Chapter 3
Materials and methods

This chapter deals with the scientific methods and techniques used in the research. It encompasses both qualitative and quantitative methods. According to Sam Goundar "The research methodology constitutes the internal environment by understanding and identifying the right type of research, strategy, philosophy, time horizon, approaches, followed by right procedures and techniques based on his or her research work." It rationalizes the steps taken to address the problem and to have valid and reliable results. Methodology consists of research approach, research setting, and target population, sampling method, sample size, selection and development of tools, description of tools, pilot study and data collection. [72]

Research approach – A mixed methods approach was used consisting both qualitative and quantitative methods. Mixed method approach is rigorous and gives holistic analysis of a multifaceted problem.

Research Design- The current study utilized mixed methods, wherein the quantitative phase is based on findings of the initial qualitative phase. Researcher used qualitative approach in phase one and quantitative approach in phase two.

- Phase I- In this phase the study involved assessment of subjects (parents and caregivers) personal experience of child's reaction to past vaccination, management of vaccine related problems done and their felt need for information. Assessment of this qualitative part was done using focus group discussions.
- Phase II- In this phase, the quantitative methods involved use of questionnaire and self-efficiency tools to measure their awareness level and their ability to perform efficient management of the child experiencing vaccine related problems.

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Phase I (Qualitative part)

Research design– the approach is qualitative as explained above. A deeper understanding of the phenomenon was attained using this approach. An exploratory design was utilized to identify gaps and knowledge and practices of primary caregivers through focus group discussions

Research setting- Research setting is the physical set up or location where the data collection takes place. Vaccination facility of Regional Hospital, Solan, Civil Hospital Kandaghat, and Community Health Centre Dharampur) was used for this purpose. A room adjacent to vaccination room was selected for the discussion and recording. It was kept in mind that the subjects felt comfortable and were given time to get acquainted with procedure.

Target population – Target population is the entire set of population to which we desire to generalize the results of the study**.** This part of the study aimed to collect information from primary caregivers of children up to two years of age. They were chosen since by this age the child usually completes his/her primary vaccination regime and the caregivers experience vaccine related problems to their children during immunization if any.

Accessible population- Primary caregivers accompanying children in vaccination facility of CHC Dharampur, Civil Hospital ,Kandaghat and Regional Hospital, Solan.

Sample size –Sample size for focus group discussion is decided according to the topic of interest. Some researchers suggest "The optimum size for a focus group is six to eight participants (excluding researchers), but focus groups can work successfully with as few as three and as many as participants."[73] It depends on the

quantity and quality of information that each participant is capable of providing. Phenomenon and experiences that are common will have early data saturation. According to some researchers, two to three focus groups are sufficient to capture 80% of themes, including the most prevalent themes; and three to six groups for 90% of themes in a homogenous study population using a semi-structured discussion.[74] In the current study overall twenty participants were interviewed in focus groups. One session per focus group was conducted that included five participants per session and per group and in total four FGDs were conducted.

Sampling method – Subject were selected purposively based on their desire to participate, availability of their time and level of cooperation.

Inclusion criteria

- Primary caregivers of immunized children aged up-to two years.
- Primary caregivers who were able to read and write.
- Primary caregivers who had experienced problems related to immunization of their children.

Exclusion criteria

- Primary caregivers of children requiring special care.

Data collection method ─ Focus group discussions were conducted with caregivers to allow an in depth discussions with the subjects. For each of the four FGDs, the caregivers were approached and explained about the study and were invited for the focus group discussion on the vaccination day. Personal details were obtained after getting written consent from each subject. The consenting caregivers were seated in the room where all arrangements for seating, discussion and recording were already done. They were formally introduced to each other. The rules for the discussion were spelt out as. Each discussion was moderated by the researcher and lasted 25- 30 minutes. Every caregiver was given an opportunity to verbalize. There was no domination over the sessions by any single participant. One FGD was conducted for

each group. On exiting the discussion they were asked to contribute anything related to the discussed topic. The session ended with the researcher thanking them.

Data collection tool- a semi structured interview schedule was used. Pre-decided guiding questions were used. The questions were related to the knowledge of caregivers about the importance of vaccination, the adequacy of information, vaccination related problems and their home management as done by them and their understanding of the need for doctor's consultation.

