CHAPTER 2
METHODOLOGY

It is primarily an empirical study using quantitative data and qualitative information. It is complemented with participant observation and focus group discussions (FGD). This study has been conducted on the patients taking leprosy treatment in the referral hospital of Gandhi Memorial Leprosy Foundation (GMLF), Wardha. The GMLF referral hospital was established in 1951 provided with Out Patient Department (OPD) and two in-patient wards. This hospital is popular in the Vidarbha region of Maharashtra state particularly for treating drug reactions, ulcers and other leprosy related complications. A large number of patients from Sevagram Control Unit area, other villages in the Wardha district and also from other districts of the state and even from adjoining states visit this hospital for treatment of complications in leprosy.

A number of patients visit this hospital also from the states other than Maharashtra for the treatment and continue receiving treatment although the same treatment is available in their local leprosy clinics. As is all over the country, the registered patients of GMLF also receive free treatment. The patients are treated with Multi Drug Therapy as per WHO regimen, i.e., 24 pulses in 36 months for MB (infectious) cases and 6 pulses in 9 months for PB (non-infectious) cases. Along with medical treatment and physiotherapeutic facilities they also receive formal advice from medical and paramedical staff. In addition, the GMLF has started a counselling service by organising a "Psycho-social Counselling and Guidance Clinic" called ‘Manobal’ (literally meaning mental strength) in which systematic
counselling is being carried out by a group of counsellors comprising a trained social worker with a Masters degree in Social Work, a Psychologist and a Paramedical worker who are trained in counselling techniques. Since the main objective of the present study is to understand the process and assess the impact of communication in such services on leprosy control activity and the patients being the main focus, the following social research methods were used.

2.1 THE UNIVERSE: Universe of the study comprised of:

1. Patients who were registered as out patients for leprosy treatment for the first time in GMLF referral hospital,
2. Members of the social network of the patients who were receiving counselling services,
3. The persons who accompanied the patients to the clinic, and
4. The counsellors.

2.2 THE SAMPLE: The sample consisted of all the patients who were registered for the first time at the GMLF referral hospital for leprosy treatment during the period from 5th March 1990 to 31st December 1990 (ten months). Thus data from a total of 301 patients were collected during the period.

2.3 THE EXPERIMENTAL AND CONTROL GROUPS: The sample patients were grouped into two. The patients who were registered in the clinic from 1st to 15th of every month, during the study period were grouped in ‘experimental group’ who received counselling services in the Manobal on every subsequent visit to hospital for collecting drugs. This was usually once a month since
they were put on MDT. The patients who were registered from 15th to the end of the month were grouped in the 'control group' who did not receive counselling in the Manobal clinic. The experimental group and the control group together are referred to as 'study category'. There were 155 patients in the control group and 146 patients in the experimental group, making a total of 301 patients. The similarity of the control and experimental groups with regard to different characteristics was tested, using chi-square test, and was found that both the groups, by and large, are similar.

2.4. DATA COLLECTION: The data for the study were collected in three phases as given below:

a) Base line data: Whenever a patient was registered in the Manobal clinic from either of the groups of the study, detailed data from the patient related to demographic, socio-cultural and economic characteristics of the patient and his/her family, along with the patient's disease status, disease perception, knowledge, patient's adjustment in the family, society, workplace, psychological adjustment and treatment compliance were collected. The base line data were collected from all the patients as and when a patient is registered for treatment during the period from 5th March '90 to 31st December '90.

b) Counselling data: These data were collected only from the patients in the experimental group who were receiving counselling. This data included the following details:

i) An account of the problems the patient perceives as well as those which the counsellor's identify as problems that may need counselling.
ii) The type of communication the counsellors made with the patient in order to assess and solve the problems.

iii) The process of identifying the situational needs of the patients.

iv) Various methods and techniques used by the counsellors to communicate their needs to the patients during the visits.

v) Rate of regularity of the patients of both experimental and control groups in attending the clinic and drug in-take.

c) Evaluation data: The necessary data for evaluation of the impact of counselling were collected from both the groups after completion of 6 pulses in the case of PB cases and after completion of a minimum of 12 pulses and before completion of treatment in case of MB cases. The same variables included in the baseline data were considered also for evaluation data so as to assess the impact of the communication during counselling sessions. The data reflect the patient's condition after counselling combined with treatment in case of the experimental group, and the patient's condition after completion of treatment devoid of counselling in the case of the control group.

