

## **Chapter 5**

### **Discussion**

#### **Phase I**

The current study was undertaken with the aim of determining the effectiveness of a need based tool on awareness and self-efficiency in caring children during primary immunization. This study is a mixed method research conducted in two phases consisting phase I, the qualitative part in which focus group discussions were conducted with the primary caregivers in immunization rooms of Regional hospital Solan, Community health centre, Dharampur and Civil hospital, Kandaghat. Guiding questions were framed and one session per group was conducted. Total four FGDs were conducted to assess the information needs of the primary caregivers. The second phase was conducted in Regional hospital, Solan. Seventy five subjects (primary caregivers) were recruited to interventional and control group each via systematic sampling. All the subjects were followed on every immunization event till nine months. Their self-efficiency and vaccine related problems were enquired at every immunization event (from birth till nine months) while awareness was assessed at birth, six weeks and nine months.

The results are discussed in a phased manner in the following content.

- a. Phase I- Description of results of focus group discussions.
- b. Phase II- Description of the results of quantitative part conducted to assess effectiveness of need based interventional package.

#### **Description of felt information needs related to vaccination and care of immunized children**

The main theme identified was information needs of primary caregivers with the following sub themes.

##### **Vaccine related information**

It was found in this study that most mothers were not much aware of importance of immunization and how vaccines provide immunity to children. Most didn't know about vaccine preventable diseases. Polio, Hepatitis, measles were some of the diseases known to mothers however most other are not known to them. Some

even named diabetes and jaundice as vaccine preventable. These results are in contrast to a study where majority mothers (73.5%) knew about importance of immunization, 59% knew about vaccine preventable diseases and about the schedule also.<sup>75</sup> Contrasting findings were also reported by another study that reported higher percentage of mothers (98.5%) having knowledge about mandatory immunization and more than 80% mothers with positive attitude towards immunization.<sup>76</sup>

The caregivers in the study reported having received little to no information about immunization from the health care providers. They reported having no information about vaccines, their side effects and their management and attributed this deficit to lack of time and overburden on the staff. Other studies have found significant association between knowledge of parents and their child's immunization completeness. Good knowledge and attitude were found predictors to complete immunization. Researchers also stressed that parents' level of knowledge and compliance depend much on their information that comes from a physician and medical. Providing adequate knowledge also leads to increased compliance with the immunization schedule.<sup>54</sup> In a literature review done on identifying communication strategies adopted with parents in relation to immunization, it was concluded that communicating effectively covering the risks associated, rare and also serious side effects also and should also be tailored to individual need.<sup>77</sup>

Most primary caregivers in the current study were aware of few vaccine related problems and were informed about the same by the vaccinators also. Other problems experienced by caregivers were feeding problems, prolonged ulceration at BCG site, sleep problems, crying, nodule formation etc. Some caregivers believed that fever is important after vaccination; else the injection is not effective. In an Iranian study, the adverse effects found among 145 children were fever, febrile seizures, restlessness, swelling at immunization site, weakness etc.<sup>78</sup> In an Indian study, the reported number of AEFIs was 23.03%. Fever was the most reported AEFI (54.90%), diarrhoea (8.30%) and vomiting (8.14%). AEFIs were more frequent during the weeks after vaccination and most of the parents of children did not report AEFI even after seven days after immunization.<sup>79</sup> Other studies have also found that primary caregivers reported vaccine related problems in about 98% children. Around

70% problems were reported after BCG and Pentavalent vaccine administration respectively. Fever and swelling of the injection sites was found in 84.0% and 38.5% of the children, respectively. 7.8% children who experienced AEFIs were hospitalized.<sup>80</sup>

