted in Regional Hospital, Solan and consisted of two group, interventional and control group. The subjects (primary caregivers) were enrolled at first immunization event (at birth) and were followed up to nine months in each group. Some subjects were lost to follow ups as shown in the table below.

Table 3 - Number of primary caregivers at each immunization event.

Time of immunization event	Number of primary caregivers	
	Interventional group	Control group
Birth	75	75
6 weeks	75	75
10 weeks	71	68
14 weeks	70	68
9 months	66	64

Description of the socio-demographic profile of the primary caregivers and their children.

This section includes baseline information about primary caregivers and attributes of the children enrolled in the quantitative phase of the study.

Table No 4 : Socio-demographic characteristics of primary caregivers and comparison between interventional and control group for homogeneity.

Variables	Categories	Interventional group (N=75)		Control group (N=75)		χ^2 value #	df	P* value
		n	%	n	%			
Age	Upto 20 Years	7	9	7	9	5.474	4	0.242
	21-25 Years	38	51	36	48			
	26-30 Years	22	29	24	32			
	31-35 Years	4	5	-	-			
	36-40 Years	4	5	8	11			
	Mean \pm SD	26.06 \pm 4.46		25.89 \pm 4.53				
Education	Up to matric	19	25	11	15	3.460	3	0.326
	Senior secondary	36	48	42	56			
	Graduate	11	15	15	20			
	Above graduate	9	12	7	9			
Occupation	Employed	23	31	18	24	2.612	2	0.271
	Self employed	13	17	21	28			
	Housewife	39	52	36	48			
Type of family	Nuclear	49	65	46	61	0.258	1	0.611
	Joint	26	35	29	39			
Type of locality	Urban	15	20	17	23	0.158	1	0.690
	Rural	60	80	58	77			
Number of children	1	54	72	56	75	0.154	2	0.926
	2	18	24	16	21			
	>2	3	4	3	4			

p* < 0.05 # chi square/fisher exact

According to the data presented in table 4, all the primary caregivers were mothers with majority in the age group of 21-25 years for both interventional and control group, followed by 26-30 years. As regards the educational status, 50% primary caregivers were educated up to senior secondary. Occupationally, equal proportion of subjects i.e. 52% in interventional and 48 % in control group were homemakers. Approximately 60 % in both interventional and control group belonged to nuclear families. Majority of i.e. 80%, in both groups were from rural area. All of them were primigravida mothers. Both the groups were found homogenous with regard to their socio-demographic characteristics with $p > 0.05$ for all variables.

Table 5: Attributes of children of primary caregivers in interventional and control group and their comparison for homogeneity.

Variables	Categories	Interventional group (N=75)		Control group (N=75)		χ^2 value	df	p* value
		N	%	n	%			
Gender	Male	25	33	28	37	0.263	1	0.608
	Female	50	67	47	63			
Birth weight (in gms)	<2500	11	15	12	16	0.114	2	0.944
	2501-3000	43	57	41	55			
	>3000	21	28	22	29			
Type of delivery	Normal	59	79	57	76	0.152	1	0.696
	Caesarean section	16	21	18	24			

$p < 0.05$

Table 5 depicts that most children in both interventional and control groups were female (67% and 63% respectively). Close to 60% had babies weighed 2500-3000 gms in both the groups. Majority were delivered via normal vaginal delivery. Chi square test established homogeneity of the children's attributes in both groups. For all variables the p value was found to be not significant ($p > 0.05$).

Effectiveness of the need based interventional package in terms of awareness of primary caregivers in managing the children during primary immunizations.

Research objective 2

To assess the effectiveness of need based interventional package in terms of awareness of primary caregivers in managing the children during primary immunizations.

Hypothesis

- H₀₁- There would be no significant difference in the level of awareness of primary caregivers regarding management of children during primary immunizations, between interventional group and control group after implementation of need based interventional package.
- H₁ - There would be significant increase in the level of awareness of primary caregivers regarding management of children during primary immunizations in the interventional group compared to those in the control group after implementation of need based interventional package, at 0.05 level of significance.

Table No 6: Comparison of baseline awareness scores (at birth) of primary caregivers in interventional and control group.

Awareness category	Score range	Interventional group N=75		Control group N=75		χ^2 value #	df	P* value
		n	%	n	%			
Good awareness	22-32	42	56	32	42.7	3.431	2	0.180
Average awareness	11-21	33	44	42	56			
Poor awareness	0-10	-	-	1	1.3			

Chi square/fisher exact, *p<0.05

Table 6 shows that the baseline awareness level of primary caregivers in interventional and control group was at average and good level. Only 1.3% in control group had poor awareness. None of the primary caregivers in both interventional and control group had very good awareness level regarding vaccination. Both the groups had comparable level of awareness at first immunization event and had no significant difference ($p=0.180$).

Table 7: Comparison of primary caregivers' awareness level at various immunization events.

Awareness category	Score range	Interventional Group n(%)			Control Group n(%)		
		Birth N=75	6 weeks N=75	9 months N=66	Birth N=75	6 weeks N=75	9 months N=64
Very good awareness	33-43	-	32 (42.7)	33 (50)	-	-	-
Good Awareness	22-32	42 (56)	43 (57.3)	33 (50)	32 (42.7)	34 (45.3)	28 (43.8)
Average Awareness	11-21	33 (44)	-	-	42 (56)	40 (53.4)	35 (54.7)
Poor Awareness	0-10	-	-	-	1 (1.3)	1 (1.3)	1 (1.6)

Table 7 shows that there was an increase in the awareness scores of interventional group at both immunization events at six weeks and nine months. 42.7% rose to very good level of awareness at six weeks and further to 50% at nine months in interventional group. None of the primary caregivers had very good level of awareness in control group at any point of measurement. The proportion of primary caregivers in average and good level of awareness remained almost same at six weeks and nine months. 1.3 % subjects in control group remained in poor awareness level category in measurement at birth and 6 weeks and remained the same (1.6%) at nine months also.

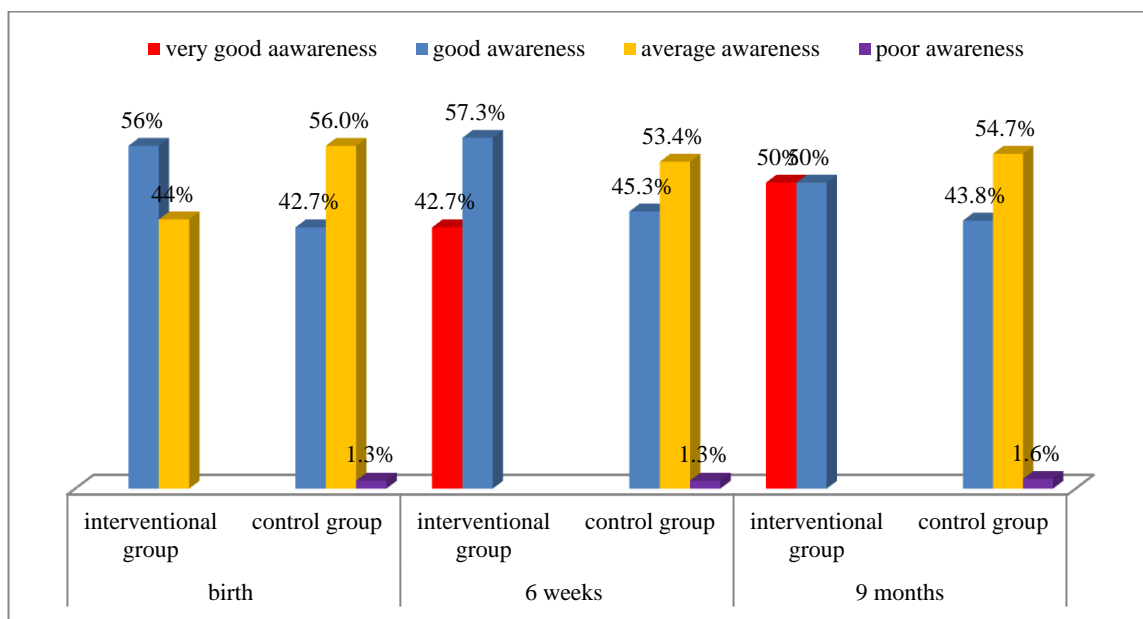


Figure 5: Awareness levels of primary caregivers in interventional and control group various immunization events.

