NATIONAL LEPROSY ERADICATION PROGRAMME

SAMPLE SURVEY ASSESSMENT UNIT GUIDELINES

LEPROSY IS CURABLE

CENTRAL LEPROSY TEACHING AND RESEARCH INSTITUTE
Ministry of Health & Family Welfare
Chengalpattu – 603 001.

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FOR
SAMPLE SURVEY ASSESSMENT UNITS

1987

DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
CENTRAL LEPROSY TEACHING AND RESEARCH INSTITUTE
CHENGALPATTU

PREFACE

The Government of India is highly committed to the goal of eradicating leprosy by 2000 A.D. In this context, one cannot but over emphasize the importance of an effective monitoring and evaluation system independent of the regular NLEP set-up to indicate the direction and extent of progress made in NLEP. With the creation of SSAUs the need has been, atleast partly, fulfilled.

This manual intends to achieve standardisation of definitions, concepts and procedures followed by SSAUs and provides operational guidelines. I hope it will serve the need and help the units in executing the job successfully.

I take this opportunity to thank Dr. C. K. RAO, DDG, (L), who has been a source of inspiration and guidance throughout the preparation of the manual.

Mention must also be made of Dr. Sundaresan, Temporary Adviser WHO, whom I thank for his active involvement in the preparation of this manual. Thanks are also due to numerous Colleagues and Friends for suggestions, criticisms and advice.

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INTRODUCTION

The Government of India has given high priority to the problem of leprosy and is committed to eradicate the disease by the turn of the country. The National Leprosy Eradication Programme (NLEP) has become the symbol of this effort. One of the most important components of any public health programme is a good information system that could generate necessary data for monitoring and evaluating the effectiveness of the programme.

NLEP is vertically organised with its own set-up in areas where the prevalence rate of leprosy is more than 5 per 1000 and it is implemented through the PHC's in areas where the prevalence rate is less than 5 per 1000. The two principal activities of the NLEP are case detection mainly through house to house survey of the population and institution of early treatment for all the cases detected. The records of all these activities are kept in prescribed forms and registers. These are the only available source of data used in computing various epidemiological and operational indicators to evaluate and monitor the progress of NLEP in an area. Hence, the importance of the data collected by the regular staff of NLEP and its reliability need not be over-emphasised.

The routine reports prepared out of the records maintained by the regular NLEP set-up do serve a useful purpose but there are some inevitable shortcomings usual in such reports, which affect the reliability of the information and limit their use for adequate evaluation and monitoring of the NLEP. An independent set-up to evaluate the programme on the basis of well-designed sample surveys has been recognised by the Government of India as a necessary component of the programme as a whole.

In recognition of this need, Sample Survey Assessment Units(SSAU) and Epidemiological Survey Teams (EST) were established in several states during the sixth plan period. Realising the relative functions, the government decided to amalgamate the erstwhile Epidemiological Survey Teams and Sample Survey Assessment units during the seventh plan. The list of state-wise break-up of SSAUs, existing and targeted for 87-88, is given in Appendix-I

2. ORGANISATION OF SSAU

Each SSAU will be headed by an SMO. of the rank of DLO to look after 2 to 4 endemic districts. Low endemic states/UTs may have one or two teams depending on the number of districts. The position of the unit is given below :

CATEGORY	NUMBER
Senior Medical Officer	*1*
Junior medical Officer	*1*
Statistical Asst.	*1*
Non-medical Supervisor	*1*
Smear Technician	*1*
PMW	*8*
Computer	*1*
Clerk	*2*
Class IV	*3*
Drivers	*2*

The list of duties and responsibilities of the staff of the SSAU is given in appendix-II.

3. OBJECTIVES OF SSAU

The objectives of formation of SSAU are the following :

1. Assessing the quality of the data generated by the District Leprosy Services by validating the data provided by the regular staff and arriving at reliable base-line epidemiological indicators on the basis of the sample survey conducted.

2. Evaluating the effectiveness of the treatment including MDT at periodic intervals by recomputing the various epidemiological and operational indicators with the help of repeat sample surveys in the district.

3. Estimating the magnitude of the leprosy situation in terms of prevalence & incidence wherever the local NLEP set up is not geared to providing such information.

It must be stressed that the Purpose of the SSAU team is not to 'find fault' with the regular service unit but to 'find facts' i.e. to compare the estimates arrived at by it with those of the local unit and, from the magnitude of divergence in the two estimates, to make an attempt at giving a near-valid projection of the disease status. Towards this end, there are a great number of parameters that can be studied, but it is useful to be selective and identify only those key parameters that are critical for monitoring the programme and evaluating its impact on the leprosy situation in the country.

Operational performance of the local unit can be assessed by the use of the following parameters.

(a) Case detection rate : From the operational point of view, there is a need to assess the intensity of the case detection activities of the local unit. The interest is in finding the extent to which this rate as reported reflects the true incidence/prevalence. The proportion of missed cases detected by the SSAU serves as an indicator of the effective case detection by the local NLEP staff.

(b) Proportion of cases with deformities among newly detected cases one of the most sensitive indicators of the delay between the onset of disease and detection by the services.

(c) Proportion of MB cases among newly detected cases an important parameter to assess because it not only indicates the efficiency of the service unit in detecting early and minimal cases but also provides useful information on the epidemiological trend of the disease.

(d) Proportion of cases detected by voluntary mode to the total cases detected by all modes reflects the popularity of the service unit in the community, and the knowledge and awareness of the disease and its curability.

(e) Treatment attendance rate, an indicator of the performance of the treatment programme and the intensity of the case holding efforts by the regular service staff.

(f) Surveillance rate both clinical and bacteriological for MB cases and clinical for PB cases–an indicator of the intensity with which cases released from treatment are contacted periodically to detect relapse, if any.

(g) Relapse rate among released patients, an indicator of the effectiveness of the control measures, of the validity of treatment procedures.

(h) The proportion of patients released from treatment in whom the criteria for release are followed correctly out of the total patients released from treatment.

(i) **Diagnostic differences** between the SSAU and the service team.

The epidemiological indicators that can be used to study the trend of the disease are :

a) **Prevalance rate** - a necessary indicator of the case load in the community.

b) **Incidence rate/Case detection rate** - an indicator for assessing the impact of the programme in interrupting the transmission of the disease in the community.

c) **Proportion of children among new cases** which is a sensitive indicator of the effectiveness of the programme in interrupting transmission. Continued observation of new leprosy cases in children indicates recent persistence of transmission. It is most desirable to compute incidence rate by age and sex as shifts in agespecific rates reflect changes in the epidemiology of the disease.

4. METHODOLOGY

Considering the objectives laid down for the SSAUs, the following methodology is proposed for adoption by the Units.

A representative sample of villages and urban blocks (Mohallas) will be selected using statistical techniques (as explained later) in every district. In the selected villages and urban blocks a complete enumeration of all the households resident there will be made by house to house visit and necessary information will be collected including screening and confirmation of suspected cases.

The data collected in the sample survey will be tabulated to compute various epidemiological indicators and the details collected by the SSAU for the confirmed patients will be used to validate the data maintained by the regular NLEP staff. This will be done in all districts of the state.

It is also recommended that the sample survey that will be done on the lines described above may be supplemented by school surveys, screening the students in the schools located in the clusters selected (or serving the cluster selected). This will yield fruitful data sets over a period of time to corroborate the findings of the sample surveys and yield more information on the active transmission of the disease in the community as the number of children that can be examined this way will be much larger than can be provided by the household survey.

In a round all the districts in the State will be covered one after the other and the duration of the round (2 years or one year) depends on the number of SSAUs the State has and the work load. Once a round is completed, the sample survey will be repeated. For repeat survey a rotational sampling scheme will be followed as explained later.

4. 1. SURVEY DESIGN

The Statistical design prescribed for the survey has been governed by the following considerations.

a) The availability of manpower and logistics.

b) Each state will have one SSAU and the SSAU could cover all the districts in the space of two years. (This is an assumption which is made just to facilitate the discussion on survey design and it is easy to carry out the necessary modifications if there are deviations from these assumptions. For example if there are two SSAUs what follows will be applicable to the zone under one SSAU)

c) In a round, all the districts in the state will be covered one after the other without leaving out any district. It is desirable to do sample checks within each of the LCUs also.

d) It is desirable to have reasonably valid estimates for the district and by suitably combining the estimates of the districts covered in a cycle, it would be possible to provide reliable estimates for the state as a whole as leprosy is a chronic disease and the endemicity changes are generally slow. However, the MDT districts should be treated separately as changes there are expected to be more rapid than in monotherapy districts.

e) Considering the field conditions and the epidemiology of the disease, the cluster sampling technique (1) will be adopted, clusters being villages/portion of villages/urban blocks.