Data analysis method – a content analysis was done. The videos recorded during FGDs were transcribed by investigator and the verbatim was prepared. The data was further coded to develop a few sub themes which were then utilized to generate main themes.

Phase II (Quantitative part)

This was interventional phase where results of phase I were utilized to develop a tool to address the problems identified by mothers and caregivers of children after receiving immunization.

Research design – Quasi experimental (pre-test post- test control group design).

Randomization	**Control group**	**O1**	**-**	**O2**	**O3**	**O4**	**O5**
	Interventional group	**O1**	**X**	**O2**	**O3**	**O4**	**O5**
	Time of assessment	First immunization (birth)	Delivery of interventional package	Second immunization (6 weeks)	Third immunization (10 weeks)	Fourth immunization (14 weeks)	Fifth immunization (9 months)

Figure 2- Schematic representation of data collection in phase II.

Where

O1-O5= assessment of awareness, self-efficiency and vaccine related problems in control and interventional group.

X= delivery of intervention (need based interventional package) in interventional group.

Time of assessment = every immunization event of child till nine months.

Research setting – used was vaccination clinic of the Regional Hospital, Solan.

Target population – Primary caregivers of children receiving primary immunization.

Accessible population- Primary caregivers of children getting vaccination from the selected health facility (Regional Hospital, Solan).

Sample size – twenty five caregivers in each interventional and control group were enrolled. The sample size was calculated by using the formula $n=Z\propto/2^2pq/I^2)$

with a desired allowable error of 20% of 'p'. P = 50%, q=1- p (50) and I (allowable error) =20% of p (10).

$$= (1.96)^2x0.5x0.5/0.10^2$$

$$n = 96.04(total) = 48 (each group)$$

Keeping in mind loss to follow ups (10%), the sample size was increased to 53 in each group. Upon final enrolment, as more subjects showed interest the final sample size of 75 in each group was achieved.

Sampling method –systematic random sampling technique was used to enrol the subjects. For the selection of subjects for intervention and control group, the first subject was randomly selected between one and the sampling interval using lottery method. Thereafter, systematic random sampling was used to select the subjects further. A sampling interval of 10 was used.(700/75 = approximately 10, where 700 is the approximate no of potential subjects in a month, and 75 is the no. of

subjects to be enrolled . After randomly selecting 4(as the first subject), every 10th subject was enrolled in the study to achieve the total sample size. Similar technique was used for both control and interventional group.

Variables of the study

- **Independent variable-** Interventional package for managing children during primary immunizations.
- **Dependent variable-** awareness and self-efficiency of primary caregivers.
- **Other variables –** vaccine related problems among children of primary caregivers, immunization compliance among primary caregivers.

Inclusion criteria – the study included primary caregivers who

- Accompanied their children for immunization.
- Were able to read and write.

Exclusion criteria

- Children requiring additional care.
- Children with any congenital anomaly.

Description of tools and Techniques for Data Collection: the following tools were used were used for data collection.

Phase I

This phase was conducted in July – August 2019. Prior to this, a thorough literature review was done related to vaccine related problems and experiences of caregivers regarding care of children post vaccination. Informal discussion was done with the vaccinators and mothers visiting vaccination room was done to get a clear picture. The investigator then developed a semi structured interview schedule consisting of five guiding questions that helped achieve first objective of the research.

Phase II

This phase consisted use of three tools, namely awareness questionnaire for primary caregivers, self-efficiency tool for primary caregivers and tool for recording vaccine related problems. These were based on content of interventional tool and responses received during phase I.

Tool description

Phase I

Part A- Profile of caregivers included in FGDs

This section consisted of basic information about primary caregivers enrolled in the focus group discussions including their age, education, marital status, area of residence, occupation, type of family, prior experience related to vaccination of child.

Part B- Guiding questions for FGDs - this tool consisted of baseline information about the primary caregivers and their socio demographic details. Total five open ended questions were framed based on literature review and opinions from the experts.

Self-efficiency tool for primary caregivers- it was self-administered Likert type scale consisting of six items related to breastfeeding, positioning during vaccination, identifying excessive crying, reducing pain and swelling, fever management, signs of allergic and serious reaction (annexure 15). The items were scored as: 1–Never, 2-Almost Never, 3-Occasionally, 4-Almost Every time, 5-Everytime

The total scores of the tool were interpreted as:

- Poor efficiency: 6-13
- Average efficiency: 14-21
- Good efficiency: 22-30

Tool for recording vaccine related problems- this tool enlisted vaccine related problems as reported by primary caregivers during FGDs and as suggested by literature. The occurrence of vaccine related problems and their duration were recorded at each immunization event.