Table 8: Comparison of mean awareness scores of primary caregivers of interventional and control group at various immunization events.

Group/ Immunization event	Interventional group			Control group		
	Birth N=75	6 weeks N=75	9 months N=66	Birth N=75	6 weeks N=75	9 months N=64
Mean ± S.D.	19.84±4.39	32.52±4.55	32.76±5.91	19.25±4.24	19.31±4.28	19.33±4.26
Range	25-11	39-22	42-22	25-10	25-10	25-11
Mean%	46.13	75.62	76.18	44.76	44.90	44.95

Table 8 indicates a clear rise in mean awareness score of interventional group was seen as against a marginal increase in control group. The mean percentage and range also increased for interventional group. For the control group, the range remained same and the mean percentage had a negligible increase. Maximum score increased from 25 to 42 for interventional and remained at 25 for control group.

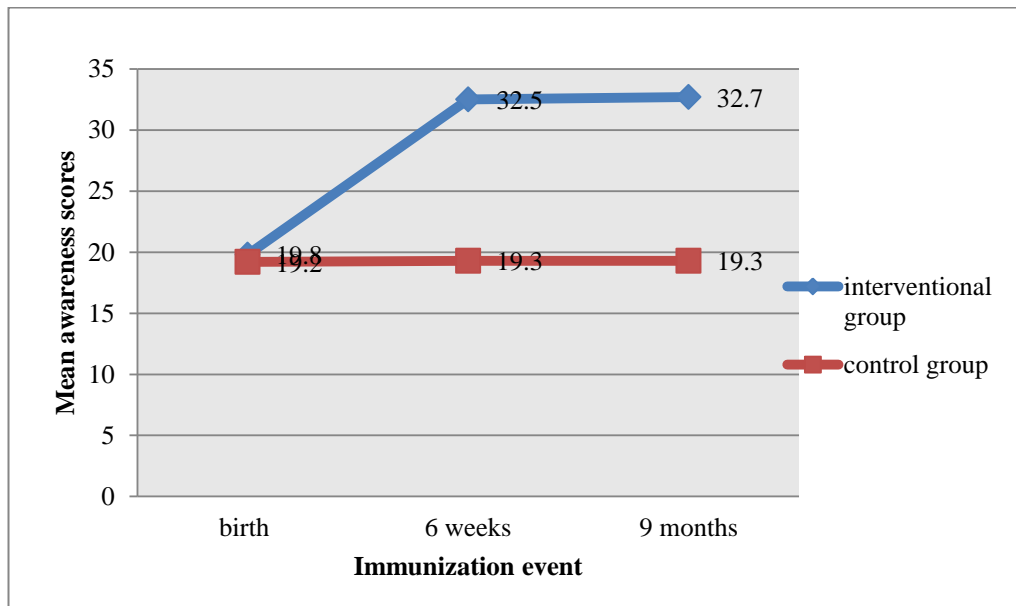


Figure 6: Comparison of mean awareness scores of interventional and control group at various immunization events.

Table 9: Mean awareness score of primary caregivers in interventional and control group at various immunization events.

Time of Immunization event	Interventional Group Mean±Sd Median	Control Group Mean±Sd Median	Mean Diff.	Unpaired T-Test	P* Value
Birth Interventional Group (N= 75) Control Group (N=75)	19.84±4.16 22	19.21±4.18 21	0.627	0.920	0.359
6 Weeks Interventional Group (N= 75) Control Group (N=75)	32.52± 4.55 31	19.31±4.28 21	13.213	18.334**	<0.001**
9 Months Interventional Group (N= 66) Control Group (N=64)	32.76±5.91 32.5	19.33±4.26 21	13.429	14.818**	<0.001**
P Value(F-Test) Interventional Group (N= 66) Control Group (N=64)	<0.001**	0.073			

*p <0.05 ** significant

Table 9 shows that gain in the awareness scores of primary caregivers in interventional group was seen from 19.84 ± 4.16 at birth to 32.76 ± 5.91 at nine months. For the control group, the awareness scores increased from 19.21 ± 4.18 at birth to 19.33 ± 4.26 at nine months. The difference in the mean awareness was found significant at six weeks and nine months ($p < 0.001$) indicating effectiveness of interventional package in improving awareness of primary caregivers levels in the interventional group. Repeated measure ANOVA for within group comparison showed significant increase for the interventional ($p < 0.001$, $f = 212.66$). The F-test and p value was not significant for the control group ($p = 0.073$, $f = 2.70$). The improved awareness in interventional group can thus be attributed to the implementation of interventional package.

Table 10: Pair wise comparison of awareness scores of primary caregivers (within the group) in the interventional and control group using Post Hoc Tukeys test.

Awareness scores of primary caregivers (M_1)		Awareness scores of primary caregivers (M_2)	Mean difference*	
			Interventional group ($M_2 - M_1$) Md	Control group ($M_2 - M_1$) Md
Immunization event	At birth	At 6 weeks	(32.52-19.84) 12.68**	(19.31-19.21) 0.11
		At 9 months	(32.9-19.84) 12.92**	(19.33-19.21) 0.12
	At 6 weeks	At 9 months	(32.76-32.52) 0.24	(19.33-19.31) 0.02

Table 10 represents pairwise comparison among mean awareness values at various immunization events done using Post Hoc Turkey's test. The mean difference was found significant among all comparison pairs except between 6 weeks and 9 months for the interventional group. For the control group the difference among mean awareness values between all comparison pairs was found not significant. The interventional package proved effective in increasing awareness of primary caregivers during first few weeks of child birth indicating more receptivity during this time.

Effectiveness of need based interventional package in terms of self-efficiency of primary caregivers regarding management of child during primary immunizations.

Research objective 3

To determine the effectiveness of the need based interventional tool in terms of self-efficiency scores of primary caregivers in interventional and control group.

Hypothesis

- H₀₂- There would be no significant difference in the level of self-efficiency of primary caregivers regarding management of children during primary immunizations, between interventional group and control group after implementation of need based interventional package.
- H₂ - There would be significant increase in the level of self-efficiency of primary caregivers regarding management of children during primary immunizations in the interventional group compared to those in the control group after implementation of need based interventional package, at 0.05 level of significance.

Table 11: Comparison of baseline self-efficiency levels of primary caregivers among interventional and control group at birth.

Self -efficiency Categories	Score range	Interventional Group N=75		Control Group N=75		χ^2 value	df	p value*
		n	%	n	%			
Average Efficiency	14-21	38	50.7	39	52	0.027	1	0.870
Poor Efficiency	6-13	37	49.3	36	48			

*p<0.05

The data in table 11 shows that none of the primary caregivers was in good efficiency category at the first immunization event (at birth). No significant difference (p=0.870) in self-efficiency levels was observed at first immunization event with all the primary caregivers in average and poor efficiency in both interventional and control group.