2.5. INSTRUMENTS OF DATA COLLECTION: Common social science research tools were used for data collection. They comprise of the following:

a) Case Sheet: A Case sheet is a structured interview schedule consisting of questions pertaining to socio-cultural and economic aspects of the patient and the family. This was
administered to the patients of both the control group and the experimental group at the time of starting treatment.

b) **Preliminary Interview Schedule:** It is a structured interview schedule comprising of questions pertaining to the patient’s disease status, present position of the patient with regard to his family adjustment, psychological adjustment, workplace adjustment, societal adjustment and treatment compliance. This was administered to all the patients of both the groups for baseline data collection.

c) **Monitoring Sheet:** This is an unstructured format used to record the patient’s condition, from time to time, the problems encountered by him/her, the possible reasons for each problem, the needs of the patients and the type of counselling provided to them. This format was referred to and new information was recorded during every visit of the patient to the Manobal clinic. This instrument was used only for the patients of the experimental group for collecting ‘counselling data’.

d) **Interview Schedule For Evaluation:** It is a structured interview schedule comprising of questions identical of those asked in the ‘preliminary interview schedule’, and administered to all the patients (whomsoever preliminary interview schedule was administered), after completion of the treatment for PB cases and after completion of a minimum of 12 pulses or counselling sessions for MB cases. This period lasted from 24th Jan.’91 to 21st Dec.’92.
e) Observation: Observation technique was used to record the communication process and interaction between the patient and the counsellors during counselling sessions, patient's adjustment in the family and the extent of his interaction with family members.

2.6. SECONDARY DATA: Secondary data pertaining to patients type of leprosy of the patient, his/her complications, type of treatment, attendance in collecting drugs etc. were collected from the OPD of GMLF referral hospital.

2.7. DATA ANALYSIS: In order to establish the impact of the communicational interventions the data has been analyzed using various statistical models and tests.

Change with regard to each specific problem: Initially data was analyzed to establish change in the number (frequency) of patients suffered from various problems such as lack of adjustment at different situations, based on the baseline data (collected through the preliminary interview schedule) as well as evaluation data. While the variation in the frequencies of the patients suffered with different problems explains the change, the percent change (p) with regard to each specific situation has been worked out in control group (p1) and experimental group (p2) separately. The significance of variation in percent change is tested using the Normal Deviate (Z) test.

Change with regard to each area of interaction: In order to study the change in each area of interaction, the following compound
indices were formulated, based on the baseline data as well as the evaluation data:

a) Patient’s Family Adjustment Index (FAI),
b) Society Adjustment Index (SAI),
c) Psychological Adjustment Index (PAI),
d) Work-Place Adjustment Index (WAI),
e) Treatment Compliance Index (TCI) And
f) Patient’s Perception Index (PPI)

**Formulation of Compound Index:** One set each of questions were selected from baseline data as well as evaluation data for each of the above index, and the responses were scored as ‘-1’ for negative response, ‘0’ for neutral response and ‘1’ for positive response. The addition of the scores achieved by each respondent for one set of questions gives the total score achieved for the respective index. By dividing the score with the number of questions considered, the achieved score for that particular index range between 0.0 to 1.0.

Using the above procedure all the patients were scaled with regard to each of the above index at both the stages, i.e., (i) before intervention and (ii) after intervention. As it is expected that the patient’s adjustment after intervention differs (possibly higher than that of before intervention) the former index is subtracted from its corresponding latter one, thus the change in the adjustment is measured and each individual is put in a scale with regard to each above said area of interaction/ adjustment. The variation between
the control and experimental groups with regard to the extent of change taken place, is verified using the Normal Deviate (Z) test.

**Statistical tests used in the study:** The following statistical tests and procedures were used at different stages of the study.

**Chi-square test:** This statistic is very useful in research and is most commonly used when data are in frequencies such as in the number of responses in two or more categories. It can be used with any data which can be reduced to proportions or percentages. The test involves calculation of a quantity, called chi-square ($\chi^2$). The advantage of this test is that it can be applied to find association or relationship between two discrete attributes when there are more than two classes or groups (Mahajan: 1989: 165). In the present study this test is used to verify significant independence or possibility of association between various socio-economic characteristics and the study category (experimental and control). The presence of significant association explains that both the groups (control and experimental) are not similar with respect to the variables under study, and the absence of which explains that both the groups are similar; thus the sample in both the groups may be said unbiased.