Since the sample size to be covered in a district works out to be small, and the intention is to get a better representation of the district characteristics in the sample, the cluster size will be kept to a maximum of 900 and, if found necessary, hamlet group formation (2) will be resorted to in order to have clusters of convenient size.

f) All available supplementary information will be used to increase the efficiency of the survey design.

g) To the extent possible, documents available with authorities like Registrar General of India, National Sample Survey Organisation, National Malaria Control Programme, etc. will be used in the construction of sampling frame.

h) For operational and administrative convenience, all the districts in the state will be divided into two contiguous zones of equal population content so that the team works exclusively in the first zone in the first year and in the second zone in the second year.

i) Wherever possible the required sample of villages will be taken in the form of two sub-samples independently of each other [called interpenetrating sub-samples] (5) to facilitate generation of quick estimates of various parameters, easy computation of sampling variance and comparison of non-sampling errors.

j) Assuming that a PMW completes his round of village surveys once in three years, in order to ensure a good representation of areas recently visited, a third of the villages selected by the SSAU have to be such that the regular NLEP Staff had enumerated them within a year. This group of villages is particularly important both for operational assessment and for epidemiological estimates based on linking service records with those of sample survey findings. Such a selection process will be done before starting the survey each year. Obviously this does not apply to areas where the routine surveys are not being undertaken by the regular staff as for example in low endemic areas.

4.1.1.
DETERMINING THE SAMPLE SIZE

With one SSAU it is possible to cover a sample of 1,00,000 population in a year and 2,00,000 population in a round (2 years), given the transportation and communication facilities obtaining in most parts of the country. (The sample size may have to be smaller where the logistics so warrant).

Thus the size of the sample to be covered by the SSAU for a state will be 2,00,000, half of which will be taken in the first year and other half in the second year. The first half of the sample will be from the first zone of the state and the second half from the second zone.

This sample size has been fixed keeping in view the workload in high endemic areas. In low endemic states the sample size can be raised further, say to 1,25,000 every year as the number of said examinations is likely to be less.

If two teams are constituted in a state, then the sample will be doubled (4,00,000 for a round). It is desirable to have more than one team in big states as the sample size which one team can cover is small, especially at the district level, which may reduce the precision of the epidemiological estimates to be computed from the sample.

The sample size of 1,00,000 to be covered in a year is to be allocated to the districts to be covered in that year in proportion to the population content of the districts constituting the zone.

$$\textit{Sample size for the i-th dist.} = \frac{\textit{Popul. of the i-th dist.}}{\textit{Total popl. of the zone}} \times 1{,}00{,}000$$

The district will be first divided into two sectors – (*a*) Rural and (*b*) Urban – and the sample size, n, fixed for the district in terms of total population coverage will be allocated to the two sectors in proportion to the general population estimated for the rural and urban sector.

All the villages in the district will constitute the rural sector and towns and cities the urban sector.

For example if the sample to be surveyed in the district is 20,000 and if the available data indicates that the rural-urban ratio of population is 4:1, then a sample of 16,000 will be selected from the rural sector and 4,000 from the urban sector.

The process of selecting the required sample in both the sectors is explained below :

4.1.2. RURAL

The following sample design is adopted only in situations where sample size to be taken in a district is around 20,000. If it is, say, less than 10,000, then a separate design is to be followed.

LARGE SAMPLE

Stratified cluster sampling design (4) is to be followed for the selection of the sample to becovered by SSAU in each of the district. In districts where NLEP is implemented by its own set-up each LCU has to be taken as a stratum. In districts where the programme is presented through the PHC (endemicity is less than 5 per 1000 population) a group of contiguous taluks/tehsils of 4 to 5 lakhs population can be considered as a stratum. This is done taking into consideration primarily the operational assessment. With the possible size, epidemiological indices such as prevalance and incidence are bound to be imprecise when computed for each LCU/Taluk. However, over period of time, it is expected that trends, even at such administrative levels, can be clearly seen.

The sub-sample size fixed for the district has to be allocated, in turn, to the strata formed (LCU/group of Taluks). The procedure of allocation is as follows :

The sub sample size to be allocated for the s-th stratum,ns, is fixed as

$$ns = (\textit{total sample size}) \times \frac{\textit{total rural population in the s-th stratum}}{\textit{Total rural population of the district}}$$

4.1.3. NUMBER OF CLUSTERS AND CLUSTER SIZE

Firstly a decision has to be made on the size of the clusters. As far as possible, whole village should be included in the sample, rather than parts of village. The village, as a unit, has certain epidemiological importance for leprosy. Apart from this, certain aspects of operational assessments which involve linking of the SSAU records with service records, will present undue problems when villages are split to form clusters. However, when villages are very large, say with populations exceeding 2000, division becomes inevitable. In such cases one of the two procedures are suggested. The first is to divide the village according to some natural boundaries, such as rivulets etc and select a division at random or choose a house at random and include all adjacent houses till a required cluster size is obtained. The second procedure is explained in detail later.

Many considerations govern the determination of the cluster size and consequently the total number of clusters in the sample. A precise consideration as explained above is that whole villages should be included. This would inevitably result in clusters of unequal size, though every effort should be made to keep the size variations from being unduly large. If the sole interest is in enhancing the precision, cluster design will take account of certain characteristics such as 'homogeneity' of population groups to the risk of the disease. Such observations are little known a 'priori' or only suspected at the utmost. Consequently logistic considerations will be the predominent factors.

Taking the situation obtaining in most parts of the country, especially in the flat agricultural land, it is expected that a village will, on the average, have 150 households with a population of 900 and using this as a basis, it is proposed that the average cluster-size be fixed at this figure for most parts of the country.

The number of villages to be selected for survey by SSAU in an LCU/Taluk is decided on the basis of the sub-sample size allocated for it [sub-sample size/900]. This number will be rounded off to the nearest multiple of two.

4.1.4. SELECTION OF CLUSTERS

The required number of villages in a stratum will be selected in the form of two independent inter-penetrating sub-samples so that it facilitates easy computation of sampling variance and also provides quick independent estimates for the stratum. This is done as follows :

(*a*) In areas where routine survey work is being carried out by the local NLEP staff, first all the villages in the stratum are classified into two groups : (i) the villages surveyed by the local NLEP staff within a year as on date ; and (ii) other villages. One-third of the required number of villages will be selected out of the first group and the remaining from the second group as explained in appendix-III. The villages with odd order of selection will form the subsample-1 and with even numbers subsample-2.

If the details as mentioned above are not forthcoming even after the visit of the unit to LCU, selection may be carried out as explained in (*b*.)

(*b*) In other areas the grouping as in (*a*) need not be done. Required number of villages will be selected from all the villages in the stratum.

For example, suppose that 6 villages are to be selected from the stratum, One-Third of the villages, that is 2, will be selected from the first group and the remaining 4 from the second group.

SMALL SAMPLE

In case the number of villages to be selected from the district is small, the stratified design

discussed above need not be adopted. A pure random sampling method may be followed in that case as explained below :

All the villages in the district are grouped into the two categories mentioned in the case of large sample and the required number of villages are selected as explained there ensuring 1/3 of the villages from the first group.

4.1.5. URBAN

A stratified cluster sampling design is proposed for the urban sector. The strata are formed as given below :

Each city coming under the NLEP setup may be considered as a separate stratum and the sample size to be taken from each stratum (town) may be decided in proportion to the population content as in the case of rural sector.

The Urban Frame Survey (UFS) Blocks formed in the towns will form the clusters to be considered for sampling [UFS is conducted by the National Sample Survey Organisation, Ministry of Planning on a continuous basis by specially trained staff. The city/town is divided into convenient, identifiable blocks of around 700 population. [Please see appendix-XII for details.]

All the UFS blocks in the stratum are arranged contiguously and the required number of blocks are selected in the form of two independent interpenetrating sub samples of required size (as explained for rural sector).

It is fully realised that house-to-house enumeration in urban blocks is operationally inconvenient and beset with problem of non-response. But without this enumeration, epidemiological indicators for the urban sectors can't be computed. Hence it is advisable to resort to enumeration of the population in the blocks selected and make an all out effort to increase the response rate and deal with the non-response as prescribed. This would mean taking the assistance of other organisation, such as social welfare, serving in that centre.

The ULCs' generally, do not resort to house to house enumeration but concentrate on contact surveys, school surveys and slum surveys. The following may be done by the SSAU to validate the records of the ULC :

(i) Schools which are located in the blocks selected or serving the block selected may be surveyed and results obtained by SSAU compared with those of the ULC.

(ii) In case the enumeration of the population in the block is not resorted to by the SSAU, it can take a 'sample of schools/slums in which the survey was done by the ULC and reexamine the population there.

(iii) Selecting a 25% sample at random from the cases being treated by the ULC and enumerating those patients' households. This is to ensure scrutiny of diagnosis and treatment ofpatients by the ULC.