In the present study the caregivers were not aware of specific sign if allergy or adverse event. Some caregivers reported having taken the child to the hospital as they didn't know about the nodule formation after immunization. None of the caregiver knew of any specific sign for which visiting a doctor/ medic is required. Similar results were reported by Afolaranmi TO et al (2020) in their study on prevalence of adverse events, mother's knowledge and action taken by them. Only 14.5% mothers took appropriate action following AEFI in their children. Appropriateness of actions taken by the mothers following the occurrence of AEFI was influenced by the their employment status.<sup>81</sup> Mishra, N et al (2021) reported good knowledge among mother regarding minor side effects like fever (98%) and local reaction (85%) was good, while only 15% of the mothers knew about serious adverse events like seizures and anaphylaxis. 66% mothers reported trust in their doctor in case of an adverse effect. Awareness regarding contraindications to immunization was poor.<sup>82</sup>

### **Management of vaccination related problems**

Few caregivers in the study reported managing fever with Paracetamol and cold sponging. They were not aware of any position to alleviate pain and had inadequate knowledge about antipyretic administration. For pain at the local site some even reported having done hot fomentation and application of vicks around the injection site. Knowledge about management of ulceration at BCG site was poor and some reported having taken baby to the doctor for infection management. According to a Nigerian study, majority of the respondents, reported adverse event after few hours of administration. The information given related to AEFI was, to take the infant to the hospital. Other management used by mothers were use of Paracetamol and tepid sponging. Fever was among 53.8% children and was the major cause of hospitalization.<sup>80</sup> A descriptive cross-sectional study was carried out among caregivers of infants attending immunization clinics. The study revealed that BCG, OPV and Pentavalent vaccines were responsible for most of the AEFI observed. Pain

at the injection site (27%), boils (27.0%), and fever (24.3%) were the common AEFI reported by the caregivers. Drugs (77.4%) and icepacks (21.4%) were mainly used to treat the AEFI by the caregivers.<sup>83</sup>

### **Description of the socio-demographic variables of the primary caregivers in the study.**

The greatest proportion of primary caregivers in the present study were in the age group of 21-25 years for both interventional and control group i.e. 51% and 48% respectively, followed by 26-30 years (29% and 32%). Few (5%) in interventional group were aged 31-35 years and none was in 41-45 years age group. The mean age was  $26.06 \pm 4.46$  for interventional and  $25.89 \pm 4.53$  for the control group. The subjects in the current study are younger compared to other studies which had had maximum mothers (59.1%) from the age group of 25-34, followed by 35-44 years (29.2%).<sup>84</sup> Also in a Cypriot study on the knowledge of mothers regarding childhood immunizations conducted on 700 subjects, the mean age was  $36.3 \pm 5$  years and between 32-39 years.<sup>85</sup>

As regards the educational status, majority primary caregivers were educated upto senior secondary i.e. 48% in interventional group and 56% in control group while graduates were 15% and 20% in interventional and control group respectively. Only 12% in interventional and 9% in control group were post graduates. Studies conducted in different countries reported greater number of graduates (61%), followed by senior secondary level (26%)<sup>76,86</sup>

Occupationally, 50% of the primary caregivers in the present study in both the groups were homemakers. Similar proportion of subjects were reported by a study conducted on 56.5% homemakers<sup>76</sup> whereas in an Indian study, 75.7% homemakers were a part of study regarding vaccination knowledge and attitude.<sup>29</sup>

Approximately 60% primary caregivers in both interventional and control group study belonged to nuclear families. In a similar descriptive survey on mother's knowledge regarding immunization, it was observed that majority of mothers i.e. 72% had nuclear families.<sup>87</sup> Majority were from rural area in the current study (80%) in both the groups. Similar distribution of subjects have been seen in previous studies that report more than 60% subjects from rural background.<sup>29</sup>

Current study has majority primigravida mothers (72-75%) in both interventional and control group. This is followed by 24% in interventional and 21% in control group had two children. Few even had more than two children. Contrasting distribution of number of children was observed by Almutairi WM et (2021) in their study and had one third (approximately 33%) mothers who had one child and an equal proportion i.e. 33% mothers with two or more than two children.<sup>76</sup> Suheir A et al (2021) in their study had maximum subjects who had one child 97% and while the remaining had two children.<sup>86</sup>

