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## **Chapter: 4**

### **Methods and Materials**

**4.1 Introduction:** Methodology is the basis of any empirical study, which gives the method to be followed and the principles in analyzing the social research. The research design is an arrangement of conditions for the collection and analysis of data so as to contribute to the already existing knowledge. It is a model of proof that allows the researcher to draw inferences concerning causal relations among the variables under investigation and test the hypotheses. The present study is based on the primary data where the Researcher directly involved in data collecting process. This chapter deals with the Methods and Materials used in this study to achieve the given objectives. It also deals with conceptual framework of the study, hypotheses, study design, sample size, selection of study subjects, data requirement and its source, the instruments used for data collection, statistical analysis, limitations of the study and operational definitions used in this study.

#### **4.2 Objectives of the Study:**

The prime objective of this study is to know the overall improvement of Routine Immunization Programme and its sustainability after the 'Service Delivery Support' (SDS) intervention. To meet this, following specific objectives have been formulated.

##### **4.2.1 The Specific Objectives of the Study:**

1. To know the immunization service delivery practices at Health Facilities and at Immunization Sessions from the providers' point of view, before the start of 'Service Delivery Support' intervention.
2. To assess the impact of 'Service Delivery Support' intervention on various components of immunization practices.
3. To assess the sustainability of field practices of service providers in the absence of 'Service Delivery Support' at Health Facilities and at Immunization sessions.
4. To know the coverage of immunization among the children 12 -23 months of age in the community and to identify the determinants of immunization.

**4.3 Hypotheses:** A 'hypothesis' is a research expectation, a tentative finding or an expected result. It is a statement of the expected relationship between the variables. Expected relationship may be positive or negative. Some of the hypotheses expected from this study are:

1. The service delivery support intervention will improve the overall performance of the Health Facilities.
2. There will be a significant improvement in programme management after the service delivery support.
3. The overall sessions' performance of immunization will have improvement after SDS.
4. Over all coverage of immunization will increase after SDS.

**4.4 Conceptual Frame Work:** There is widespread agreement among those in the International health community that supervision is a critical part of human resource management for the delivery of basic health services (ReproLine, 2001). Though most of the systems provide supervisory techniques, which are traditional in nature, especially in Government Sector and they could not show the results as expected. This is evident in most of the cases where there is wide gap between reported data and surveyed data, which indicates some lapses in the monitoring system. The reasons for failure of traditional supervisory system are:

- These systems absorb the basic worker as supervisors by promotion without concern for upgrading of their skills.
- Secondly, absence of training and capacity building in the supervisory cadres, and
- Lastly, absence of performance and root cause analysis at all levels.

In this context supportive supervision framework makes continuous improvements in the quality of service delivery by providing the necessary leadership and support for quality improvement with in the existing system.

The components which need to be strengthened for quality service delivery are - an action plan for maximizing coverage, effective programme management, necessary training & capacity building, provision of logistics and Social Mobilization/Behavior Change Communication activities. The conceptual frame work of supportive supervision is explained in *Fig: 4.1*. There are four stages, which work as a continuous loop.

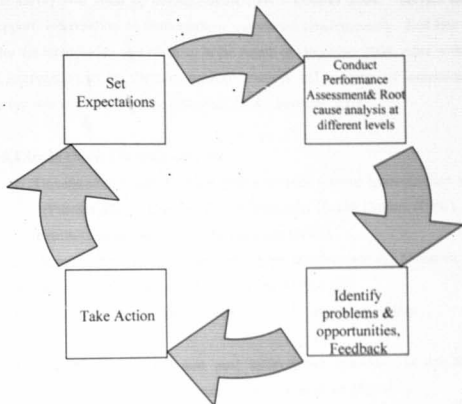
In the first stage, set the expectations or guidelines of the programme, which is to be monitored. In general many programmes have these guidelines. If they do not exist define and frame such guidelines for strict implementation. These are the prerequisites for any effective supervision.