5. SPECIAL SITUATIONS

In states like Kerala where the population density is very high and the villages are likely to be large, the population coverage per village (cluster size) has to be restricted to around 900 so as to have a better spread of the villages in the strata and thus better representation.

A. The ideal solution is to divide the village into natural hamlets of convenient size (say 900) number them in serpentine order and select one of the hamlets randomly. This is operationaly difficult if the village to be divided does not have natural hamlets or boundaries and the population is well distributed as in urban areas. Alternative procedures have to be followed to form clusters in such sample villages.

B) The census house-list (refer appendix-XII) for the village may be obtained from the census authorities. The households listed there and their size will be utilised to form notional groups of 900 population each and one of them is selected randomly. The households constituting the selected group will be the sample. The households are identified in the field with the help of identification particulars available in the census house-list and enumerated. Normally these houses will be contiguous. If any new houses have sprung up between the houses listed during 1981 census, they should also be enumerated.

C) A random point in the village is selected and a population of around 900 is covered around that point by proceeding from that point in a systematic way.

The nodal point can be decided by selecting one of the houses from among the houses listed in the 1981 census, (or in any other available house-list of the village) identify the house with the help of census number and other identification particulars available in the census house-list. With this as the centre cover a square of the area consisting of around 900 population.

6. REPEAT SURVEY

One of the main objectives of the sample survey is to measure the changes in the prevalence and incidence rates over a period of time. The SSAU after completing the sample survey in all the assigned districts in the first round, will start the second round of its assessment work by going back to the first district it covered in the first round and resurvey the area with the help of another sample in order to assess the impact of the programme on the leprosy situation by recomputing the epidemiological indicators. The repeat survey will be helpful in estimating the changes that have taken place in the disease profile during the interval between the two surveys.

Sampling on successive occasions can be done in many ways. These are :

(i) None of the sample units common with the samples selected on the previous occasions.

(ii) Some of the sample units common.

(iii) All of the sample units same.

In the first method, a particular unit (village) cannot be followed again during the repetition in order to study the incidence of lepsory in the intervening period. The 3rd method may theoretically be the most efficient under certain conditions to measure the changes in the epidemiological situation but repeated visits might lead to a sort of 'conditioning' of the respondents in the sample and hence may be inexpedient. As a compromise the second method is adopted wherein a partial replacement of the sample units in the previous sample is carried out according to a specified rule. This is called 'rotation sampling with partial replacement'.

A rotation sample scheme to be adopted by the SSAU for the repeat surveys. The sample design is given below :

6. 1. SURVEY DESIGN

For repeat surveys, the rotation sample to be taken will be constituted by retaining in the new sample 50% of the sample units belonging to the previous sample and replacing the other 50% with new sample units. This is done as below.

The previous sample had been selected in the form of 2 interpenetrating sub-samples from each of the strata (LUCS/Taluks/towns). These sample units are numbered serially and 50% of the units are selected randomly by

referring to the random number table. The remainder of the 50% of the sample units for the survey are selected in the form of two independent interpenetrating sub-samples as explained for the first round but considering only those units (villages) which were not surveyed during the previous round, In selecting this part the number of villages to be selected out of the villages covered within an year as on date by the service staff should be fixed in such a way to ensure, in the full sample, the 1/3-rd representation.

For example, suppose that the district has 1000 villages, and that 20 clusters are to be selected for the repeat survey. During the 1st round 18 clusters are selected as per the procedure laid down. During the repeat survey, 10 out of those villages selected already are again included randomly and another 10 selected at random out of the remaining 982 villages. If two villages out of the ten common villages have been visited by the service staff within one year by the time of a repeat visit, since there should be one third representation out of twenty (seven villages) from the first group of villages, five villages should be selected out of the villages forming the first group from the 982 villages.

7. PROBLEM OF NON-RESPONSE

During enumeration and examination of the population in the selected villages/urban blocks, not all the population can be examined during the first visit even if it is made at the time convenient to the community. It may be possible that 60 to 70 percent of the population can be examined during the first visit. Repeated visits are necessary to cover the left out population of the first visit and with each visit the yield will become less and less. So it won't be advisable, taking into consideration the time factor and other operational constraints, to insist on too many visits to examine the population thoroughly. Hence it is convenient to restrict the number of regular visits to one only. Attempts will be made to cover as much population as possible during the 1st visit. The problem of non-response will be handled as below :

After completing the first visit, make a list of non-respondents as it appears in the enumeration list. A sample of 20% is selected from among the non-respondents using circular systematic sampling (5) and an attempt is made to cover that sample only for examination. It is necessary that nearly all the selected persons are examined. Since names of the persons to be examined are known, examining almost all these individuals may not be very difficult.

For example, let us assume that we have enumerated a cluster of size 900 and at the end of the first visit we have examined 600 persons only. Our nonresponse Population is 300 in number. Now instead of attempting to cover all the 300 people, we take a 20% sample consisting of 60 persons, and examine these selected persons only. 60 persons will be selected out of 300 as below.

After arranging the house-list prepared during enumeration in the order of house numbers, a continuous serial number is given starting with 1 and ending with 300 to the non-respondents only in the margin. A random number is selected in between 1 to 300 using random number table. Let us say it is 133. The first unit selected is the person having the number 133. Then every k-th unit is selected in a cyclical way, k being the integral part of 300/60 i.e. 5. Hence the units selected will be 133, 138, 143, ...293,298,3 (303-300), 8, 13,.....123, 128. Now the examination will be confined to these 60 selected persons only.

The rationable behind this approach is evident, i.e., instead of trying to examine the whole of the population of non-respondents,

thereby wasting time and resources, a sample of it is taken and studied. The results obtained from the sample are used to make inferences about the whole of the non-response population. This is a more appropriate statistical way of treating the non-response problem rather than attempting to cover as much of the non-respondents.

8. SUPPLEMENTARY SURVEYS

Prevalence rates of leprosy are rather small in a statistical sense and population based sample surveys usually yield estimates with low precision. Very large sample sizes are required to obtain estimates with acceptable precision even in hyper-endemic areas. The situation becomes all the more critical when the prevalence and incidence decline as is expected with an intensive eradication programme especially using MDT. Measuring the changes in the epidemiological parameters become practically impossible.

It is proposed, therefore, that the estimations based on population based surveys be supplemented by two other epidemiological methods. Epidemiological judgments can be based on all the methods. The two methods suggested are ihe following :

(1) Examine all school-children in the schools situated in or serving the clusters selected for the sample survey. Given a stable level of endemicity the prevalence rates in the lower age groups (say 5-14) should be around 20% of the overall rate. The actual observed ratios over the clusters selected can be plotted on a graph-paper and an appropriate (6) "regression" can be fitted to the observed data, However, when transmission of the disease is being interrupted, the ratio of the prevalence and incidence rates among children to the overall rates may also be undergoing a rapid change. On the other hand this age-group is relatively very sensitive to respond to reductions of transmission and if a consistent reduction is seen in most of the clusters after a period of time, this fact would lend greater confidence in the effectiveness of the programme.

ii) In the clusters selected, relate the cases already registered or known to the services, to the cases detected by the SSAU in those clusters. It is expected that the ratios computed for all the clusters selected will permit an extrapolation based on the total registered cases. However, this ratio is affected by (i) the efficiency of the service team operating in that area and (ii) the popularity of the treatment available such as MDT. However, taken over all, the clusters selected and stratifying for districts according to whether MDT has been introduced or not may permit valid extrapolations after suitable adjustment. It is difficult to lay down rules at this stage for the combination of esti,mates based on the three methods : viz, (1) Population based survey (2) School survey and (3) Extrapolating from the 'known' proportion of cases on the service registers. The actual observations should be subjected to analysis centrally by expert statistician and epidemiologist.

School survey is an additional work for the SSAU and the school population surveyed will be over and above the 1,00,000 population to be covered in the year by SSAU. Hence the SSAU may utilise the services of the regular staff where available in conducting the school survey alone. This being a separate study inclusion of regular staff will not harm the working of SSAU.

9. DATA REQUIREMENTS

For the purpose of enumeration of the hamlet/village selected, a household schedule as given in appendix-V will be used. Required information on each member of the household will be collected and recorded in the schedule.

When a case is confirmed a small patient card (appendix-VI) will be filled-in for each case.

These two documents will be used to validate the data collected by the regular staff of the NLEP and compute epidemiological and operational indicators.

10. NON-SAMPLING ERRORS

Under the conditions usually obtaining in large-scale population based surveys, especially in leprosy, which is viewed with aversion and apathy, occurance of non-sampling error is not only possible, but also unavoidable. Non-sampling error can occur at every stage of planning and execution of the survey. Non-sampling errors will seriously upset the estimates and offset any advantage gained from a sophisticated sampling design to control sampling error. For this reason, every effort should be made to effectively control them. Some of the non-sampling errors and their causes are discussed below.