Vaccine related problems have been studied in the current study among children that consisted of more than 60% females in both the groups. A similar proportion of children weighed 2500-3000gms in both the groups. Most (80%) subjects in interventional and two third subjects in control group had normal delivery Other studies have reported around 48% females<sup>85, 88</sup> A study on epidemiological study of adverse events following immunization in under 5 year children had birth weight of most cases (44.06%), of AEFI between 2 and 2.4 kg followed by range of 2.5 and 2.9 kg i.e. 32.20%.<sup>89</sup>

In an another prospective study on active surveillance of AEFIs among children up to three years had 84.2% children with birth weight of 2.4-4 kg and 11.9% were low birth weight( 2.5-1.5 kg). Birth weight was studied as a predictor of AEFI among children.<sup>90</sup>

### **Effectiveness of the need based interventional tool in terms of awareness among primary caregivers.**

Awareness regarding immunization was studied using a validated forty three item self -structured questionnaire administered on primary caregivers at time of enrolment (at birth) and then again at 6 weeks and 9 months of child's immunization. The pre-existing awareness of primary caregivers in both groups was between good and average level and the difference was statistically not significant. Poor awareness was seen in 1.3% in control group only. None was found to have very good awareness. The pre-test awareness in the current study was better as compared to a study done by D'Souza VP et al which reported alarmingly 86% in experimental and 94% in control group having inadequate knowledge regarding immunization. The rest had moderate level of knowledge.<sup>91</sup> A yet another study the knowledge level of

mothers was found to be inadequate for 15%, moderately adequate for 81.7% and adequate for 3.3% at the time of pre-test.<sup>92</sup>

In the current study post-test for primary caregivers' awareness was conducted twice for interventional and control group during follow ups of primary caregivers at second and fifth immunization event i.e. 6 weeks and 9 months. The interventional group had significant rise in the number of primary caregivers whose awareness scores increased to very good level of awareness from 42.7% at 6 weeks to 50% at 9 months. The control group however didn't show much improvement in their awareness scores. While none of the subject's awareness increased up to very good awareness in the control group, the number of primary caregivers in the good awareness category increased to 45.3% from 42.7% and was 43.8 % at 9months. The increase in the awareness score can be attributed to the effect of pretesting which however was later found not significant. The mean awareness scores for interventional group at 6 weeks and 9 months were  $32.52 \pm 4.55$  and  $32.76 \pm 5.91$  respectively while being  $19.84 \pm 4.393$  at birth. As for the control group it was  $19.31 \pm 4.28$  and  $19.33 \pm 4.26$  at 6 weeks and 9 months respectively as against  $19.25 \pm 4.243$  at birth. While the interventional group had significant increase in mean from birth till 6 weeks, the mean at 9 months is not significantly from 6 weeks indicating the effectiveness of the interventional package in first few months after birth. The mean awareness scores in control group also didn't change much from their values at 6 weeks. Unlike the current study, most studies related to awareness of mothers regarding immunization have conducted post- tests once after intervention. Current study is an effort to understand the need of informative intervention during the whole process of immunization.

Previous studies have also reported a significant improvement in the mean post-test knowledge of mothers in the interventional group. In the control group however it was seen that mean knowledge remained at the same level. In a study, 80% of subjects in the experimental group rose to the adequate knowledge category and 20% remained in moderate knowledge category<sup>91</sup>. Francis L et al. (2019) observed in their study that most subjects in the moderately adequate category moved to adequate knowledge. Also the mean in the post test increased to  $22.23 \pm 1.817$  from  $12.40 \pm 3.163$  in the pre-test phase.<sup>92</sup>

Unpaired t-test was computed to determine significant differences in the mean awareness scores of interventional and control group. At first immunization event (birth) the mean awareness scores had no significant difference between them ( $p=0.359$ ). Further assessments at six weeks and nine months revealed significant difference in awareness levels with  $p < 0.001$  indicating the effectiveness of interventional package in increasing primary caregivers' awareness regarding immunization. Repeated measure ANOVA compared mean awareness within the groups (both interventional and control group). Statistically, the differences were found significant for interventional group. Post HOC Tukeys test revealed that awareness improved significantly after implementation of interventional package; however awareness after 6 weeks is not significantly increased. This necessitates that any informative intervention should be planned and is well received during early life of the child.