In the second stage, conduct performance assessment and root cause analysis of problems at all levels of the system, to know how the guidelines are implemented and the difficulties or problems faced. The prominent root causes may be lack of basic equipment and medical supplies, lack of client-centered approach, ineffective service provider practices and low employee motivation and morale. This must be an ongoing activity that occurs at all levels of the system for individual health care providers, within and among health facilities and at the district level.

In the third stage, identify the gaps and opportunities at different levels of the system. If gaps exist between expectations and results, they may be technical or functional. Then the supervisor facilitates a team approach for examining potential causes and possible solutions. By facilitating open communication and teamwork, the supervisor can help spot opportunities to improve the overall quality of service delivery.

The fourth stage is 'take action'. The supervisor helps to line up the resources necessary (human, financial, material, Institutional and skill up gradation), motivates and supports providers to implement interventions to address performance gaps or opportunities for improvement. This loop never stops. It continues as new activities begin, with the establishment of new expectations.

**Fig: 4.1 Conceptual Frame Work of Supportive Supervision**



#### **4.5 Methodology**

**4.5.1 Study Design:** This study requires multi study designs as it has different levels. It is a combination of an observational, follow up and community based cross sectional study designs. There are four levels in this study:

1. Before the intervention of Service Delivery Support (Base line survey),
2. After the intervention of Service Delivery Support (Impact Assessment),
3. After the withdrawal of Service Delivery Support (Assessment of Sustainability),
4. Coverage Evaluation of immunization (Community based study).

**4.5.2 Setting:** The study covers all areas –Rural, Urban and Tribal areas of East Godavari District, AP. It is essentially a district-based study.

**4.5.3 Period of Study & Time Frame:** Three points of time data was analyzed. Base line survey was taken up during August 2004 – October 2004. 'Service Delivery Support' intervention on immunization was started simultaneously. End line survey after the intervention was taken up in the month of December 2006. After withdrawal of intervention to see the sustainability practices and coverage of immunization, a survey was conducted during December.2008 – February 2009.

**4.5.4 Study Units:** The study units are:

1. Government Health facilities which provide routine immunization services {(Primary Health Centers (PHC)/Community Health Centers (CHC), /Urban Health Centers (UHC), Post Partum Units (PPU)}
2. Immunization Sessions which takes place at Sub centre and Outreach,
3. Service Providers (Medical Officers and ANMs) and
4. Households having children between 12 – 23 months age group.

**4.5.5 Sample Size for pre and post intervention rounds:** In pre and post intervention rounds, two types of study units were involved (*Fig: 4.2*).

- a. Health Facilities
- b. Immunization Sessions.