10.1. SELECTION ERRORS

Error may arise due to defective frames (list of villages being considered for selection together with identification particulars) and faulty selection of sampling units (villages/Blocks). Care should be taken in forming the strata as prescribed in the procedure, identifying the villages/blocks in the strata and selecting the required number of villages/blocks as per the random procedure laid down. This work is best undertaken by the SMO in an objective way making use of the available statistical expertise.

10.2. SPECIFICATION ERRORS

These errors occur due to imprecise definition of data requirement, ambiguous schedules, definitions and instructions, improper identification of the area to be surveyed and faulty methods of enumeration of households.

Majority of these sources of specification errors can be taken care of while planning the survey and drafting the schedule and procedures. While organising the fieldwork. the area should be correctly identified with the help of census/revenue maps and, if necessary by taking the help of local authorities. The enumeration of the population in the clusters selected should be done by only one team in a sequential order to avoid omission and duplication of households.

10.3. ASCERTAINMENT ERRORS

These errors arise due to the following factors :

(i) **Informant bias,** recall error and other difficulties involved in actual data collection. This is very much true in leprosy surveys because of the social stigma attached to the disease which makes a person refuse to be identified as a case of leprosy and total lack of knowledge about the early manifestations of the disease.

(ii) **Non-response error** arising out of refusal by informants to subject themselves to screening or their being not at home or houses being inaccessible, and so on. This problem is particularly acute in urban areas where there is general apathy towards house to house surveys.

(iii) Lack of trained and experienced investigators resulting in **investigator bias** and non-comformity to the standard definitions, concepts and procedures.

The first of the three type of errors can be taken care of by launching an intensive public health education campaign regarding leprosy and the need for its early treatment. Better screening methods and deep probing may be adopted to reduce the bias. Women workers attached to the community will help in better screening of the female population.

Non-response is one of the most serious problems encuntered in conducting leprosy surveys. This can be overcome by timing the survey to get the maximum response, ensuring confidentiality of the data collected etc.. With the help of local influential persons response can be improved considerably. A statistical procedure for dealing with this problem is to take a sample of non-response dopulation and make an all out effort to examine the sample completely (as explained earlier).

Investigator bias is also a serious problem in large scale sample surveys. It is better to engage well trained, experienced staff for this survey. On-the-spot inspections of their work should be done, the type of mistakes committed by them studied and suitable remedial measures mmediately instituted (retraining, etc.) This is the most effective way of reducing investigator bias.

10.4. TABULATION ERRORS

The sources of these errors are internal inconsistencies in the data collected due to inadequate scrutiny of the schedules canvassed, improper coding, tabulation and calculations.

These may be overcome by prescribing validation checks for the data collected, superscrutiny of the coding and tabulation work done. Automation of the data processing work will result in considerable reduction of the error.

11. ORGANISATION OF FIELD WORK

11.1. PLANNING THE SURVEY

The first job of SSAU before launching the field work is to finalise the sample list of villages and urban blocks to be surveyed in each district assigned to it. The selection will be done by the SSAU with the help of available statistical expertise. The sample list should be kept confidential till the survey is over.

Since the field work during the year is to be organised in the first zone, the SMO. should draw a tentative programme of work for the whole year, in consultation with SLO/ NLEP consultant, clearly specifying the period of field work in each of the districts in the zone. While drawing the plan of action for the year, the following factors warrant careful consideration.

1. Easy execution of field work and operation from the Headquarters.

2. Climatic pattern and economic activity in the districts.

3. In areas where the regular surveys are undertaken by the NLEP staff, the SSAU Team will visit the villages ideally within six months from the period of the recent survey done by the regular staff. Effective monitoring of operational efficiency of the regular service will be realistic only if the SSAU visits districts a short time after the visits by the regular service. The Statistical design stipulates that a third of the villages selected would be such that they had been enumerated by regular service staff within the last one year. The stipulation is best met by requesting the DLOs to send a list of villages visited by PMWs in each of the LCUs/SET under the jurisdiction with the dates of such visits. In case such a list is not forthcoming, the final selection of villages will have to be done by the leader of the SSAU after visiting the LCU.

The plan of action for the field work in the districts should be decided by the SMO. and the SLO./NLEP consultant will be

informed about the programme. Additional information that is required to conduct the survey in the selected villages/urban blocks should be collected from the concerned authorities like the R.G.Offlce, the NSSO(F.O.D.) without fail.

The SSAU will have 8 PMWs who will be divided into 4 teams of 2 PMWs each. The composition of the teams may, as far as possible, be kept the same during the course of the survey. Effort should be made to involve female health workers/guides including traditional 'Dais' in the work. They may prove useful especially in examining women members of the community.

Distribution of work for the 4 teams is made on the basis of number of villages/ mohallas to be surveyed in each LCU/SET/ ULC. It is advisible to assign the work in the selected village/UFS Blocks exclusively to one team except in situations when it may not be operationally possible to do so. This is suggested with a view to avoid possible duplication of households and non-coverage which may occur otherwise.

A temporary Head Quarters may be established in the LCU or PHC or any other institution in such a way that daily operation from theH.Q. to the sample points is convenient. These places will be of help in getting facilities for doing smear examination and preliminary data analysis.

The list of sample villages/Urban blocks to be surveyed in an LCU is grouped into two sub samples called subsample-1, and sub sample-2. One team of PMWs may be given the work of covering the villages in one sub sample entirely. This would facilitate computation of non-sampling errors. Hence it is necessary that the work in 2 LCUs/SETs/ ULCs is taken up simultaneously so that all the 4 teams are engaged fully.

Once the work in one district is over the team will shift its operation to the next district as per the calendar drawn-up.

During the visit of the SSAU to the concerned NLEP Unit, the records and registers maintained by the unit will be withdrawn and will be made available to the SSAU for matching only at the end of field work.

11.2. SURVEYING THE VILLAGE

11.2.1. PRELIMINARY WORK

The team should

(*a*) visit the area to be surveyed well in advance. Meet the local revenue and block development offlcials to procure the necessary maps, etc, of the vilages selected. Identify the villages selected properly with the help of the maps and the other identification particulars ;

(*b*) assess the present population of the village from the local authorities or from other health services. The 1981 census population may also be projected to the present year with the help of annual growth rate of the population for the area and validate the figure obtained from the authorities. If the population is around 900 then the whole village should be enumerated. If the population is far greater than 900, then any of the three methods suggested will be used depending on field convenience, to form clusters of required size. It is felt that in majority of the states formation of halmets might be the easiest, exceptions being states like Kerala. In states like Kerala, either the random point method or census house list may be used and a block of households selected as explained earlier. In these situations enumeration will be restricted to the selected hamlet only ; and

(*c*) discuss with the local offlcials about the local population, its composition, socioeconomic condition, occupation, population struct-

ure, their general attitude towards leprosy, level of cooperation of the people with the existing services, problem areas, etc. This will help in better organisation of the survey work and also in tackling the respondents during the survey.

In areas where the enumeration and examination of the population has already been carried out by the regular NLEP staff, the community may very well be aware of the work that is to be carried out by the SSAU. As there will be reluctance among the community to subject themselves to another screening, the reasoning behind this screening may be explained to remove any suspicion. The SMO should meet the local leaders, influential members and explain to them (a) what is planned, (*b*) the purpose of the survey, and (*c*) the likely benefit to the community. Though one may comouflage the intent under a technically winning title such as dermatological survey to avoid social stigma, it is advisible to be honest and candid in order to avoid any unsettling queries in future. They should also be assured of confidentiality of leprosy diagnosis. It is also useful to discuss the problem that might be encountered and to invite suggestions from them.

11.2.2. ENUMERATION AND EXAMINATION

Since, generally, we can expect the household members to be present in their house early in the morning, it is always advisable to start work in the early morning to optimize the response rate. However each team after studying the condition prevalling in the village will decide on the convenient working time.

To avoid both duplication and omission of households and enumeration, the team should follow the order of the latest census house number where available or any number which has been given serially to the houses in the entire village. The team should go to the house with the first number and after enumerating the house-hold residing there go to the second house serially. For the structures which come up after the number was given, a seperate continuous number is given.

The team should visit each and every house in the selected village. identify the households which are residing there, decide about the members constituting each house-hold and list them one after the other in the house-list (see appendix-V). For each member of the household, particulars like age, sex, leprosy status should be elicited and recorded in the schedule. All the members of the house-hold present should then be examined in detail for evidence of leprosy. Examination should be done under bright illumination so that lesions may not escape detection (See appendix-VII & VIII for screening procedures). If a traditional dai or village health guide or local Auxiliary Nurse Midwife (ANM) is available, her help can be taken in examining women. Of the two members in the team one will do enumeration and the other will do examination. If there is a suspect case, charting is done and other details are filled in the individual case card (see appendix-VI) Skin smears should be taken from these persons See) appendix - IX for procedure for taking skin smears). The slides should be despatched along with the smear slip, duly filled, to the temporary headquarters the same day. Smear results should be made available to the team by the lab technician within 24 hours. The suspect cases should be examined by the JMO. or SMO. the same day or the next day for confirmation of diagnoses and classification.