Table 12: Mean self-efficiency scores of primary caregivers in interventional and control group at various immunization events.

Time of immunization event	Interventional group					Control group				
	Birth	6 weeks	10 weeks	14 weeks	9 months	Birth	6 weeks	10 weeks	14 weeks	9 Months
Mean ± SD	12.91 ± 2.25	17.24 ± 1.61	19.27 ± 1.40	21.53 ± 1.55	23.17 ± 1.91	12.97 ± 2.19	13.00 ± 2.16	13.00 ± 2.16	13.00 ± 2.16	13.03 ± 2.19
Range	15-9	20-14	21-16	24-17	27-19	15-9	15-9	15-9	15-9	16-9
Mean%	43.02	57.46	64.23	71.76	77.22	43.24	43.33	43.33	43.33	43.43

Table 12 shows a marginal difference in the pre-test mean self-efficiency existed both interventional and control group initially at birth. It increased consistently for interventional group at every successive assessment while remained at same level for control group. The maximum score increased from 15 to 27 for interventional and increased to 16 at 9 months from 15 at birth for the control group. The mean percent improved to 77.22 in interventional and remained 43.43 for the control group.

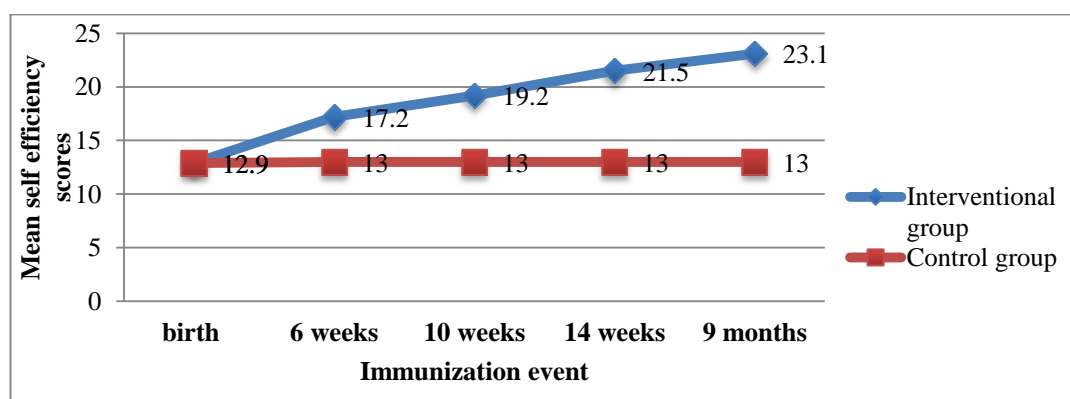


Figure 7: Comparison of mean self- efficiency scores of interventional and control group.

Table 13: Self- efficiency level of primary caregivers at various immunization events.

Self- efficiency categories /score range	Interventional Group n(%)					Control Group n(%)				
	Birth N=75	6 weeks N=75	10 weeks N=71	14 weeks N=70	9 months N=66	Birth N=75	6 weeks N=75	10 weeks N=68	14 weeks N=68	9 months N=64
	Good Efficiency (22-30)	-	-	-	36 (51.4)	52 (78.8)	-	-	-	-
Average Efficiency (14-21)	38 (50.7)	75 (100)	75 (100)	39 (48.6)	23 (21.2)	39 (52)	39 (52)	35 (51.5)	35 (51.5)	33 (51.6)
Poor Efficiency (6-13)	37 (49.3)	-	-	-	-	36 (48)	36 (48)	33 (48.5)	35 (48.5)	31 (48.4)

Table 13 shows that self -efficiency of primary caregivers in interventional group remained at average level till ten weeks and then rose to good efficiency level. Maximum (78.8%) had attained good efficiency by nine months. For the control group the proportion of primary caregivers with average and poor self -efficiency remained same at all successive assessments till nine months. The primary caregivers in interventional group had improved self -efficiency as a result of need based interventional package.

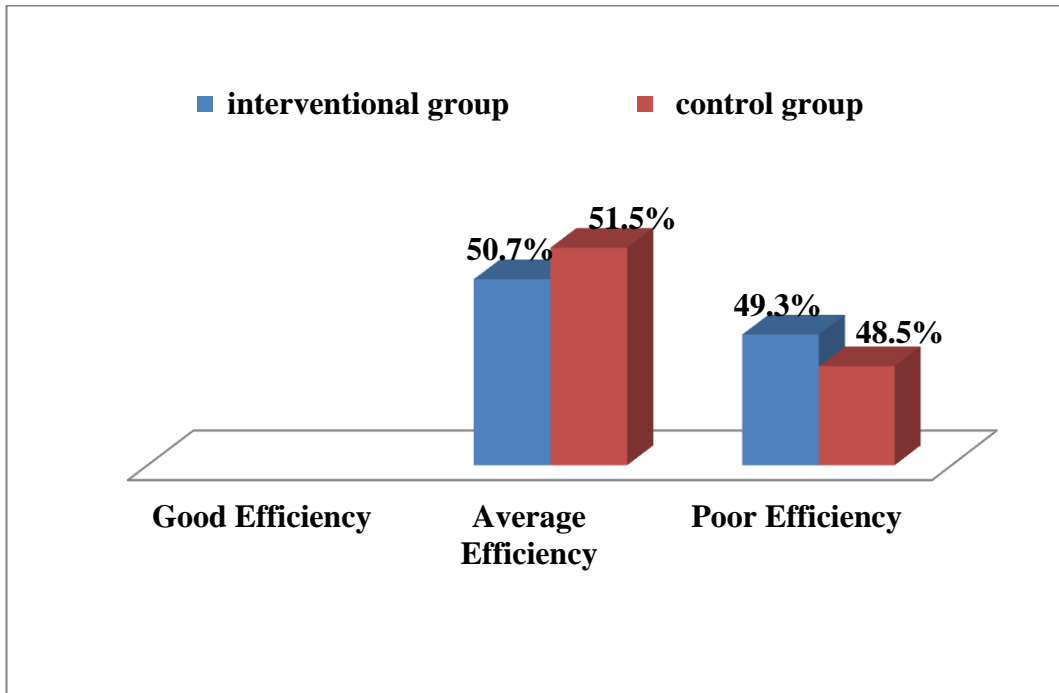


Figure 8: Comparison of self-efficiency levels of primary caregivers of interventional and control group at birth.