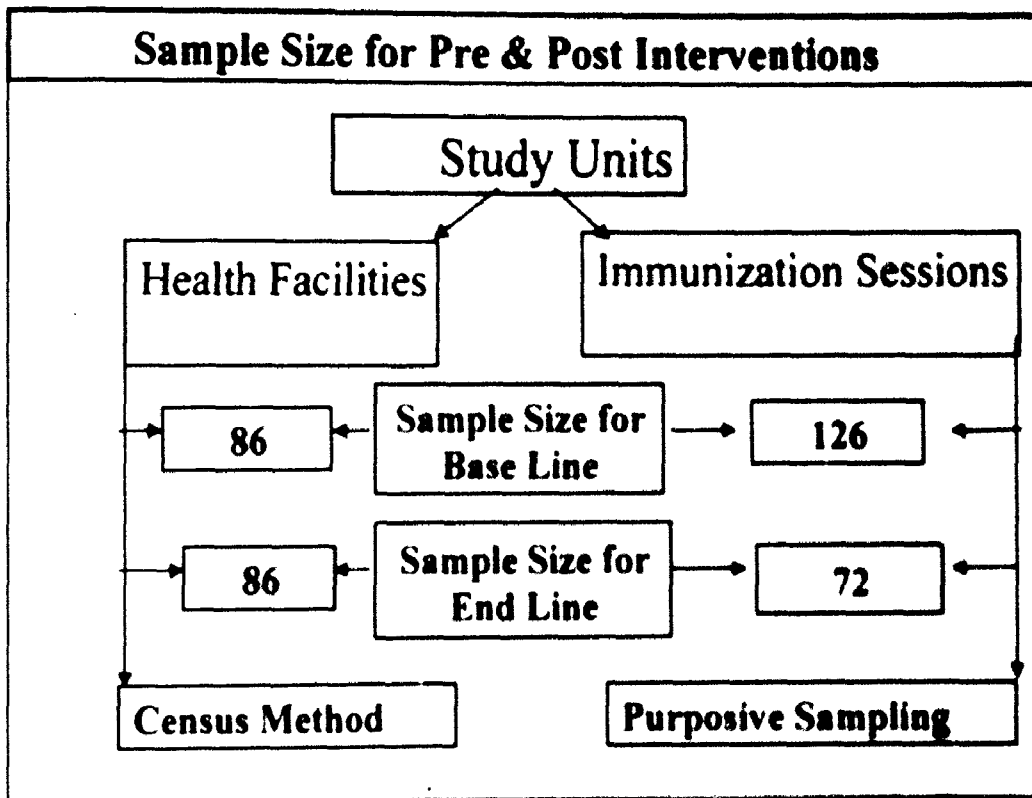
The sample size is considered in the following manner.

**a. Health Facilities:** No sampling technique was used for the pre and post interventional visits of health facilities (PHCs/UHCs/PP units). Because all the units, which provide immunization services and exposed to supervisory visits by SDS team in pre and post intervention rounds were included in the study. East Godavari District is having 90 health facilities providing immunization services (56 Rural PHCs , 10 Tribal PHCs and 24 Urban units which consist of UHCs and PP Units). Out of these 4 facilities excluded from analysis (Three facilities could not be visited in the pre intervention round and one facility in the post intervention round). Thus sample size was limited to 86 units in both rounds.

**b. Immunization Sessions:** It is difficult to visit all the immunization sessions going on in different sub centers in a health facility. Therefore, it is decided to visit one or two sessions of a health facility, selected through purposive sampling. Depending on the number of sessions conducted on the day of visit in the health facility area one or

two sessions were selected for the study. In addition to this, the distances involved to reach the places, where the sessions are going on, and availability of time for the monitoring the sessions are also taken in to consideration. So with regards to immunization sessions there was a separate sampling for pre and post intervention rounds. The sample size was, 126 sessions in pre intervention round and 72 sessions in post intervention round.

**Fig: 4.2 Sample Size for Pre & Post Intervention**



**4.5.6 Sample Size for Sustainability Round:** In sustainable round (after the withdrawal of SDS) three types of study units involved (Fig 4.3).