Validity of tools- All the tools were validated by experts from the fields of community health nursing, paediatric nursing, obstetric and gynaecological nursing, medical surgical nursing, psychiatric nursing and community medicine. Modifications as per their suggestions were incorporated in tools. The tools were finalized after achieving more than 80% agreement on each item. Content validity index for awareness questionnaire, self- efficiency scale and tool on vaccine related problem was 0.81, 0.83 and 0.84 respectively.

Reliability of awareness questionnaire: Test retest method was used to establish reliability of the tool. Cronbach's alpha for internal consistency was obtained as 0.82 and Spearman Brown's correlation coefficient was 0.94.

Reliability of self-efficiency tool: Test retest method was used and the tool was found reliable as Cronbach's alpha value was 0.95 and Spearman Brown's correlation coefficient was 0.86.

Reliability of tool for recording vaccine related problems: the reliability of this tool was also measured using Cronbach's alpha for internal consistency and Spearman Brown's correlation coefficient for test retest method. The values were 0.84 and 0.95 respectively and were hence found reliable.

Pretesting of the tools

- A checklist of criteria for pretesting was prepared and was conducted on five mothers of infants. Feedback was obtained regarding logical ordering, comprehension, and ambiguity of items. The time taken to comprehend and fill the tools was 15-20 minutes. Their suggestions related to the tools were incorporated. Overall the items were clear, concise and understandable.

Ethical considerations-

- Ethical clearance for the conduct of study was obtained from the institutional ethical committee of Swami Rama Himalayan University.[Annexure-1]
- The subjects were explained in Hindi language, about the aims, objectives, methods and information desired from the study.
- Participants of focus group discussions were also informed about the time required, videotaping and its purposes for the researcher.
- Written consent was obtained from all the participant.[Appendix-6]
- They were informed about their right to withdraw from the study at any point of time.
- Confidentiality and anonymity of the participants was maintained.

Administrative permission - was obtained from Director of health services, Himachal Pradesh for conduction of research. [Appendix 3]

Pilot study

It was conducted on five primary caregivers in each interventional and control group from Dec 2020 to January 2021 in vaccination facility of Regional Hospital, Solan,(H.P). The main aim was to determine the feasibility of the methodology. It was found feasible and practicality of planned intervention was established.

Development of need based interventional package on care of children during primary immunization.

The intervention package was developed keeping in mind the gaps in knowledge and practices identified during focus group discussions. The information thus obtained was combined with literature support and national AEFI guidelines. First draft of need based interventional package was prepared and was validated by experts in related field. It was then translated to Hindi language to make it understandable to the targeted population. Pre-testing was conducted on mothers of infants visiting vaccination room. Their suggestions were taken into account and final draft of need based interventional package was prepared.

The interventional package consisted of the following sections:

- Importance of immunization.
- Immunization schedule.
- Vaccine related information.
- Minor problems associated with vaccination.
- Pain management during administration.
- Home management of vaccine related problems.
- Identifying sick conditions in which child can be immunized.
- Identification of severe and allergic reaction to vaccination.