As far as possible all the households and individuals constituting the households in the sample should be covered (enumerated & examined) in the first visit itself. Coverage is important. Non-coverage of a large segment of the sample population will upset the netire work. Since it involves considerable ex-

penditure of resources to cover 100% of sample population by repeat visits, all the nonrespondents are listed and a 20% sample (random) selected and covered by a repeat visit.

If the coverage of the population is less than 70% in the first instance, it should be be given in detail. Specifically the numbers that were casualities because of non-cooperation, illness etc. should be indicated. After very effort, if it is not possible to improve the coverage and even if the team has time, **another area not previously included in the sample should not be selected.** It is best to give clear statement of facts, and the reasons for non-coverage. The SSAU with its experience in the area may give its opinion on the possible bias the non-coverage may intorduce. For example if there is every reason to believe that a number of individuals have gone away for work or for some festival, the absence may be unrelated to the risk of the disease. Even then if the age/sex distribution of the examined population is grossly different from the age/sex distribution of the normal enumerated population of the village, standardization method should be employed at the analysis stage.

11.2.3. REFERRAL SERVICES

In view of the expertise available with SSAUs, their presence in areas such as those of low endemicity can profitably be used to render referral services to the local NLEP staff. At the same time such services will provide an idea of the magnitude of the diagnostic and other differences.

11.3 SUPERVISION

One of the reasons why sample survey is resorted to is to reduce to the minimum level the non-sampling errors which assume alarming proportions in a complete enumeration. Hence it is of paramount importance to ensure that the survey teams adopt uniform definition, concepts and procedures. This can be achieved only by way of close supervision of the work of PMWs. The inspection should be both concurreent and non-concurrent. Non-concurrent inspections may be resorted to sparingly.

A multi-tier inspection system is envisaged for the field work in which the work of the PMWs is subjected to scrutiny at two or three levels - NMS, JMO / SMO. (This, in turn, ensures inspection of the work of NMS also). The responsibility for supervision of PMWs, NMS and other staff should be shared among SMO and JMO. The NMS should not only observe the way the work is being carried out by the PMWs but select and examine at least 5% of population examined and declared to be free of disease by PMWs to detect any cases missed by them.

The JMO should also examine records and registers. The Junior Medical Officer or in his absence SMO should go with the team to

(*a*) do the concurrent supervision of the work being carried out by the PMWs/ NMS ;

(*b*) Confirmation of cases detected by the PMWs ;

(*c*) Discuss problems and give suggestions and advice ; and

(*d*) Give support and guidance to the staff.

The records and registers can be checked at the end of day's work. If the mistakes are found soon after they are made, the worker will usually remember what happened and correction can be done easily. Each PMW will submit an extract of population enumerated, examined and cases detected at the end of day's work.

The SMO/JMO should compare the case cards and registers of the team with the case cards and registers of the local unit for validating *a*) diagnosis, *b*) Classification, *c*) Deformity status, *d*) Bacteriological status, *e*) Coverage- *f*) Missed cases and *g*) Population size and structure. From the existing records (a sam- ple of 10% MB & 5% PB) he can also find out the regularity of treatment. In addition, the cases found in the register of the LCU/SET/ULC but not detected by the SSAU will also be traced and re-examined, atleast on a sampling basis.

An interim report on the work done and discrepancies noticed may be prepared and sent to SLO,NLEP Consultant and Central Leprosy Teaching and Research Institute. A specimen monthly reporting form is given as appendix-XIV. Detailed analysis of the data for various epidemiological indicators will be done by the SSAU after completing the work in the assigned district and a comprehensive report submitted to SLO, NLEP consultant and CLTRI. The report should present all the tables prescribed in appendix-X and indicators mentioned in appendix-XI at the district level, generally, and at LCUs level, if necessary, and comment on the salient features emerging out of these tables and indicators.

12. TABULATION PLANS

After the completion of the field work in an LCU, the data collected in the house-list and patient card by the SSAU should be matched with the data available in the LCU records. This is done at the temporary headquarters and a major portion of this work should be handled by the clerical staff including the statistical assistant available with the SSAU. PMWs involvement should be kept to the minimum so as to make them available for field work.

One-to-one matching of the records of the patients as prepared by SSAU and LCU should be done and diagnosis and treatment compared taking special precautions in matching the records of the villages where hamlet group formation is done. Here the records available with the LCU/SET for the selected hamlet-group have to be identified and compared with those of SSAU. Various tables to be generated through this exercise are given in appendix-X. These tables should be generated for each of the villages surveyed by SSAU.

13. INDICATORS

Various epidemiological and operational indicators to be computed out of the data collected by the SSAU are discussed in appendix-XI.

The statistical formulae for calculating estimates for various epidemiological indicators at the LCU, and district level and the standard error of these estimates can be obtained from CLTRI on request.

NOTES

(1) CLUSTER SAMPLING : Cluster sampling consists of first forming suitable groups called clusters of individual items from the population (grouping neighbouring units or units which can be conveniently surveyed together), selecting some of the clusters according to an appropriate sampling procedure and surveying all the units in the selected clusters. In order to get the best results out of this design, the clusters should be formed in such a way that the clusters are heterogenous within and homogenous in-between (with respect to the study variable or its dummy) to the extent possible. For example, in a population survey, each household can be considered as a cluster of individuals and after selecting sample of households all the individuals in the selected households are surveyed.

(2) HAMLET-GROUP FORMATION : If the population of the selected village is very large, the village is divided into certain number of sub-divisions called 'Hamlet-groups' having approximately the same population and one such group is selected at random. The hamlet groups will be formed as follows :

(i) Identification of the natural hamlets i.e. pockets or localities where the houses of the village tend to cluster together. In case there are no recognised hamlets in the village, the census sub-divisions of the village (e.g. Enumerator's Blocks) or groups of census house numbers or geographically distinct blocks of houses may be treated as hamlets ;

(ii) Estimating the present population of each of the hamlets ;

(iii) Drawing a notional map showing the approximate locations of the hamlets and number them in a serpentine order starting from north-west corner and proceeding southwards ;

(iv) Grouping of the hamlets into hamlet groups. The criteria to be adopted for hamlet group formation are equality of population content and geographical contiguity. (As such, the numbering of hamlets is not to be adopted as a guideline for grouping.) In case there is a conflict between the two aspects, geographical contiguity is to be given priority over equality of population content. Indicate the grouping in the map. (However, large hamlets may be divided artificially to achieve equality of population.) ;

(v) Numbering the hamlet groups. Hamlet-groups will be serially numbered in the order of the first hamlet included in each ; and

(vi) Select one of the hamlet groups at random.

(3) INDEPENDENT INTERPENETRATING SUBSAMPLES : If a sample of required size is selected in the form of two or more subsamples drawn according to the same sampling procedure such that each subsample provides a valid estimate of the characteristic under study, the sub-samples so drawn are called interpenetrating subsamples (IPS). The subsamples may or may not be independently selected. For instance, if 10 villages are to be selected from the stratum and if it is to be drawn in the form of two independent IPS, then two subsamples of 5 villages each are selected according to the same random sampling scheme (Simple random, Systematic, etc.) independently.

(4) STRATIFIED SAMPLING : In stratified sampling design, the population of sampling units is classified into groups or "strata" before selection of the sample. Then independent samples are selected from each group or stratum according to a random procedure like simple random, cluster or systematic. These strata may all contain the same number of units or differing numbers of units.

Stratification has two purposes : the first is to increase the accuracy of the overall population estimates, and the second is to ensure that the information required is got for sub-divisions of the population which are of interest (like villages, taluks, etc.). Maximum overall accuracy will be attained if the strata are so chosen that the units within each stratum are as homogenous as possible.

(5) CIRCULAR SYSTEMATIC SAMPLING Quite often this sampling procedure is used in deference to simple random procedure due to its operational convenience though the sample taken is not fully random. According to this procedure, a sample is obtained by taking every k-th unit in the population after the units in the population have been numbered or arranged in some way. The number K is taken as

the sampling ratio of the size of the population (N) to the size of the sample (n). Thus, if the population consists of 10,000 sampling units and sample 150 is desired, then $K = 10000/150 = 67$ and the sample is obtained by taking every sixty seventh unit in the population.

But we should decide which should be the starting point. This is decided by choosing a random number, called random start, from 1 to N (population size) and then selecting every k-th unit from that start.

(6) REGRESSION : In many situations we frequently encounter variables which are functionally related ; that is, they are associated in some functional way. Although a functional relation between two variables implies nothing about the cause-and-effect, it enables us to predict the value of one variable on the condition that we have prior information about the other. This type of functional relationship is called 'regression'.