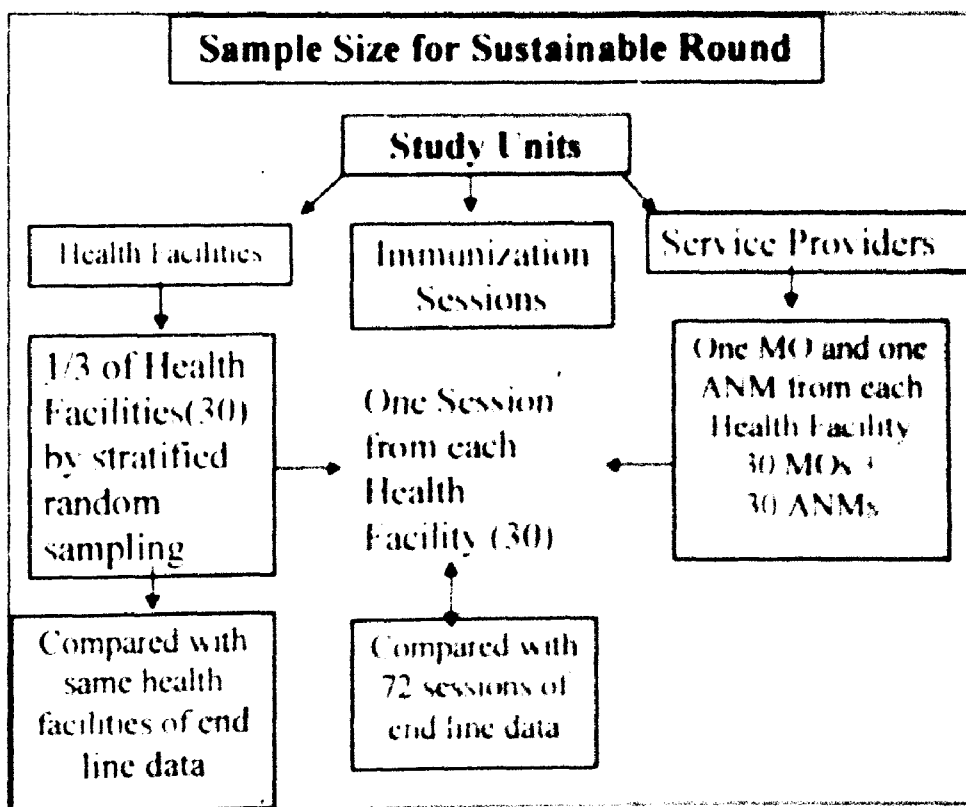
- a. Health Facilities
- b. Immunization Sessions
- c. Service Providers

were visited in the previous two rounds. The sample size worked out for the sustainability round was 30 health facilities covering urban, rural and tribal areas. All these health facilities' sustainability status is compared with the end line status of same health facilities.

**b. Immunization Sessions:** One immunization session was observed from each health facility which were selected by stratified random sampling as mentioned above i.e. 30 immunization sessions are being selected and these are compared with end line data of 72 sessions' observations.

**c. Service Providers.** In addition to above, service providers' feedback on SDS was also taken from the Medical officers of the health facilities and from the concerned ANMs of the sessions which were visited by the SDS monitor, to know their perception on SDS. Operational problems faced by ANM also collected through an in-depth- interview.

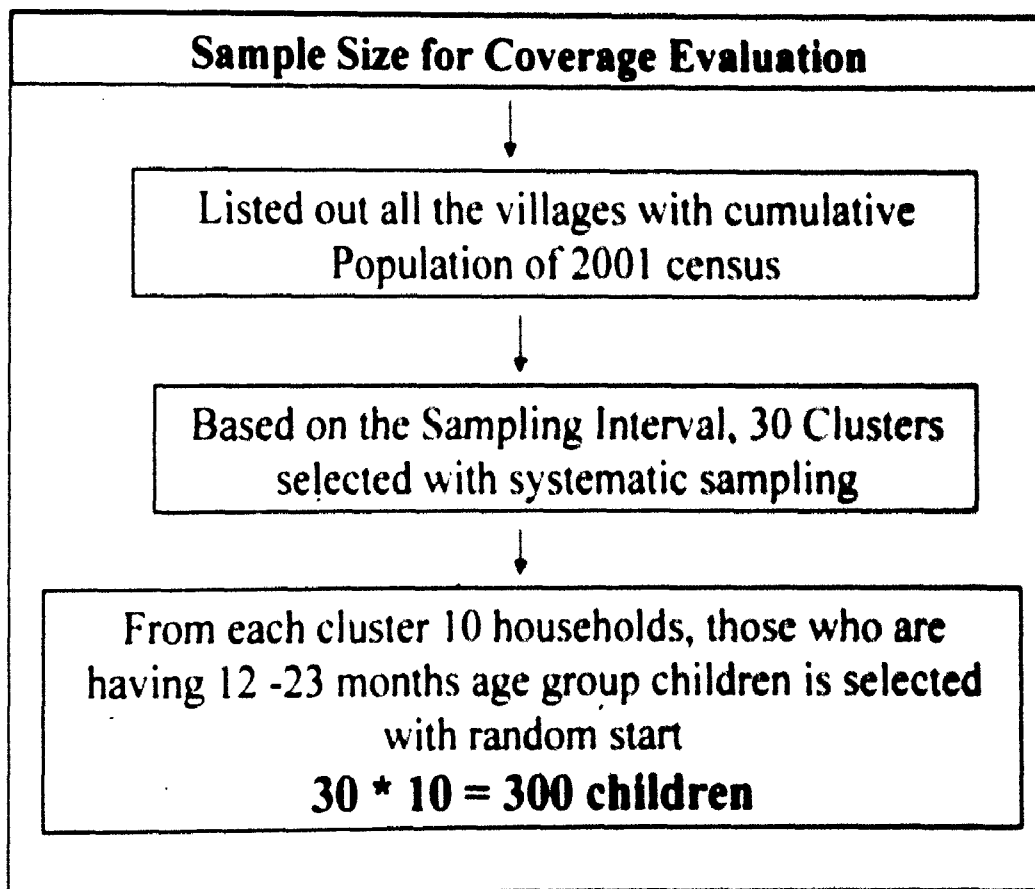
**Fig: 4.3 Sample Size for Sustainable Round**