The results corroborate with previous studies on knowledge and vaccination compliance. Significant increase in knowledge level of mothers was also reported by other studies where post test scores were significantly higher than pre-test scores with  $p < 0.05$ .<sup>91,92</sup> Similar results were obtained by Jackson PT et al(2018) in a randomized controlled trial to assess effectiveness of information intervention among mothers related to DPT immunization and measles. The intervention improved the awareness of mothers related to several aspects of tetanus but did not affect their perceptions of vaccine efficacy. Immunization rate for DPT and measles vaccine was also found to have increased for subjects in intervention arm “( $p < 0.05$ ).<sup>30</sup>

Mothers are primary caregivers and decision makers for matters related their child's health. Previous studies propose that their awareness impacts the timeliness and post immunization care of the child. Hence their awareness regarding the schedule, minor and major vaccine related problems and post immunization care is an important aspect of this study.

Assessment of awareness among primary caregivers was done at first immunization event (at birth), then at second immunization event (6 weeks) and at fifth immunization event (at 9 months). The comparison of awareness scores (annexure-16) showed that at birth, 94.6% understood about the protection provided

by immunization and it increased to 95.4% at 9 months. The first five years of a child's life are crucial for survival due to his vulnerability for several infections. This was acknowledged by 56% initially and rose to 86.3% at 9 months. Nurse or a health worker was identified as an important source of information by 38.6% initially and 86.3% at last assessment. Health workers role in providing immunization related information was supported by AHM Ali et al (2020).<sup>84</sup> Majority were aware of BCG related reaction (74.2%), 54.5% understood the course of action in absence of a scar formation at last assessment. Awareness regarding management of BCG scare also increased to 86.3%.

Post-polio paralysis is rarely life threatening but can cause permanent disability among children. Despite its elimination, the fear of imported infection necessitates polio vaccination. Paralyzing effect of polio was known to more than 70%. Understanding oral intake around polio vaccination increased to 66.6% from an initial level of 20%. The awareness increased to more than 80% primary caregivers was observed related route of rotavirus and PCV vaccine, age for MR vaccine, conditions prevented by MR vaccine, symptoms associated with most vaccines, minor local reactions with vaccine injections, pain reduction during vaccination, BCG scar management, indication of polio vaccine reaction, fever management, and related to identification of mild and severe reactions at nine months. The interventional package was successful in increasing primary caregivers' awareness for, maximum age until which immunization is done, site of MR vaccine administration, symptoms associated with most vaccines to 100%. Alarming low level of awareness was observed (4%) related to, serious reactions after immunization and indication of allergy initially. This however increased to motivating level of more than 70% at last assessment. Results of this study corroborate with other studies which also report an improvement of knowledge regarding immunization upto 70% in experimental group. The control group the level didn't change much and remained around 25%.<sup>91</sup>

In a yet another study, awareness of mothers from urban and rural background was compared. Mothers from urban area were found more knowledgeable. Knowledge related to effects of polio was good (more than 60%) irrespective of type of locality.<sup>29</sup> An another study by Balbir Singh HK et al (2019)



found that association between knowledge of mothers and their age, education and occupation was statistically significant.<sup>75</sup> Previous studies have also supported that barring a few variables, mothers awareness, attitude and practice related to immunization is not influenced by their socio demographic variables.<sup>76,87</sup>