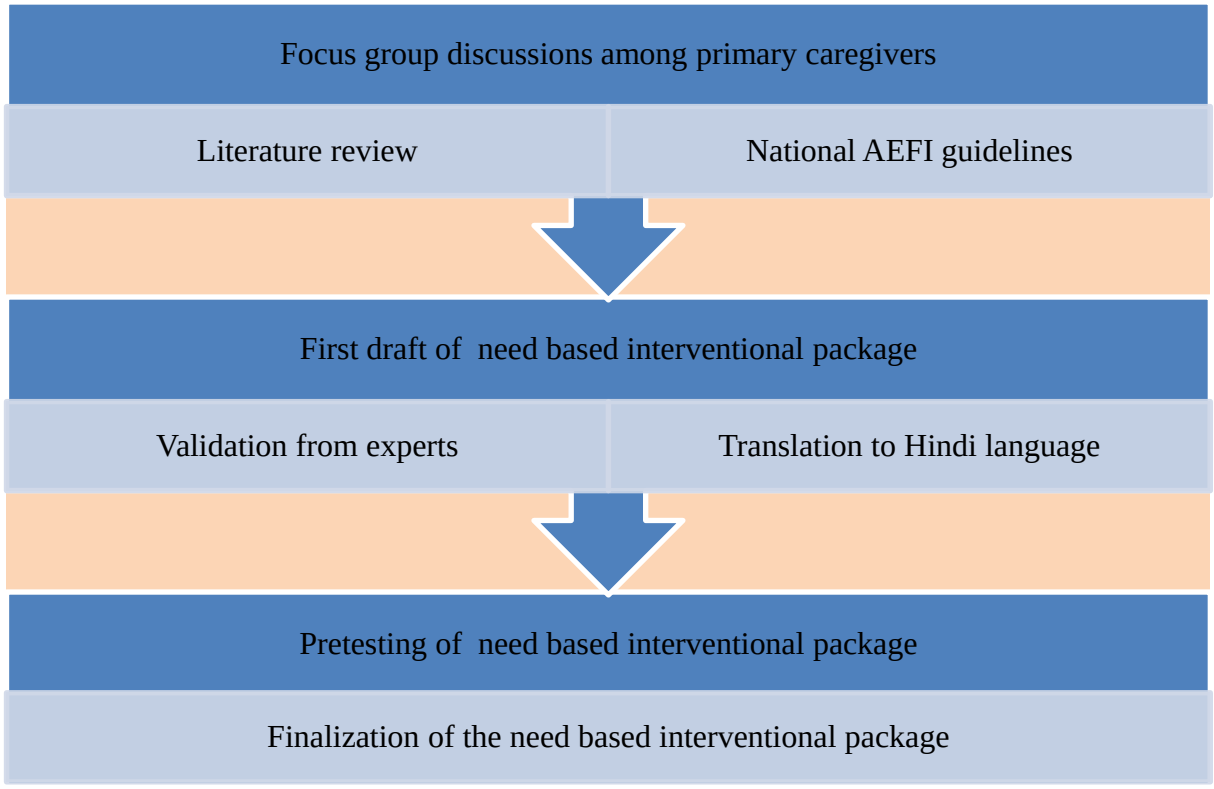

Figure 3- Steps of development of need based interventional package.

Implementation of interventional package in the interventional group.

The interventional package was delivered to the primary caregivers in the intervention group after assessment of their baseline awareness and self-efficiency at the first immunization of their children. The teaching was delivered individually to the primary caregivers in a room adjacent to vaccination room. It was delivered via

interactive discussion and audio visual aid to demonstrate few sections like facilitated tucking, breastfeeding positions, signs of attachment and temperature monitoring. The various sections of the package were discussed. Overall delivery of intervention took 15-20 min and any concern raised by the primary caregiver was addressed. The written content in Hindi was handed over to them for further reading at home. Verbal reinforcement to go through the content was given to them at each successive visit for immunization.

Data collection procedure – The enrolment was done in vaccination room of Regional Hospital. Selection of primary caregivers was done according to sampling plan. To prevent contamination of the study groups, the enrolment of the control group was completed prior to enrolment of subjects of the interventional group. This method thus prevented any information exchange at subsequent vaccination events. Baseline assessment (pre-test) for awareness and self-efficiency was done at first immunization event. The interventional package was delivered to the interventional group in an adjacent room after their baseline assessment. The intervention delivery was done individually and took 15-20 minutes. Afterwards the subjects were followed in each group on every immunization event namely on 6weeks, 10 weeks, 14 weeks and 9 months. The administration of awareness questionnaire was repeated on 6 weeks and 9 months. Self-efficiency was assessed at 6 weeks, 10 weeks, 14 weeks and 9 months. Vaccine related problems were enquired from the caregivers of children about on every follow up till 9 months for both control and interventional group.