**4.5.7 Sample Size for Coverage Evaluation:** Cluster sampling method was adopted for coverage evaluation, which was proposed by WHO and often used for coverage evaluation studies especially in health research. The clusters were identified through Probability Proportional to Size (PPS) sampling technique based on 2001 census population and finally 30 clusters were selected (Henderson RH 1982, Therese McGinn,2004).). In each cluster the first household was selected at random and continued to inquire the adjacent houses that have children of 12 -23 months of age group till the required sample of 10 children was reached. Thus the sample size was 300 children (Fig: 4.4).

**Fig: 4.4 Sample Size for Coverage Evaluation**



**4.5.8 Instruments:** There are five types of instruments used in this study. All these instruments are pre tested before final administration. They are:

1. **Health Facility Check List:** to get the information from health facility in each round
2. **Immunization Session Check List:** to get the information from session observations
3. **Service Providers' Feedback Form** (only in sustainable round): to know the perceptions of the service providers (ANMs, MOs)
4. **Village Schedule:** to get the village information
5. **Household Schedule:** to get household profile and coverage of immunization.

The instruments 1 and 2 were prepared by PATH, and the same were used with slight modification by the researcher.

**4.5.9 Descriptions of the instruments:**

1. **Health Facility Check List:** It comprises of general information, staff position, staff training, programme planning & management, cold chain management, injection safety & waste disposal, vaccine utilization, vaccine supply, stock sufficiency, supervisory visits and Adverse Events Following Immunization (AEFI) reporting etc.(Appendix: I ).

2. **Immunization Session Check List:** It consists of general information, field practices i.e cold chain management at session level, injection safety, Information Education and Communication (IEC), community mobilization, vaccine administration and record maintenance. (Appendix: II)

3. **Service Providers' Feedback Form:** It consists of problems and logistics in service delivery, and their perceptions towards service delivery support. (Appendix: III a & III b)

4. **Village Schedule:** Its focus is mainly on availability and accessibility of various facilities in the village i.e irrigation, transport, education, health and other facilities (Appendix: IV).

**5. Household Schedule:** Household schedule consists of two parts. In Part-A, demographic characteristics of family members and socio economic characteristics of household were taken. In Part-B, general information on mother and child, immunization knowledge, practice and quality assessment & client satisfaction were focused (Appendix: V).

**4.6 Data Collection and initiation of 'Service Delivery Support':** Primary data was collected from the study units as mentioned above. All the Health facilities were visited before the intervention of Service Delivery Support by the trained faculty from the Dept. community medicine on the day of National Immunization Day's(NID) i.e Wednesdays & Saturdays and obtained data in Health Facility check list. One or two immunization sessions from each health facility were also visited and observations were noted in the Immunization Session check list. These two checklists help in performance analysis. Based on these analyses 'the Service Delivery Support' intervention was initiated simultaneously. The necessary on site job training was given wherever required. The overall feed back was given to the staff about the way they are carrying their job responsibilities. The good work of the workers was appreciated and they were given a pat on the back. The others are expected to change accordingly by following these good practices. If any wrong practices were noticed, they were advised to correct and informed to follow the right practice.