### **Effectiveness of the need based interventional tool in terms of self-efficiency of primary caregivers.**

The concept of self-efficiency as is under this study has been frequently studied earlier in terms of self-efficacy. Self-efficiency here can be described as the actual performance of the primary caregivers over time than just being a perceived concept (efficacy). Limited literature in this direction mandates researcher to make comparison with self-efficacy. Bandura's remarkable goal attainment theory forms the base for this concept. Studies conducted in the past propose that self-efficacy leads to persistence in face of difficulties. Self-efficacy has been mainly studied among mothers related to parenting, breastfeeding initiation and others concept related to parenting. Self-efficacy has also been associated with parenting satisfaction. Studies revealed lower self-efficacy scores lead to low parenting satisfaction. Unemployed or part time working mothers report higher self-efficacy.<sup>93</sup> During post immunization period the infants are emotionally negative. Studies partially support that maternal self-efficacy is high among mothers of irritable infants. Self-efficiency of primary caregivers in the current study was measured using a self- structured six item scale administered at every vaccination event .Pre-test conducted at first immunization revealed, average efficiency among half of primary caregivers in interventional and control group respectively while the rest had poor self-efficiency. Self-efficiency increased consistently in the interventional group after implementation of interventional package while remained stagnant for control group. By nine months most (78.8%) in the interventional group had good self-efficiency. For the control group, they remained in average efficiency category and in poor efficiency category in equal proportion. Initially a marginal difference existed in the mean self-efficiency score was  $12.91 \pm 2.255$  and  $12.97 \pm 2.193$  in interventional and control group respectively. The differences in mean at all successive assessments was found significant ( $p < 0.001$ ). The control group didn't have significant difference in the mean self-efficiency at any point of measurement.

Comparison of within group self-efficiency scores of primary caregivers in interventional group found significant change in self-efficiency ( $p < 0.001$ ). For the control group it was found to be not significant ( $p = 0.412$ ). It can hence be concluded that the interventional package significantly improved self-efficiency among interventional group. Post hoc test also revealed significant improvement in all paired comparison of self-efficiency in interventional group as compared to control group.

Nurhasanah, I et al (2018) studied the application of Health belief model and observed its association with the completeness of the vaccination among children. The study elucidated that HBM components associated with complete immunization among children were namely, knowledge, perceived benefits and self-efficacy. However other components like social demographics, perceived susceptibility, perceived severity and perceived barriers did not influence vaccination coverage.<sup>68</sup> Many researchers advocate broader applicability of this construct than just limiting it to parenting of an infant.

#### **Vaccine related problems among children of primary caregivers.**

Minor problems after immunization are common and occur in among 50-60% children. The immunogenic component of a vaccine often produces adverse reactions. These are local and systemic noticeable signs and symptoms occurring as the immune system respond to vaccine. Pain/soreness at vaccination site, fever, nodule formation, irritability, persistent crying, drowsiness, muscle and joint pain are common. Lesser common are encephalopathy, convulsions etc. According to previous studies the reported incidence of adverse events was 15.8% for swelling, redness(10.9%), 44.2% for pain, 12.6% for mild fever, 0.1% for high fever, 20.0% for drowsiness, 15.0% for loss of appetite, 32.9% for irritability, 4.6% for vomiting and 5.5% for persistent crying.<sup>94</sup> Studies also report fever with the highest incidence ( 10.9%) and is followed by persistent crying (0.24%) and diarrhoea(0.17%).<sup>90</sup>

The vaccines given at various immunization events are different. At birth , vaccine administered are BCG, Hep B and OPV zero dose. Pentavalent, rotavirus, OPV, PCV, FIPV are given at six weeks, at ten weeks vaccines are Pentavalent, rotavirus, OPV. At fourteen weeks, Pentavalent, rotavirus, OPV, PCV, FIPV are provided and MR-1, booster PCV at nine months. A combination of vaccines given

at every vaccination leads to a spectrum of local and systemic symptoms. Few vaccines like BCG, Pentavalent are associated with increased adverse events. Similar pattern was also observed by Mittal et al and Sebastian J et al and reported problems maximum number of AEFIs after Pentavalent vaccination followed by BCG administration.<sup>90,95</sup>

The current study observed that pain at vaccination site, excessive crying, feeding problems and redness and swelling were most common vaccine related problems at first vaccination event. Redness and swelling at immunization site was seen at all immunization events. Nodule formation after Pentavalent vaccination occurred commonly among all children. The current study reports more diverse problems among children after vaccination compared to most other studies.