If two variables are involved, the variable that is the basis of estimation is called the independent variable and is designated x, and the variable whose value is to be estimated is called the dependent variable and is designated y. When an equation is formulated for estimating y from x, such an equation is called a regression of y on x. The equation may be of the form $Y = A + BX$; $Y = AB^X$; etc.

In this instance, the independent variable X is the prevalence rate among children and dependent variable Y, the overall prevalence rate. With the available data on these variables for each of the cluster, a regression equation has to be fitted to predict Y from X or vice-versa.

APPENDIX—1

STATE-WISE LIST OF SSAUs

State	Strength	
	Existing	Target (87-88)
Andhra Pradesh	3	2
Bihar	3	1
Gujarat	2	1
Karnataka	1	1
Haryana	–	1
Kerala	1	1
Madhya Pradesh	3	1
Maharashtra	4	2
Orissa	1	2
Rajasthan	1	1
Sikkim	–	1
Tamil Nadu	2	–
Uttar Pradesh	1	2
West Bengal	–	1
Total	22	17

APPENDIX-II

DUTIES OF SENIOR MEDICAL OFFICER

1. Planning and Organization of the survey work.
2. Organize smooth functioning of the Unit.
3. Organize periodic meetings and interaction with various Organizations.
4. Confirmation of cases.
5. Supervision and assistance in work.
6. Supervision of the work of the Unit.
7. Maintenance of equipment and vehicles.
8. Verification of records & reports.
9. Maintenance of accounts and control of expenditure.
10. Routine correspondence.
11. Timely preparation & despatch of reports of survey - interim & final.

DUTIES OF JUNIOR MEDICAL OFFICER

1. Assist Senior Medical Officer in Planning and Organization of work.
2. Coordinate the activities of the team.
3. Daily meeting with team members.
4. Verify records.
5. Confirmation of cases.
6. Assist SMO. in preparing reports.
7. Supervision of the staff.
8. Encourage and motivate staff.
9. Improve their technical skills and knowledge.
10. Support them and help them solve problems.

11. Monitor staff programme.
12. Assist Senior Medical Officer & Statistical Assistant in analysing the data.
13. Any other job entrusted to him by SMO.

DUTIES OF NON-MEDICAL SUPERVISOR

1. Organize smooth functioning of the team.
2. Assist SMO and JMO - in preparing work Schedule & Planning the work.
3. Confirmation of cases detected by PMWs.
4. Supervision of performance of PMWs by observations and checking of records.
5. Examination of 10% of healthy population for detecting missed cases.
6. Assist JMO and SMO in preparation of interim report.

DUTIES OF PARAMEDICAL WORKER

1. Plan his daily routine in advance in confirmity with work schedule.
2. Enumeration of sample population.
3. Detect and list people with suspicious signs, make provisional diagnosis & get them confirmed by NMS/SMO/JMO.
4. Take skin smears from confirmed cases.
5. Repeat visits to 20% of non-responders.
6. Maintain records and registers.
7. Compilation at the end of day.
8. Liaison with other Co-workers in the area. (MPW, VHG etc).

DUTIES OF STATISTICAL ASSISTNAT

1. Assist the SMO in selecting the sample during various stages of survey as prescribed.
2. Scrutinize and validate the data collected.
3. Matching the records of LCU with the data collected by SSAU.
4. Tabulation of the data collected by the PMWs as per the prescribed tabulation scheme and compute various indices as prescribed with the help of the computer and clerks.
5. Preparation of various monthly and annual returns.

DUTIES OF COMPUTER

1. Consolidating the data collected by the SSAU as per the direction of the Statistical Assistant.
2. Helping the Statistical Assistant in all the work carried out by him.

APPENDIX—III

RANDOM SAMPLE AND METHOD OF SELECTION

WHAT IS A SAMPLE ?

A sample consists of units selected in a suitable manner from the population in order to estimate some characteristics of the population which are of interest. Thus in a sample survey only a portion of the population is selected according to an objective strategy, and studied for the characteristics of interest and inferences made about the whole population.

A good sample should be representative of the population and should enable one to infer the population characteristics from the results obtained from the sample. A sample is a part of the population and can never be a substitute for the whole. On the other hand a sample when selected suitably, enables one to make inferences about the population with an acceptable level of precision. The most important thing is that the sample should be representative which is best achieved by using statistical principle of random sampling.

The exact manner in which a random sample is selected is explained below.

WHY A SAMPLE ?

An alternative to sample survey in this case is to completely enumerate the population of the district just to validate the records and compute some epidemiological indicators. The following are the reasons for resorting to a sample survey :

(*a*) The purpose of SSAU is to assess as quickly as possible the magnitude of the divergence in the observation as between those of the regular staff and the SSAU, and to make use of the information for deriving national estimates of various indices.

(*b*) Reliability of the data is to be tested not for very small administrative level (villages) but for DLUs and LCUs. A properly designed sample survey will be sufficient to satisfy the need.

(*c*) Non sampling errors will not be reduced by complete enumeration. With available resources it is much more important to reduce these errors. This is best done by taking a sample and concentrating efforts to keep these errors to a minimum.

PROCEDURE FOR SELECTION OF A RANDOM SAMPLE

The principal aim of any objective sampling strategy is to secure a sample which, to the extent possible, will reproduce the characteristics [of interest] of the population. A sample can be selected in many ways. One is called a random sample in which the units (villages or urban blocks) are selected in such a manner that each unit in the population has a pre-assigned chance of being selected. One type of random sampling is the simple random sampling in which each element such as an individual, is given an equal chance of being selected. In practice, in field surveys one often takes a random sample of households, villages, etc. rather than individuals. In such cases the chance of selection of individuals may not be equal, but the design will ensure that the chance of selection is known.

Another type of sampling is the judgement or purposive sampling in which the investigator uses his judgement in the choice and includes, deliberately, only those items of the population in the sample which he considers are representatives of the universe In purposive sampling, units are selected by considering the available supplementary information more or less subjectively with a view to reflect the population characteristics in the sample. Though this type of sampling seems to be very easy to resort to and at first sight may appear to yield the most accurate results it is seldom used in large-scale surveys mainly because it is not generally possible to get strictly valid estimates due to the risk of personal bias in subjective selection and also the need for a thorough knowledge of the population under consideration.

Let us assume that one is interested in estimating the prevalence rate of leprosy in a district by selecting, say, 20 villages from the district consisting of 200 villages. The investigator may use his personal judgement about the villages in the district and select 20 villages with the best intention of getting a cross-sectional representation of the district in the villages selected. Though the intentions are good, it has been shown time and again that personal biases are invariably introduced, either consciously or unconsciously, thereby destroying the representative character of the sample. In particular, if averages only are of interest, average villages might be selected which appear to be nearest to the average. Such a sample may well be biased, that is, the selection of all the villages may be affected by similar errors. In any case the chance of selection of the individual is not known and extrapolation of sample findings to the general population becomes a guesswork. It is impossible to compute the precision of the estimates.

In the random sampling method, the judgement of the investigator does not play a role. The villages are listed one after the other and given numbers starting from 1 to 200. Out of these twenty are selected using the same procedure adopted in the lottery method. This can be simplified by the use of a **table of random numbers.** This is explained below.

The random numbers are generated by some mechanism which, when repeated a large number of times, ensures approximately equal frequencies for the numbers from 0 to 9 and also proper frequencies for various combinations of numbers that could be expected in a random sequence of the digits, 0 to 9. Several standard tables are available two pages of one such table is reproduced in appendix-IV. Since our problem is to select 20 villages from 200 villages and since each village is identified uniquely by its serial number, we have to select 20 of the numbers 001 to 200 at random.

A three-digit column of random numbers is consulted since the highest serial no. is 200, a three – digit number and the villages corresponding to the first 20 numbers, which are less than or equal to 200, is chosen. [000 may be ignored and if a village which is already selected is not to be considered for further selection, repeated numbers are ignored] The starting can be from any column and any row. Starting from the 1st row, the following numbers are selected by confining to the first 3 columns from left – 112, 059, 116, 124, 090 037, 078, 088, 143, 133, 094, 189, 193, 083, 092, 062, 155, 077, 111, 087. It is to be noted that the 2nd column also is consulted after failing to select the required twenty numbers from the 1st column.