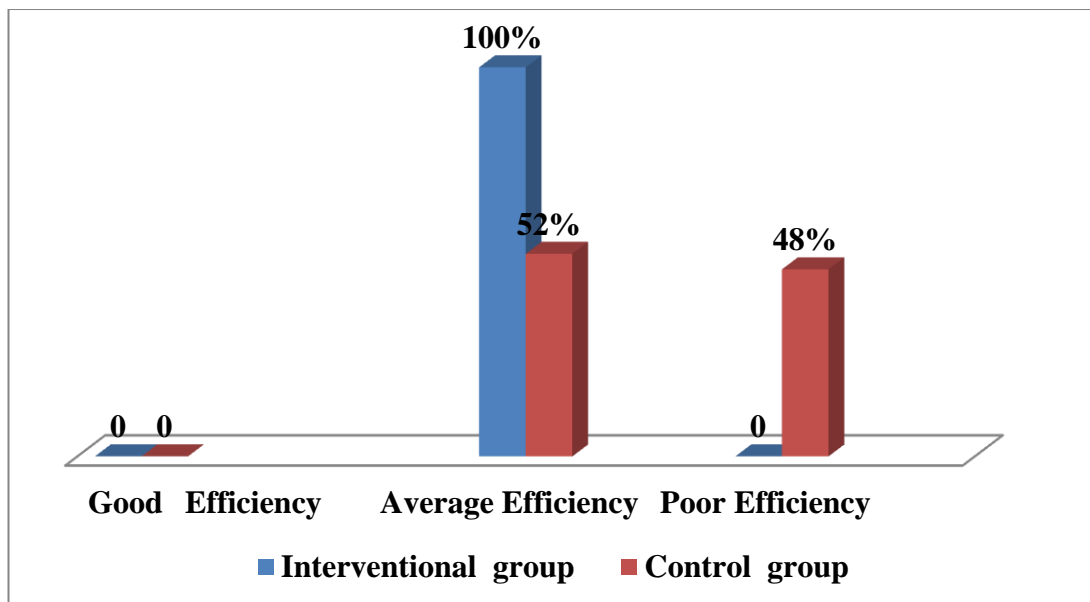


Figure 9: Comparison of self-efficiency levels of primary caregivers of interventional and control group at six weeks.

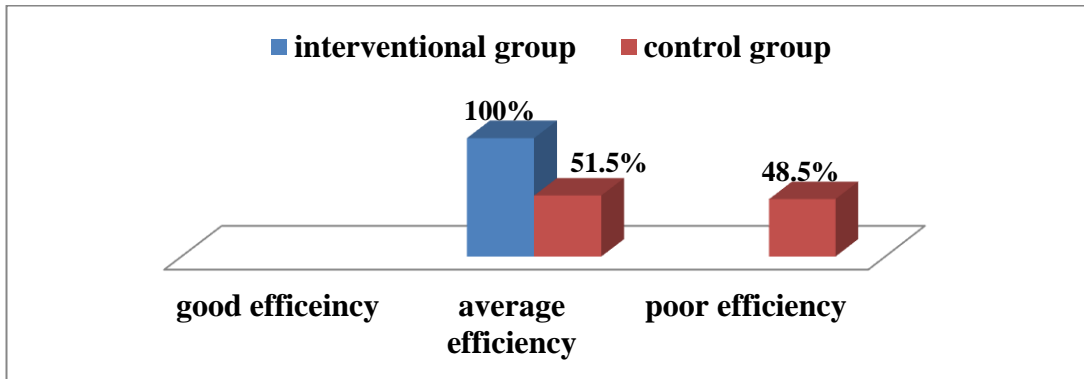


Figure 10: Comparison of self-efficiency levels of primary caregivers of interventional and control group at ten weeks.

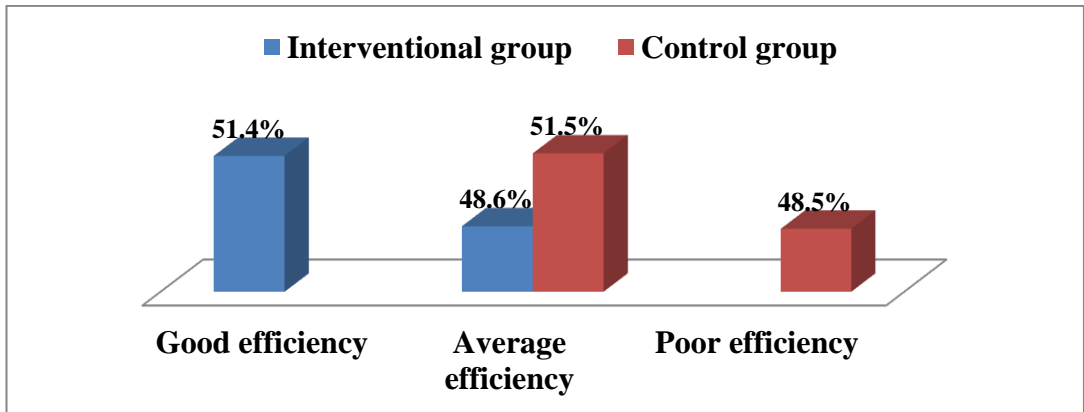


Figure 11: Comparison of self-efficiency levels of primary caregivers of interventional and control group at fourteen weeks.

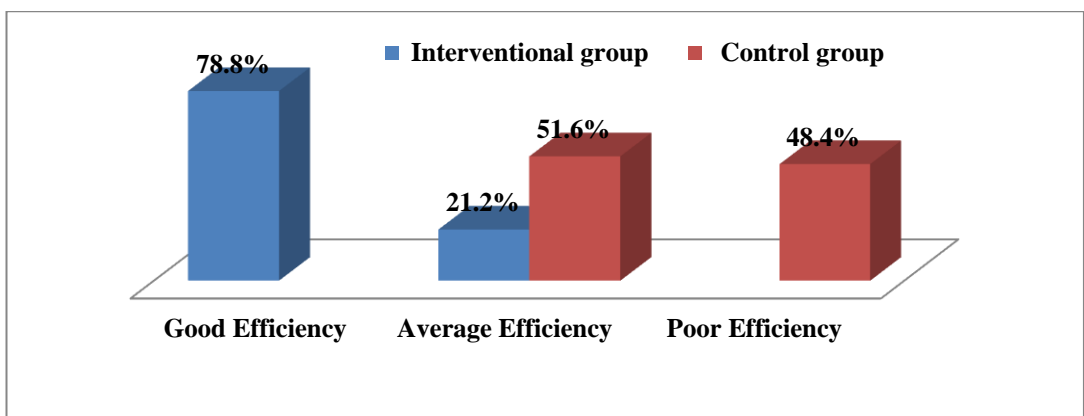


Figure 12: Comparison self-efficiency levels of primary caregivers of interventional and control group at nine months.

Table 14: Comparison of mean self-efficiency of primary caregivers in interventional and control group at various immunization events.

Time of immunization event	Interventional group Mean \pm SD Median	Control group Mean \pm SD Median	Mean Diff.	Unpaired T Test value	p* value
Birth Interventional group (N=75) Control group (N=75)	12.91 \pm 2.255 15	12.97 \pm 2.193 14.5	-0.067	-0.184	0.855
6 weeks Interventional group (N=75) Control group (N=75)	17.24 \pm 1.618 18	13.00 \pm 2.168 14.5	4.200	13.415	<0.001**
10 weeks Interventional group (N=71) Control group (N=68)	19.27 \pm 1.409 19	13.00 \pm 2.168 14.5	6.183	19.917	<0.001**
14 weeks Interventional group (N=70) Control group (N=68)	21.53 \pm 1.551 22	13.00 \pm 2.168 14.5	8.386	25.221	<0.001**
9 months Interventional group (N=66) Control group N=64	23.17 \pm 1.918 23	13.03 \pm 2.196 14.5	10.135	28.048	<0.001**
P Value(F-Test) Interventional group (N=66) Control group (N=64)	<0.001**	0.412			

*p<0.05, ** significant,

Table 14 depicts within group and between group analyses for determining significant difference in mean self –efficiency. Between the groups analysis was done using unpaired T-test. Except at first immunization event the difference in mean self -efficiency score of interventional and control group at all point of assessment was found significant(p<0.05). Repeated measure ANOVA revealed significant difference in self- efficiency within the group for interventional group p<0.001 (F-test value of 389.21, df 4, 84) and not significant for the control group (F-test value 1.00, df4, 84) p=0.412. It is therefore interpreted that need based package significantly increased self-efficiency of primary caregivers. The research hypothesis is thus accepted and null hypothesis is rejected.