According to medical literature, fever is known to be associated with pertussis component of Pentavalent vaccine. In the current study it was reported among more than 80% children. Contrary to previous studies that reported a decrease in fever incidence at successive Pentavalent vaccine administration<sup>90</sup>, current study did not observe same pattern. It was observed from six to fourteen weeks of immunization mainly. Pentavalent vaccine and BCG have long been majorly implicated for AEFIs among children.<sup>90</sup> Results from researches conducted in other countries also report mild fever and injection site reaction after Pentavalent vaccination.<sup>96,97</sup> An another study reported similar adverse reactions among children after vaccination. Fever, pain /swelling at vaccination site was present in around 25%, while lesser common symptoms like somnolence, lack of appetite, allergy were in less than 10% children while in the current study sleep disturbance was seen at six and fourteen weeks.<sup>98</sup>

Studies in the past have correlated children's attributes and parents' variables with the incidence of adverse reactions among children and AEFI reporting. Selective studies propose relationship of parental level of education and attitude with reporting of AEFI among children.<sup>100</sup> Gender, low birth weight and very low birth weight have been proposed as predictor for AEFI by previous literature.<sup>90,99</sup> The investigator of the current study observed that vaccine related problems were associated with gender and birth weight of children. Every vaccine related problem under study was found associated with these variables at some point during the

process of immunization at varying events and hence corroborate with the findings of the previous studies. None of the variables (gender and birth weight) associated consistently with vaccine related problems from birth till nine months of vaccination.

### **Immunization compliance among primary caregivers.**

Complete immunization of a child requires coverage and timeliness that starts from first year of a child's life. Timeliness of vaccination is an indicator of effective immunization program. Full compliance with the immunization schedule, appropriate to age was present in both interventional and control group at birth. Thereafter at six weeks, 20% in the interventional and 17.3% in control group received vaccination late. At 14 weeks 12.9% in intervention group and 11.2% children received vaccine late. At 9 months, all the children in intervention group were vaccinated on time but 1.6% in control group was vaccinated after the recommended age. Every child under the study had his/her first vaccination within days of birth and there was no delay. Majority of the subjects had good compliance regarding vaccination schedule. Lower rate of vaccination completion have reported from other countries where only 26% children received the recommended vaccines on time.<sup>100</sup>

Hu Y et al (2017) studied timeliness of primary immunizations among children and factors related to delayed immunization. In the study, 90% of the surveyed children had received BCG by 2.3 months of age; HBV1 by 3.1 months of age, OPV1 by 2.9 months of age, DTP1 by 4.0 months of age. Ninety per cent of the surveyed children had received MR by 9.7 months of age. More than 95% of the children studied had their primary immunization before 1 year of age. Only few were immunized with these vaccines (except for HBV1 and OPV1) at the recommended age.<sup>96</sup> The current study reports completion of primary immunization in over 98% children within the recommended time frame.

New interventions for vaccination compliance should be planned considering the socio demographic variables of caregivers affecting it. Factors like maternal education, occupational status, place of delivery, number of children and low socio-economic status can delay immunization.<sup>97</sup> Studies propose younger maternal age, large family size, low socio economic status and unemployment, perceived self-efficacy are associated with vaccination compliance. Whereas parents in

government sector, high socio economic status and older maternal age ensure compliance.<sup>101,102</sup>

The current study revealed that type of locality; educational status of primary caregivers and their occupational status affect compliance with immunization schedule and ensure timeliness. None of the other variables related to primary caregivers influenced immunization compliance.

### **Limitations**

- Only self- reported responses of primary caregivers were recorded.