TABLE OF RANDOM NUMBERS

row no.	column number									
	1	2	3	4	5	6	7	8	9	10
1	3436	6833	5809	9169	5081	5655	6567	8793	6830	1332
2	6133	4454	2675	3558	7624	5736	2184	4557	6496	8547
3	9853	3890	5535	3045	9830	5155	8218	9090	7266	4784
4	5807	5692	6971	6162	6751	5001	5533	2386	0004	2855
5	6291	0924	1298	7386	5856	2167	8299	9314	0333	8803
6	4725	9516	8555	0379	7746	9647	2010	0979	7115	6653
7	7697	6486	3720	6194	3552	1081	6141	7613	5455	3731
8	3497	2271	9641	0301	4425	6776	1205	2953	5669	1056
9	8910	4765	1641	0606	4970	7582	7991	6480	2946	5190
10	1122	6364	5264	1267	4027	4749	0338	8406	1213	5355
11	4333	0625	3947	1373	6372	9036	7046	4325	3191	8989
12	7685	1550	0853	4276	1572	9348	6893	2113	8285	9195
13	0592	8341	4430	0496	9613	2643	6442	0870	5449	8560
14	3506	0774	0447	7461	4459	0866	1698	0184	4975	5447
15	8368	2507	3565	4243	6667	8324	3063	8809	4248	1190
16	2630	1112	6680	4863	6813	4149	8325	2271	1963	9569
17	3883	3897	1848	8150	8184	1133	6088	3641	6785	0658
18	1123	3943	5248	0635	9265	4052	1509	1280	0953	9107
19	1167	9827	4101	4406	1254	6814	2479	5924	5071	1244
20	7831	0877	3806	9734	3801	1651	7169	3974	1725	9709
21	2487	9756	9886	6776	9426	0820	3741	5427	5293	3223
22	1245	3875	9816	8400	2938	2530	0158	5267	4639	5428
23	5309	4806	3176	8397	5758	2503	1567	5740	2577	8899
24	7109	0702	4179	0438	5234	9480	9777	2858	4391	0979
25	8716	7177	3386	7643	6555	8665	0768	4409	3647	9286
26	9499	5280	5150	2724	6482	6362	1566	2469	9704	8165
27	3125	4552	6044	0222	7520	1521	8205	0599	5167	1654
28	3788	6257	0632	0693	2263	5290	0511	0229	5951	6808
29	2242	2143	8724	1212	9485	3985	7280	0130	7791	6272
30	0900	4364	6429	8573	9904	2269	6405	9459	3088	6903
31	7909	4528	8772	1876	2113	4781	8678	4873	2061	1835
32	0379	2073	2680	8258	6275	7149	6858	4578	5932	9582
33	0780	6661	0277	0998	0432	8911	8946	9784	6693	2491
34	8478	8093	6990	2417	0290	5771	1301	3306	8825	5937
35	2519	7869	9035	4282	0307	7516	2340	1190	8440	6551
36	2472	0823	6188	3303	0490	9486	2896	0821	5999	3697
37	8418	5411	9245	0857	3059	6689	6523	8386	6674	7081
38	8293	5709	4120	5530	8864	0511	5593	1633	4788	1001
39	9260	1416	2171	0525	6016	9430	2828	6877	2570	4019
40	6568	1568	4160	0429	3488	3741	3311	3733	7882	6985
41	6694	5994	7517	1339	6812	4139	6938	8098	6140	2013
42	2273	6882	2673	6903	4044	3064	6738	7554	7734	7899
43	6364	5762	0322	2592	3452	9002	0264	6009	1311	5873
44	6696	1759	0563	8104	5055	4078	2516	1631	5859	1331
45	3431	2522	2206	3938	7860	1886	1229	7734	3283	8487
46	4842	3765	3484	2337	0587	9885	8568	3162	3028	7091
47	8295	9315	5892	6981	4141	1606	1411	3196	9428	3300
48	4925	4677	8547	5258	7274	2471	4559	6581	8232	7405
49	5439	0994	3794	8444	1043	4629	5975	3340	3793	6060
50	2031	0283	3320	1595	7953	2695	0399	9793	6114	2091

TABLE OF RANDOM NUMBERS (*contd.*)

row no.	11	12	13	14	15	16	17	18	19	20
51	0883	2339	1363	4219	0189	4453	0806	1970	4130	7998
52	4634	0385	8760	3555	0567	8815	4700	5092	0231	5757
53	5432	9770	2781	6469	7152	0256	6137	0458	0968	9610
54	2317	5966	3861	0210	8610	5155	9252	4425	7449	0449
55	6836	2472	0385	4924	0569	6486	0819	9121	8586	9478
56	9358	5197	4910	0263	2372	6446	0252	0383	6518	0707
57	5936	9276	7805	3690	7473	5954	3164	3482	1845	7686
58	4306	9165	6438	6777	4671	2360	3382	2686	8767	6827
59	5951	7275	3713	5951	1452	1986	5034	0518	9314	7164
60	2108	6157	6254	7483	2407	8609	2114	4095	2456	8169
61	9566	6198	4546	8964	4473	5657	9152	3956	6235	9991
62	3981	3873	6448	0871	2825	7693	9304	9016	5871	9251
63	8696	2811	5419	9481	4498	1718	7871	1245	7915	2534
64	1433	1167	7332	0970	0159	1218	4679	9568	5533	8206
65	2141	6763	3519	7475	5991	8210	6588	5652	2636	7328
66	5445	0443	2930	1322	7296	4063	9397	4389	1295	3782
67	1339	4168	2508	0980	4184	7238	1406	9956	8366	9846
68	0948	6094	9141	8128	5545	9938	2129	7718	3561	2918
69	4252	3165	2934	4966	8313	0339	3724	9779	3113	9747
70	1898	4922	5411	9237	4511	6360	1905	9126	8473	8258
71	4014	3915	9924	2185	0045	5419	3618	0388	8833	7820
72	2177	3510	0681	6548	5318	7449	5776	5519	2420	5532
73	6625	0747	4812	5649	1408	3724	3681	1637	8352	4305
74	8271	1876	2939	1452	3071	0649	4840	9228	5237	5551
75	5745	1306	9341	2202	9409	3255	7968	6629	6267	4004
76	6164	6330	1234	4065	0816	7058	6369	1947	7346	4723
77	9956	5248	7969	9843	3265	5024	0971	4740	3295	2557
78	9811	9364	8786	4365	7833	0898	5798	9136	3829	5329
79	7346	9293	7714	6558	1103	9861	4270	3645	0912	3498
80	8061	5526	9875	6795	9549	2156	0845	0166	5267	1713
81	8425	0589	3180	4949	9893	8201	4108	6655	5819	1862
82	6464	9513	4697	4312	8602	7950	6790	1419	0407	6701
83	5382	7915	3116	5410	2990	9157	6348	3856	6925	0790
84	1933	3542	9212	3714	7075	1858	9857	1252	0681	5627
85	6426	5146	8050	5391	0055	6736	6866	0829	7983	3239
86	6984	3252	3254	1512	5402	0137	3837	1293	9329	1218
87	9080	7780	2689	8744	2374	6620	2019	2052	1163	7777
88	5583	3674	4040	8915	2860	9783	2497	6507	5084	8877
89	8578	8170	3723	8433	3395	2329	7783	7511	7075	1126
90	3899	0413	0663	3896	2100	3516	7169	0934	8257	9755
91	9372	7493	9462	3932	7468	3383	4358	7937	2542	5480
92	4747	1794	4498	1693	0955	5373	5400	5226	4811	0379
93	3545	6861	4232	3952	9316	1867	0537	2144	1034	9889
94	0836	9910	8303	7618	9262	7540	1802	7089	7172	0442
95	9742	4735	1085	9715	2103	5485	3740	4117	2786	5815
96	9890	5980	2778	5956	6128	2384	8501	2302	7232	6363
97	5960	4185	7079	8917	2378	6868	6472	9093	8609	4008
98	9017	3136	4463	4174	8453	5045	4925	7889	7188	6990
99	8520	7719	6078	0293	0525	7426	8334	2367	5490	4960
100	1436	3124	0072	5146	8555	7584	8382	1378	3848	7323

APPENDIX — V

NATIONAL LEPROSY ERADICATION PROGRAMME

EPIDEMIOLOGICAL SURVEY

1. IDENTIFICATION OF THE VILLAGE :

1.1. State :

1.2. District :

1.3. Taluk/Tahsil :

1.4. Village/Town :

1.5. LCU/SET/ULC :

1.6. Organisation responsible for the programme :

1.7. 1981 census population :

1.8. Present population :

2. PARTICULARS OF FIELD OPERATIONS :

2.1. Name of the PMWs :

2.2. Date of starting the survey :

2.3. Date of completing the survey :

2.4. Name & Signature of the Supervisor :

3. SUMMARY :

3.1. No. of household listed :

3.2. Total population enumerated :

3.3. Total population examined :

3.4. Total child population :

3.5. No. of cases detected Child :

Adult :

4. LIST OF HOUSEHOLDS

Sl. No.	House No.	H. H. Sl. No.	Household Members	Rel to HOH	Sex	Age	Leprosy status &	New or Old case	If code 1 to 4 in column 8			
									Type of Leprosy $	Deformity status ✱	Whether registered with LCU/SET/ULC VOL	Patient Card number
1	2	3	4	5	6	7	8	9	10	11	12	13

& — Leprosy status : 0 — No history of leprosy ; 1 — Has leprosy & under DDS treatment ; 2 — Has leprosy & under MDT treatment. 3 — Has leprosy but not under treatment. 4 — Had leprosy, under surveillance. 5 — Had leprosy & completed surveillance

$ — Type of Leprosy : PB / MB

✱ — Deformity status : 0 — Not present ; 1 — Present.