Table 15: Pairwise comparison of self- efficiency scores of primary caregivers (within the group) in the interventional and control group using Post Hoc Tukey’s test.

Self- efficiency scores of primary caregivers(M ₁)		Self- efficiency scores of primary caregivers(M ₂)	Mean difference*	
			Interventional Group (M ₂ . M ₁)Md	Control Group (M ₂ . M ₁) Md
Immunization event	At birth	At 6 weeks	(17.24-12.91) 4.3**	(13.00-12.97) 0.03
		At 10 weeks	(19.27-12.91) 6.36**	(13.00-12.97) 0.03
		At 14 weeks	(21.53-12.91) 8.62**	(13.00-12.97) 0.03
		At 9 months	(23.17-12.91) 10.26**	(13.03-12.97) 0.06
	At 6 weeks	At 10 weeks	(19.27-17.24) 2.03**	(13.03-13.03) 0
		At 14 weeks	(21.53-17.24) 4.29**	(13.03-13.03) 0
		At 9 months	(23.17-17.24) 5.93**	(13.03-13.00) 0.03
	At 10 weeks	At 14 weeks	(21.53-19.27) 2.26**	(13.03-13.03) 0
		At 9 months	(23.17-19.27) 3.9**	(13.03-13.00) 0.03
	At 14 weeks	At 9 months	(23.17-21.53) 1.64**	(13.03-13.00) 0.03

*p<0.05, ** significant

Table 15 indicates that Post Hoc Tukey’s test for different pairs of comparison of self-efficiency showed no significant mean difference for the control group. However, for the interventional group it was found significant at p<0.05.

Vaccine related problems among children of primary caregivers.

Research objective 4

To determine the rate of occurrence of vaccine related problems.

Table 16: Vaccine related problems at various immunization events.

Time of immunization event	Pain (%)	Excessive crying (%)	Redness & swelling (%)	Nodule formation (%)	Restlessness& irritability (%)	Drowsiness / sleep disturbance (%)	Feeding problems (%)	Fever (%)
Birth	77 (51.3)	33 (22)	120 (80)	-	21 (14)	-	49 (32.7)	-
6 weeks	141 (94)	150 (100)	132 (88)	123 (82)	72 (48)	63 (42)	66 (44)	113 (75.3)
10 weeks	128 (92.08)	21 (15.10)	117 (84.2)	110 (79.1)	122 (87.8)	-	74 (53.2)	110 (79.1)
14 weeks	101 (73.2)	63 (45.7)	117 (84.8)	92 (66.7)	84 (60.9)	36 (26.1)	70 (46.4)	58 (42)
9 months	83 (63.8)	23 (16.9)	12 (9.2)	-	69 (50)	-	27 (20.8)	7 (5.4)

Table 16 depicts that some vaccine related problems like pain at vaccination site, redness and swelling, excessive crying, restlessness& irritability and feeding problems were seen at all immunization event. Fever, redness & swelling and formation of nodule at vaccination site were reported high among children from six weeks till fourteen weeks. Pain peaked and excessive crying peaked at six weeks while redness and swelling remained consistently in around 85% children from six weeks till fourteen weeks. Fever was reported among children from six weeks till fourteen weeks with a decreasing frequency and was seen among very few children (5.4%) at nine months. Drowsiness / sleep disturbance was reported only at six weeks and fourteen weeks.

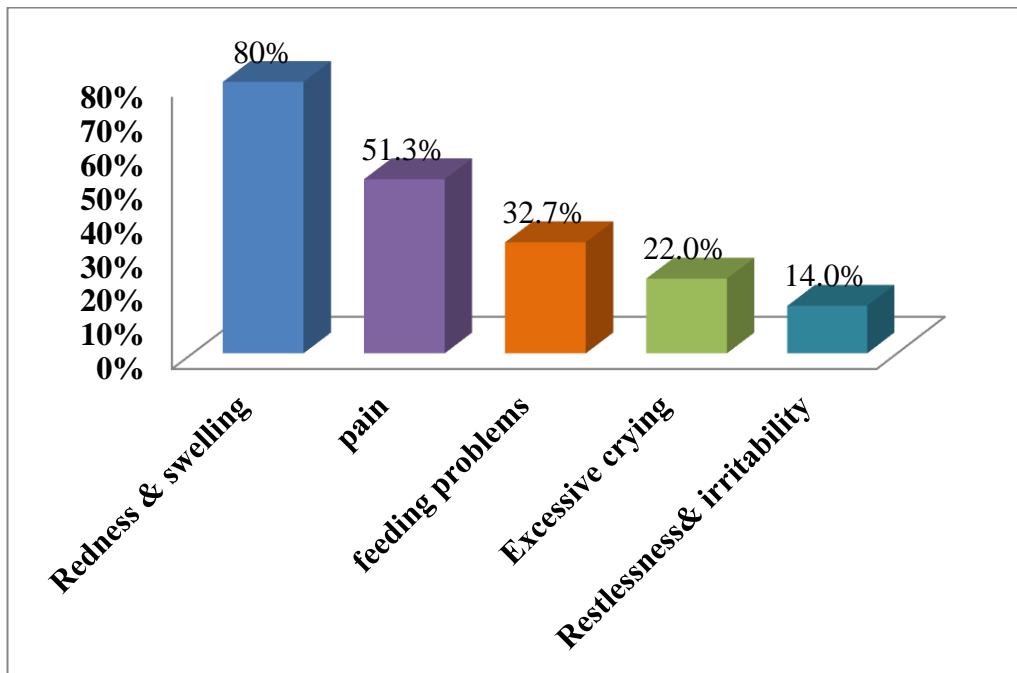


Figure 13: Vaccine related problems among children of primary caregivers at birth.

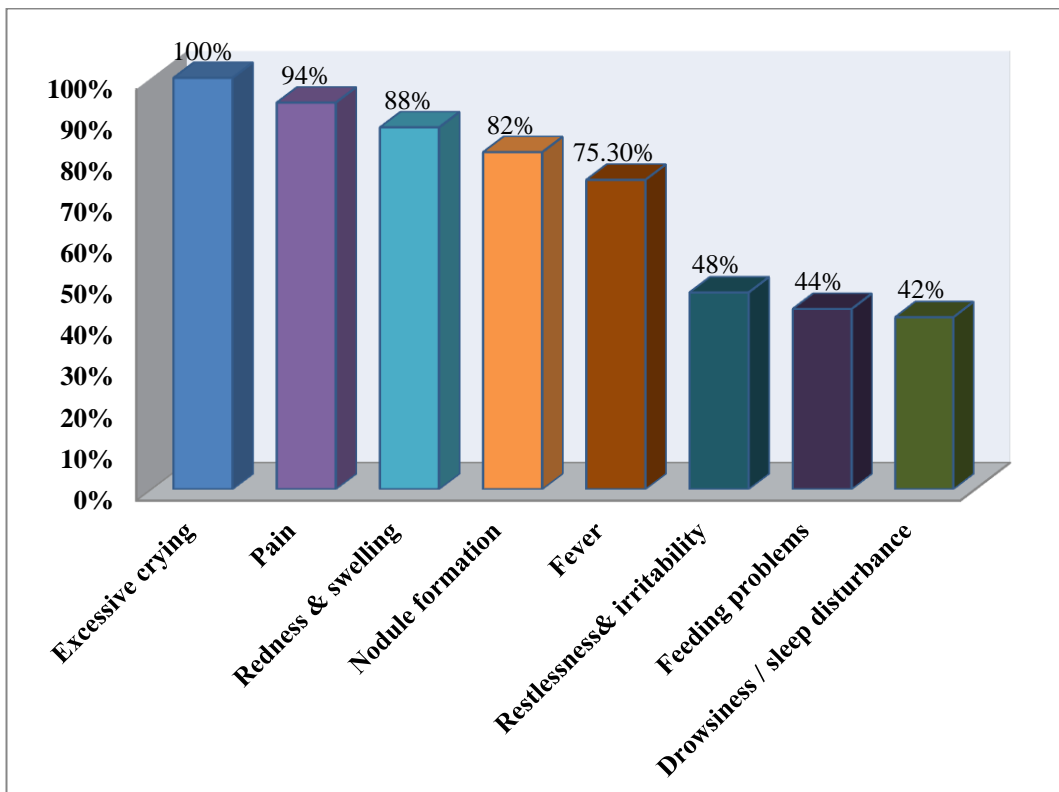


Figure 14: Vaccine related problems among children of primary caregivers at six weeks.