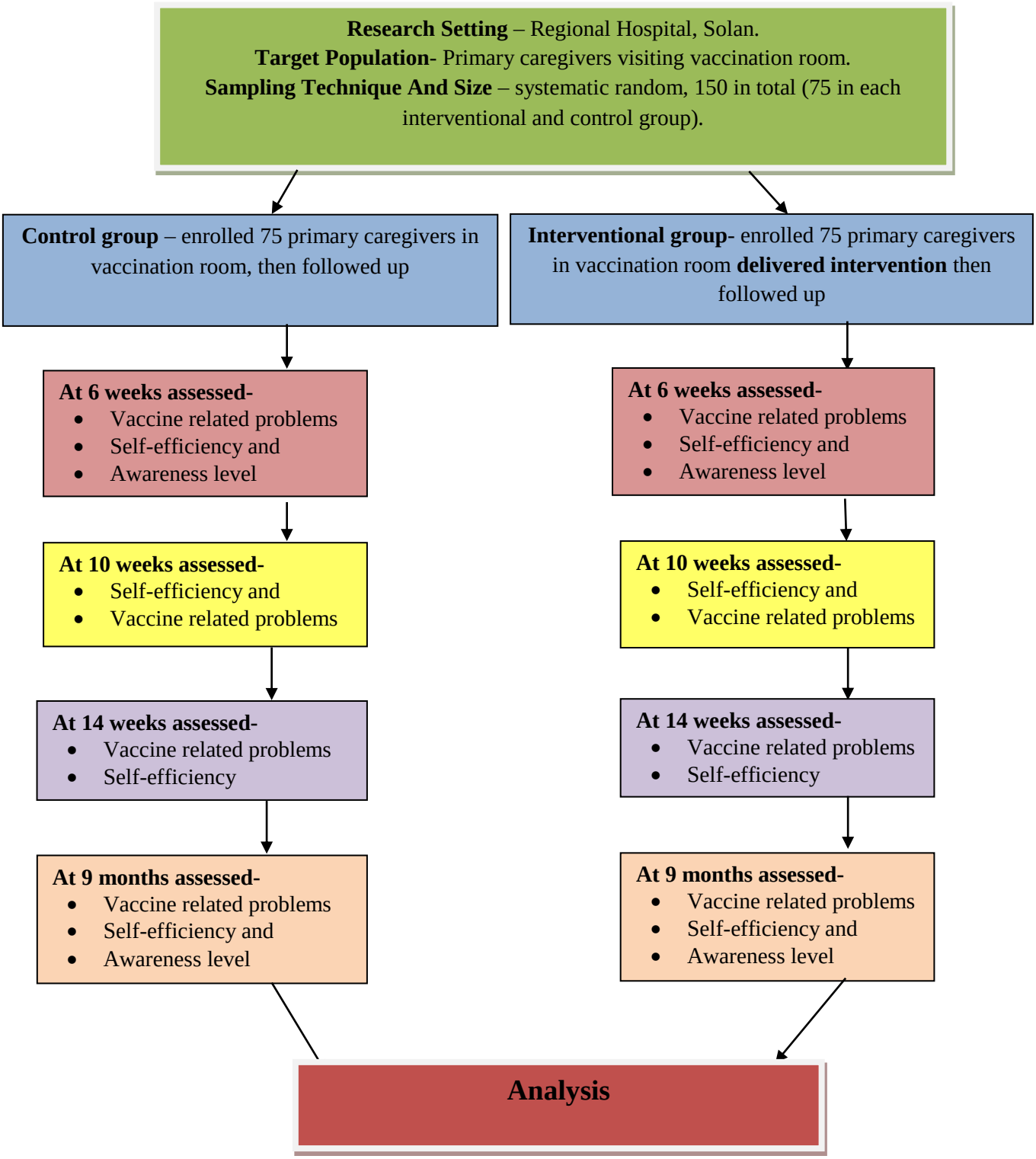

Figure 4: Data collection procedure for phase II

Analysis of data

Phase I- The qualitative data generated via focus group discussions was analysed using content analysis. The verbatim obtained from videotaping was transcribed. Common themes were identified to arrive at felt information needs of the primary caregivers.

Phase II – The data obtained through the tools was coded and entered into excel worksheets. Further analysis was done using SPSS 21. Data distribution was normal as analysed using Kolmogorov – Smirnov test. Categorical data was expressed in frequency and percentage. Descriptive data was expressed in mean, standard deviation and mean percent. Chi square test was used for testing homogeneity. For the analysis of significant differences between the groups unpaired t-test was used. For within group comparison of variables, repeated measure ANOVA was used. Post hoc analysis was done using Tukey's test for pairwise comparison to determine which of the pairs made significant differences in the variables. Association of scores with the socio demographic variables was established using chi square method.