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*Derived from the Greek letter 'Chi' and pronounced as 'kye'.
If the data is summarised into a *fourfold* (four-cell) or 2 x 2 contingency table, as shown below,

<table>
<thead>
<tr>
<th>Four-fold contingency table</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Control group</td>
</tr>
<tr>
<td>Experimental group</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

$\chi^2$ is calculated using the formula:

$$\chi^2 = \frac{(ad-bc)^2}{(a+b)(c+d)(a+c)(b+d)}$$

In case of 2 x 3 and larger tables as shown below,

<table>
<thead>
<tr>
<th></th>
<th>Low income</th>
<th>Middle Income</th>
<th>High Income</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>P + Q + R</td>
</tr>
<tr>
<td>Experimental Group</td>
<td>d</td>
<td>e</td>
<td>f</td>
<td>S + T + U</td>
</tr>
<tr>
<td>Total</td>
<td>P + S</td>
<td>Q + T</td>
<td>R + U</td>
<td>P + Q + R + S + T + U</td>
</tr>
</tbody>
</table>

the chi-square($\chi^2$) is calculated independently to each cell eg. $\chi_a^2$, $\chi_b^2$, $\chi_c^2$, $\chi_d^2$ using the formula, $\chi^2 = \frac{(O-E)^2}{E}$ *(O = observed value and E = expected value).*
if the observed value \( O_a = P \), for the cell \( 'a' \), the expected value \( (E_a) \) can be calculated using the formula:

\[
E_a = \frac{(P + S) \times (P + Q + R)}{(P + Q + R + S + T + U)}
\]

Thus, \( \chi^2_a = \frac{(O_a - E_a)^2}{E_a} \)

and the addition of chi-square of all the cells is the chi-square of the total distribution, e.g., \( \chi^2 = \chi^2_a + \chi^2_b + \chi^2_c + \chi^2_d + \chi^2_e + \chi^2_f \).

The level of significance of the association is verified at the respective degrees of freedom with the help of \( \chi^2 \) probability (P) table. Normally \( P < 0.05 \) is considered significant at 5% and above levels.
Normal deviate (Z) test: This test is used to verify the Significance of Difference in Proportions of Large Samples i.e. between the two groups with regard to one or more characteristics when the sample could be divided into two classes or the data are summarised and expressed in the form of proportions, as in case of the present study- adjusted and not adjusted, aware and not aware, worried and not worried etc. In this study this test is used to verify the variation between the two groups with regard to the percent change taken place during the period between base line data collection and evaluation data collection. This test is applied as per the following formula:

$$Z = \frac{p_1 - p_2}{\sqrt{\frac{p_1 q_1}{n_1} + \frac{p_1 q_2}{n_2}}}$$

$p_1 =$ Percent change in Control Group

$p_2 =$ Percent change in Experimental Group

$n_1 =$ Total sample in Control Group

$n_2 =$ Total sample in Experimental Group

$q_1 = (100-p_1)$

$q_2 = (100-p_2)$
p is calculated using the following formula:

\[
\frac{\text{Frequency (after)} - \text{Frequency (before)}}\text{Frequency (before)} \times 100
\]

If the Z value is less than 1.96, the critical level of significance, the variation is insignificant at 95% confidence limits (Mahajan:1989:163).

The Regularity Index (RI) has been worked out using a formula:

\[
\text{RI} = \frac{\text{Total No. of Pules received}}{6\text{months or actual duration of treatment}} \times 100
\]

2.8. PRE-TESTING OF THE INSTRUMENTS: The applicability of the instruments was pre tested on the patients who registered for treatment in the GMLF referral hospital and the patients in Dattapur leprosy colony.
2.9. PROBLEMS IN DATA COLLECTION: The following are the problems faced during data collection stage:

1. As the patients came from far off places and the study was hospital based, (the services were made available in the hospital) the data collection was mostly done either in the hospital or in the Manobal clinic based on the respondents' response.

2. Due to timely unavailability of the patient's family members, collecting more information and cross checking of the information has been very difficult.

3. There had been great difficulty in collecting the evaluation data from all the patients covered in the baseline data collection as they were not easily available.