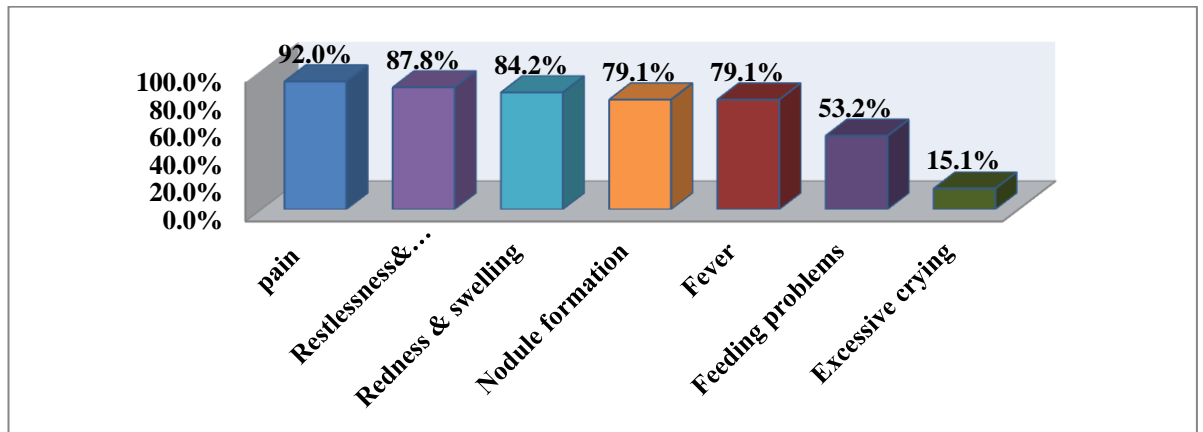


Figure 15: Vaccine related problems among children of primary caregivers at ten weeks.

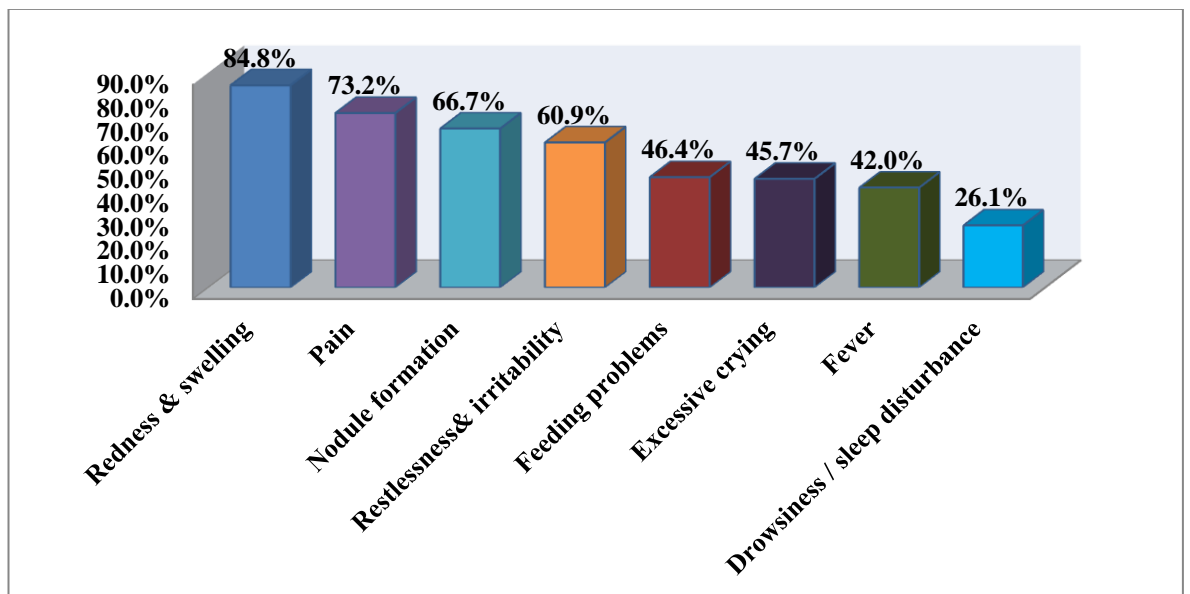


Figure 16: Vaccine related problems among children of primary caregivers at fourteen weeks.

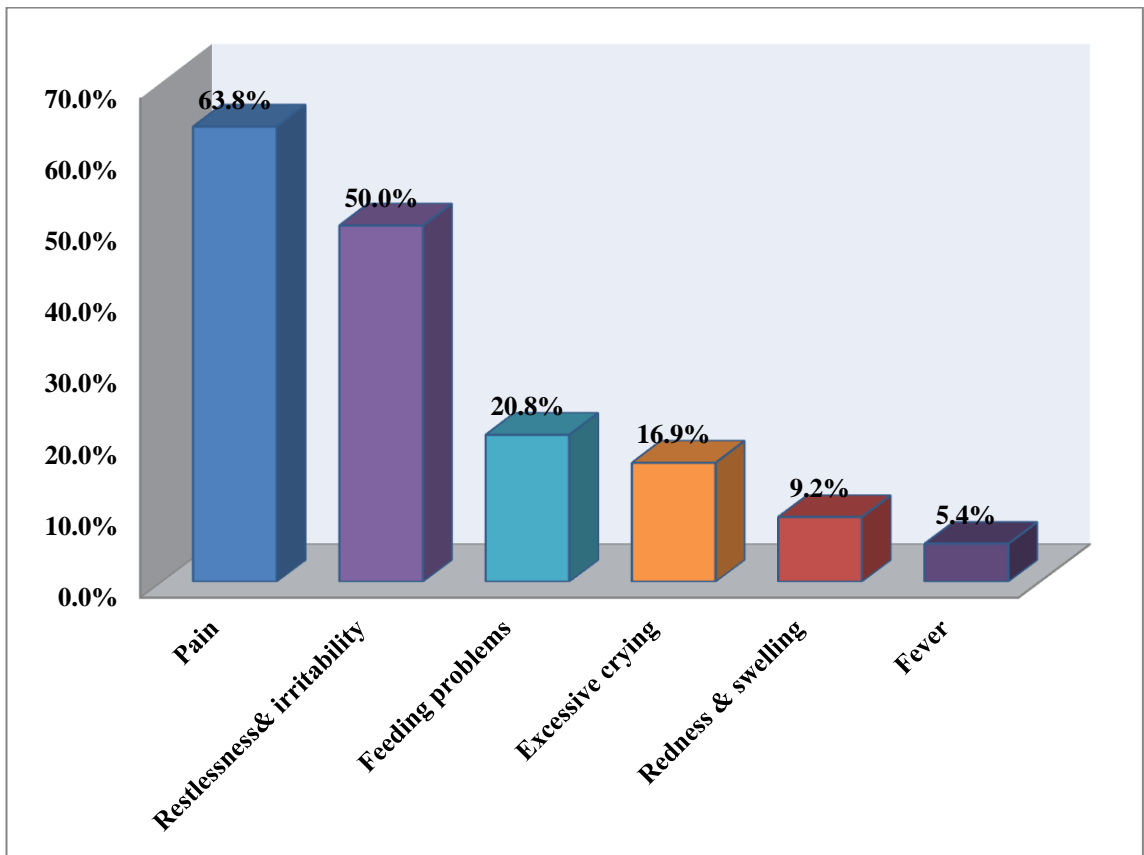


Figure 17: Vaccine related problems among children of primary caregivers at nine months.