The data collected from this round (during August 2004 –Oct, 2004) was considered as base line data or pre intervention data. Then all staff members were reoriented on the following topics:

- | <b>PHC Level</b>                                | <b>Immunization Session level</b> |
|---|-----------------------------------|
| ➤ Action Plans                                  | ➤ Cold Chain                      |
| ➤ Vaccine Logistic Form                         | ➤ Vaccine Administration          |
| ➤ Sessions planning & implementation            | ➤ IEC                             |
| ➤ Supplies                                      | ➤ Injection Safety                |
| ➤ Cold Chain                                    | ➤ Documentation                   |
| ➤ IEC &AEFI                                     | ➤ Community Mobilization          |
| ➤ Safe Disposal of Waste and Supervisory Visits |                                   |

This practice was continued for 5 rounds with periodic intervals of 6 months. However the researcher took the first and fifth rounds' data to see the impact of supportive supervision interventions. The fifth round was carried out during Dec.2006. The exposure of intervention was around for 2 years. Again from this point, after a period of 2 years, during February 2009, sustainability round was taken up on a sample basis. Data collected with the same check lists used in previous rounds. In addition to this, service providers' (ANM,MO) feedback were collected to know their perceptions. A community based coverage evaluation was also taken up during the same period.

**4.7 Data Analysis:** All the collected data was fed into the computer through SPSS software. Each observation in the checklists of Health facility and Immunization session has been given a score on the basis of its importance. The total score was graded on an ordinal scale so as to form 3 groups' i.e 'Poor', 'Average', and 'Good' for all the major functional parameters. Pre intervention data was analyzed on various functional parameters and is presented in chapter Five. Pre intervention data was compared with post intervention data for impact assessment and is presented in chapter Six. Sustainability of service providers' field practices were compared with previous rounds and are presented in chapter seven. Household data was analyzed to know the demographic profile, the coverage of immunization against other background characteristics, and also to know the determinants of immunization (Chapter 8). The necessary statistical applications like chi-square, test of proportions and McNemar's test of proportions and logistic regression were used wherever required.

**4.8 Limitations of the Study:** This study has certain limitations. They are:

1. This study does not have control group as all the districts in the state are under intervention, and the impact assessment is based on base line data only.
2. Supportive supervision depends on skills, knowledge, initiative and interest of the supervisor.
3. The levels of receptiveness, attitudes and behavioral change of health workers will influence in the implementation of programme.
4. Knowledge update through media and health seeking behavior of community may also create demand for immunization. Thus limiting the role of SDS.

### **Operational Definitions used in this Study:**

**Health Facility:** A health facility which provides immunization services under Universal Immunization Programme and also having provision for cold chain equipment to keep vaccines for one month requirement is called Health Facility. Whether it may be a Primary Health Centre or Urban Health Centre or Post Partum Unit or Hospital.

**Immunization Session:** Immunization Session is a place where the immunization activity is being done under UIP, either in the Outreach or Sub-centre/PHC/UHC.

**Head quarters Session:** If immunization session takes place in Sub-centre/PHC/UHC, then it is called as Head quarter Session. Usually Wednesday sessions takes place at Head quarters.

**Outreach Session:** If an immunization session takes place other than the Head quarter, then it is called as Outreach Session. Outreach is place where the service provider provides service away from his/her Head quarter.

**Cold Chain:** the system of storing and transporting the vaccines at recommended temperatures from the point of manufacture to point of use.

**Full Immunization:** An infant who has received BCG; three doses each of DPT, OPV and Hepatitis B; and Measles before one year of age.

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