Research objective 5:

To determine the association of vaccine related problems with selected attributes of children.

Table 17: Association of pain at vaccination site among children with their attributes.

Variables	Categories	Pain at vaccination site									
		At birth N=150		6 weeks N=150		10 weeks N=139		14 weeks N=138		9 months N=130	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Gender	Male	40	13	51	3	29	21	32	17	27	20
	Female	37	60	90	7	87	2	69	20	56	27
		χ^2 19.115 p 0.000		χ^2 0.154 p 0.694		χ^2 36.637 p 0.000		χ^2 2.405 p 0.120		χ^2 1.306 p 0.253	
Birth weight (in gms)	≤ 2500	16	9	23	2	16	9	11	14	13	12
	>2500	61	64	118	7	100	14	90	23	70	45
		χ^2 1.926 p 0.165		χ^2 0.212 p 0.644		χ^2 8.353 p 0.003		χ^2 13.255 p 0.000		χ^2 0.669 p 0.413	

Table 18: Association of excessive crying among children with their attributes.

Variables	Categories	Excessive crying									
		At birth N=150		6 weeks N=150		10 weeks N=139		14 weeks N=138		9 months N=130	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Gender	Male	16	37	53	-	11	39	23	26	10	37
	Female	17	80	97	-	22	67	40	49	12	71
		χ^2 12.46 p 0.000		NA		χ^2 0.130 p 0.717		χ^2 0.051 p 0.138		χ^2 1.245 p 0.10	
Birth weight (in gms)	≤ 2500	12	13	25	-	10	15	4	21	1	24
	>2500	21	104	125	-	23	91	59	54	21	84
		χ^2 11.818 p 0.000		NA		χ^2 4.450 p 0.034		χ^2 10.819 p 0.001		χ^2 3.678 p 0.055	

Table 19: Association of redness and swelling among children with their attributes.

Variables	Categories	Redness and swelling									
		At birth N=150		6 weeks N=150		10 weeks N=139		14 weeks N=138		9 months N=130	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Gender	Male	50	3	43	10	44	6	40	9	4	43
	Female	70	27	89	8	73	16	77	12	8	75
		χ^2 10.533 p 0.001		χ^2 3.660 p 0.055		χ^2 9.184 p 0.002		χ^2 0.584 p 0.444		χ^2 0.045 p 0.830	
Birth weight (in gms)	≤2500	15	10	15	10	19	6	17	8	5	20
	>2500	105	20	117	8	98	16	100	13	7	98
		χ^2 7.5 p 0.006		χ^2 22.27 p 0.000		χ^2 = 1.528 p=0.216		χ^2 6.667 p 0.009		χ^2 4.284 p 0.038	

Table 20: Association of nodule formation among children with their attributes.

Variables	Categories	Nodule formation								
		At birth N=150	6 weeks N=150		10 weeks N=139		14 weeks N=138		9 months N=130	
			Yes	No	Yes	No	Yes	No		
Gender	Male	NA	43	10	42	8	39	10	NA	
	Female		80	17	68	21	53	36		
			χ^2 0.0418 p 0.837		χ^2 1.118 p 0.290		χ^2 5.711 p 0.016			
Birth weight (in gms)	≤ 2500	NA	20	5	16	9	10	15	NA	
	>2500		103	22	94	20	82	31		
			χ^2 0.081 p 0.775		χ^2 4.230 p 0.039		χ^2 9.769 p 0.007			

Table 21: Association of irritability and restlessness among children with their attributes.

Variables	Categories	Irritability and restlessness									
		At birth N=150		6 weeks N=150		10 weeks N=139		14 weeks N=138		9 months N=130	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Gender	Male	10	43	13	40	40	10	28	21	22	25
	Female	11	86	59	38	82	7	56	33	43	40
		χ^2 1.616 p 0.204		χ^2 18.090 p 0.000		χ^2 4.391 p 0.036		χ^2 0.443 p 0.505		χ^2 0.299 p 0.598	
Birth weight (in gms)	≤2500	8	17	8	17	20	5	18	7	15	10
	>2500	13	112	64	61	102	12	66	47	50	55
		χ^2 8.073 p 0.004		χ^2 3.076 p 0.079		χ^2 1.714 p 0.190		χ^2 1.588 p 0.207		χ^2 1.238 p 0.265	

Table 22: Association of feeding problems among children with their attributes.

Variables	Categories	Feeding problems									
		At birth N=150		6 weeks N=150		10 weeks N=139		14 weeks N=138		9 months N=130	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Gender	Male	10	43	23	30	28	22	25	24	9	42
	Female	39	58	43	54	46	43	39	44	18	65
		χ^2 7.094 p 0.007	χ^2 0.012 p 0.912	χ^2 0.200 p 0.654	χ^2 0.200 p 0.654	χ^2 0.320 p 0.571					
Birth weight (in gms)	\leq 2500	6	19	6	19	12	13	12	13	10	15
	$>$ 2500	43	82	60	65	62	52	52	61	17	88
	χ^2 1.024 p 0.311	χ^2 4.870 p 0.027	χ^2 0.335 p 0.562	χ^2 0.324 p 0.172	χ^2 6.956 p 0.008						

Table 23: Association of fever among children with their attributes.

Variables	Categories	Fever									
		At birth N=150		6 weeks N=150		10 weeks N=139		14 weeks N=138		9 months N=130	
		Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Gender	Male	NA	31	22	37	13	20	29	2	45	
	Female		82	17	73	24	38	51	5	78	
			χ^2 2.152 p 0.144	χ^2 0.027 p 0.867	χ^2 0.045 p 0.830	χ^2 0.184 p 0.667					
Birth weight (in gms)	\leq 2500	NA	13	12	18	7	12	13	1	24	
	$>$ 2500		100	25	92	22	46	67	6	99	
	χ^2 8.878 p 0.003		χ^2 0.940 p 0.332	χ^2 0.446 p 0.503	χ^2 0.116 p 0.73						

The data in table 17-23 depict that all vaccine related problems were found associated with gender and birth weight at one or more events of vaccination. At birth, gender was found associated with pain at vaccination site , excessive crying, redness and swelling and feeding problems while birth weight was found to have association with excessive crying, redness and swelling and irritability and restlessness. It was observed that at six weeks, gender was found associated with irritability and restlessness while birth weight influenced occurrence of redness and swelling, feeding problems and fever. Further at ten weeks, gender was found associated with pain at vaccination site, redness and swelling and irritability and restlessness. Birth weight was found associated with pain at vaccination site, excessive crying, and nodule formation. At fourteen weeks , gender was observed to influence nodule formation whereas birth weight influenced pain at vaccination site, excessive crying, redness and swelling and nodule formation. At fifth immunization event (at nine months) only birth weight was found associated with redness and swelling and feeding problems, gender of the child didn't associate with any of the vaccine related problems. None of the child's attributes was found to influence drowsiness /sleep disturbance among children (annexure 11).

Immunization compliance among primary caregivers.

Research objective 6:

To determine immunization compliance among primary caregivers.

Table 24: Immunization compliance among primary caregivers in interventional and control group.

Vaccine dose	No of doses on time n(%)	
	Intervention group	Control group
BCG	75(100)	75(100)
Hep B birth dose	75(100)	75(100)
OPV birth dose	75(100)	75(100)
OPV 1	60(80)	62(82.7)
2	63(88.7)	54(79.4)
3	61(87.1)	60(88.2)
Fipv 1	60(80)	62(82.7)
2	61(87.1)	54(79.4)
Pentavalent(DPT, Hep B, HiB)		
1	60(80)	62(82.7)
2	63(88.7)	54(79.4)
3	61(87.1)	60(88.2)
Rotavirus vaccine		
1	60(80)	62(82.7)
2	63(88.7)	54(79.4)
3	61(87.1)	60(88.2)
PCV 1	60(80)	62(82.7)
2	61(87.1)	60(88.2)
Booster	66(100)	63(98.4)
MR	66(100)	63(98.4)

Table 24 shows that both the groups had full compliance initially at first immunization. From six weeks till fourteen weeks both the groups had almost equal number of non-complaint primary caregivers who vaccinated their children beyond one week of their recommended age. Their number however decreased in both the groups. For the fifth immunization event, 1.6% in control group got vaccinated beyond the recommended age.

Research objective 7

To determine association of immunization compliance with selected variable of primary caregivers.

Table 25 – Immunization compliance among primary caregivers of interventional group at 6 weeks and association with selected variables.

Variables	Categories	Vaccination received as per schedule	Vaccination received late	χ^2 value#	df	P Value
		n	n			
Age (in years)	Upto 20	6	1	3.129	2	0.2091
	21-25	33	5			
	>25	21	9			
Education	Upto matric	15	4	0.575	2	0.749
	Senior secondary	30	6			
	Graduate & above	15	5			
Occupation	Employed	18	5	1.505	2	0.125
	Self employed	12	1			
	Housewife	30	9			
Type of family	Nuclear	33	12	3.125	1	0.051
	Joint	27	3			
Type of locality	Urban	17	3	0.426	1	0.219
	Rural	43	12			
Number of children	1	42	12	0.456	2	0.199
	2	16	2			
	>2	2	1			

Chi square/fisher exact test

Table 26: Immunization compliance among primary caregivers of interventional group at 10 weeks and association with selected variables

Variables	Categories	Vaccination received as per schedule	Vaccination received late	χ^2 value#	df	P Value
		n	n			
Age (in years)	Upto 20	6	1	0.787	2	0.674
	21-25	31	5			
	>25	26	2			
Education	Upto matric	15	2	0.839	2	0.657
	Senior secondary	33	3			
	Graduate & above	15	3			
Occupation	Employed	21	2	3.011	2	0.097
	Self employed	13	-			
	Housewife	29	6			
Type of family	Nuclear	36	6	0.937	1	0.200
	Joint	27	2			
Type of locality	Urban	15	4	2.484	1	0.099
	Rural	48	4			
Number of children	1	44	6	2.075	2	0.243
	2	17	1			
	>2	2	1			

Chi square/fisher exact test

Table 27 - Immunization compliance among primary caregivers of interventional group at 14 weeks and association with selected variables.

Variables	Categories	Vaccination received as per schedule	Vaccination received late	χ^2 value#	df	P Value
		n	n			
Age (in years)	Upto 20	7	-	1.721	2	0.422
	21-25	29	6			
	>25	25	3			
Education	Upto matric	16	1	1.360	2	0.506
	Senior secondary	29	6			
	Graduate & above	16	2			
Occupation	Employed	20	3	0.111	2	0.153
	Self employed	11	2			
	Housewife	30	4			
Type of family	Nuclear	39	3	3.060	1	0.067
	Joint	22	6			
Type of locality	Urban	14	5	4.216	1	0.045**
	Rural	47	4			
Number of children	1	44	5	2.159	2	0.192
	2	14	4			
	>2	3	-			

Chi square/fisher exact test

Table 28–Immunization compliance among primary caregivers of control group at 6 weeks and association with selected variables.

Variables	Categories	Vaccination received as per schedule	Vaccination received late	χ^2 value#	df	P Value
		n	n			
Age (in years)	Upto 20	5	2	2.050	2	0.358
	21-25	32	4			
	>25	25	7			
Education	Upto matric	6	5	7.386	2	0.024**
	Senior secondary	36	6			
	Graduate& above	20	2			
Occupation	Employed	13	5	1.805	2	0.074
	Self employed	18	3			
	Housewife	31	5			
Type of family	Nuclear	37	9	0.414	1	0.207
	Joint	25	4			
Type of locality	Urban	23	5	0.009	1	0.244
	Rural	39	8			
Number of children	1	47	10	1.340	2	0.511
	2	13	3			
	>2	1	1			

Chi square/fisher exact test

Table 29 - Immunization compliance among primary caregivers of control group at 10 weeks and association with selected variables.

Variables	Categories	Vaccination received as per schedule	Vaccination received late	χ^2 value#	df	P Value
		n	n			
Age (in years)	Upto 20	5	2	0.504	2	0.777
	21-25	25	7			
	>25	24	5			
Education	Upto matric	6	2	0.566	2	0.753
	Senior secondary	31	9			
	Graduate & above	17	3			
Occupation	Employed	13	4	0.547	2	0.144
	Self employed	17	3			
	Housewife	24	7			
Type of family	Nuclear	34	8	0.159	1	0.221
	Joint	20	6			
Type of locality	Urban	19	7	1.033	1	0.144
	Rural	35	7			
Number of children	1	40	12	2.803	2	0.246
	2	13	1			
	>2	1	1			

Chi square/fisher exact test

Table 30 - Immunization compliance among primary caregivers of control group at 14 weeks and association with selected variables.

Variables	Categories	Vaccination received as per schedule	Vaccination received late	χ^2 value#	df	P Value
		n	n			
Age (in years)	Upto 20	6	1	0.115	2	0.943
	21-25	28	4			
	>25	26	3			
Education	Upto matric	7	1	0.325	2	0.849
	Senior secondary	36	4			
	Graduate & above	17	3			
Occupation	Employed	14	3	8.075	2	0.021**
	Self employed	15	5			
	Housewife	31	-			
Type of family	Nuclear	39	3	2.260	1	0.102
	Joint	21	5			
Type of locality	Urban	22	4	0.531	1	0.226
	Rural	38	4			
Number of children	1	45	6	0.486	2	0.253
	2	12	2			
	>2	3	0			

Chi square/fisher exact test

Data from the table 25 till 30 shows that vaccination compliance in interventional group was not found associated with any of the socio-demographic variables of the primary caregivers at 6 weeks and 10 weeks. However at 14 weeks, type of locality was associated with $p < 0.05$. For the control group, vaccination compliance among primary caregivers was found associated with education at 6 weeks and occupational status at 14 weeks with $p < 0.05$.

Summary -it can be inferred from the above results that the need based interventional tool was effective in increasing the awareness and self-efficiency among primary caregivers/subjects in caring for children undergoing primary immunization. Gender and birth weight were found to influence vaccine related problems among children. Immunization compliance among primary caregivers was seen to be influenced by their education, occupation and type of locality.