EXPLANATORY NOTES ON THE HOUSEHOLD SCHEDULE

1. House : Every structure, tent, shelter etc. is a house irrespective of its use. It may be used for residential or non-residential purpose or both or even may be vacant.

2. Household : A group of persons normally living together and taking food from a common kitchen will constitute a household. The members of a household may or may not be related by blood to one another. The following cases are to be noted :

(i) Each inmate (including residential staff) of a mess, hotel, boarding and lodging house, hostel, etc. will constitute a single-member household. If, however, a group of persons among them normally pool their income for spending, they together will be treated as forming a single household. For example, a family living in a hotel, will be treated as a separate single household by itself.

(ii) Undertrial prisoners in jails and indoor patients of hospitals, nursing homes etc. are to be excluded but residential staff therein will be listed, while listing is done in such institutions. The former persons will be considered as normal members of their parent households and will be counted there.

(iii) Floating population, i.e. persons without any normal residence will not be listed. But households residing in open space, roadsideshelter, under a bridge etc. more or less regularly in the same place will be iisted.

3. Household size : The number of normally resident members of household is its size. It will include temporary stay-aways but exclude temporary visitors and guests. Even though the determination of the actual composition of a household will be left to the judgment of the head of the household, the following procedures will be followed as guideliness :

(i) In deciding the composition of a household, more emphasis is to be placed on "normally living together" than on "ordinarily taking food from a common kitchen". In case the place of residence of a person is different from the place of boarding, he will be treated as a member of the household with whom he resides.

(ii) A resident employee, or domestic servant or a paying guest (but not just a tenant in the house) will be considered as a member of the household with whom he resides even though he is not a member of the same family.

(iii) When a person sleeps in one place (say, a shop or a room in another house because of space shortage) but usually takes food with his family, he should be treated not as a single member household but as a member of the household in which other members of his family stay.

(iv) One member of a household (say, a son of the head of the household) stays elsewhere in hostel for studies or any other reason. He will not be considered as a member of his parent's household.

4. Age : The age in completed years of all the members listed in column (1) will be ascertained and recorded in column (5). For a new born baby or the baby who has not completed one year of age at the time of listing, the entry to be made in column (5) will be '0'.

5. Leprosy status

0 – No history of leprosy : the person has not had the disease at any time before.

1/2 – Has leprosy and under DDS/MDT treatment : has been diagnosed to be a case of leprosy and is under DDS/MDT treatment either at a government clinic or elsewhere.

3 – Has leprosy but not under treatment : has been diagnosed to have leprosy but not received treatment anywhere.

4 – Had leprosy under surveillance now : has completed the prescribed period of treatment and is under surveillance now.

5 –Had leprosy and completed surveillance : self explanatory.

6. Type of leprosy : MB– Multibacillary

PB– Paucibacillary

7. Deformity status : self explanatory.

8. Whether registered with

LCU – Leprosy control unit

SET – Survey education & treatment centre

ULC – Urban leprosy centre

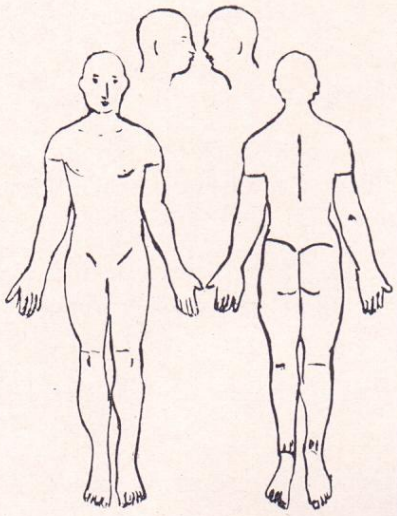
VOL – Voluntary organisation (mention the name of the organisation)

9. Patient card number : if the patient card number is available with the local unit it should be entered in the schedule in column 13.

APPENDIX—VI

INDIVIDUAL CASE CARD

Patient No. :
[as in NLEP Records]



1. State :———— Dist. :————
2. LCU/SET/ULC :———Village/town :————
3. Name :————
4. House Number :————
5. Household Number :————
6. Sex : M/F.
7. Duration of stay :
8. Age :
9. New / Old / Under Surveillance.
10. Duration of disease :
11. Type : PB / MB
12. Clinical Activity :
    Active / Inactive.
13. Deformity : H/F/E/Others/No deformity
14. B.I. :
15. On Treatment : at the NLEP centre / Private / not treated.
16. DDS / MDT. :
17. Regularity * of the patient during the last three months in
    (i) drug collection : Y/N
    (ii) drug consumption : Y/N
18. Surveillance : whether NLEP staff contacted after release from treatment : Yes / No.
    If yes, date of last visit by NLEP staff :

* (i) atleast two collections; (ii) two-third of prescribed daily doses

1. Number :
2. Appearance :
   1. Flat / Raised.
   2. Erythematous / Hypopigmented
   3. Symmetrical / Asymmetrical.
   4. Infiltration : Normal / Mild / mod/ Severe.
   5. Margin : Vague / ill-defined/ Well-defined.
   6. Nodules : None / Few / Many.
   7. Anaesthesia : Not anaesthetic / Partial / Total.
3. Earlobes :
   Normal / Thickened / Nodular / Wrinkled.

Signature of MO Signature of NMS. Signature of PMW.

KEY TO BODY CHARTING OF LEPROSY PATIENTS

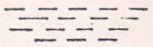
Definitions :

Macule	:	A skin lesion flush with the surface of the skin.
Papule	:	A thickened lesion in the skin of a size below 1 cm. in diameter.
Nodule	:	Similar to a papule but larger than 1 cm. in diameter.
Plaque	:	A patch in the skin with its entire surface raised above the surface of the skin.

1. Hypopigmented macule:

2. Infiltration:

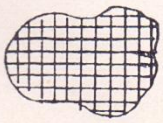
3. Resolving macule:



4. Partial sensory loss:

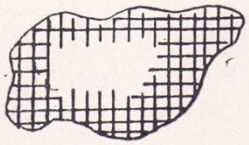
5. Anaesthesia:

6. Hypopigmented macule with anaesthesia:
7. Well defined patch with anaesthesia:



8. Well defined macule:

9. Well defined patch, anaesthetic with central healing:



10. Well defined anaesthetic patch with infiltrated borders which are raised:

11. Pebbly appearance:

12. Patch with one margin illdefined macular:

13. Nodules:

14. Nerves which are thickened:

15. Loss of digits:

Claw fingers

16. Gynecomastia:

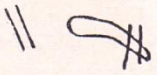
Gyneothelia

17. Foot drop, wrist drop against area:

18. Ulcer on sole of foot:
Ulcer scar

19. Collapse Nose:

20. Loss of eye brows:



APPENDIX - VII

PROCEDURES & CRITERIA FOR DIAGNOSIS

Problems in diagnosis arise mainly in two areas. (*a*) Early lesions, particularly when some of them have only minimal or marginal evidence of Leprosy. This would mean that examiners should try to be as objective as possible. (*b*) Inactive lesions which have become so either due to treatment or spontaneously. As far as possible these should be identified and excluded from the list of active cases.

Procedures for diagnosis :

Procedures for diagnosis should include the following :

Inspection Inspection of total body surface in good light and in a systematic manner. Where cultural situations demand, women examiners may be required. Asking the examinee about any patch or sensory loss noticed by him may be of value. Inspection involves looking for macules, papules, diffuse infiltration, nodules, dry areas of skin, plantar ulcers, and deformities.

Palpation : Palpation of nerve trunks should always include ulnar and lateral popliteal nerves. Other nerves should be examined as a routine.

Testing for sensory loss : Testing for sensory loss should be carried out (*a*) on all skin lesions the appearance of which is compatible with those of leprosy, (*b*) when a patient complains of numbness and (*c*) when there is a nerve trunk thickening even in the absence of any skin lesion. Testing for sensation will be confined to light touch (touch) and pin prick (pain). In some situations only pin prick will be possible.

Skin smear examination : Skin smear examination should be carried out on all individuals identified as having definite or doubtful leprosy. The examination, including reading of smears, should be carried out in the standard manner.

Diagnostic criteria and categories :

For the purpose of the survey the examined population could be categorized as below :

I. **Multibacillary leprosy :** Skin lesions clinically and/or bacteriologically compatible with leprosy.

II. Paucibacillary leprosy active : (*a*) Anaesthetic skin lesions compatible with leprosy and with AFB negative smears, or (*b*) Area of sensory loss over apparantly normal skin with thickened and tender nerve and with AFB negative smears.

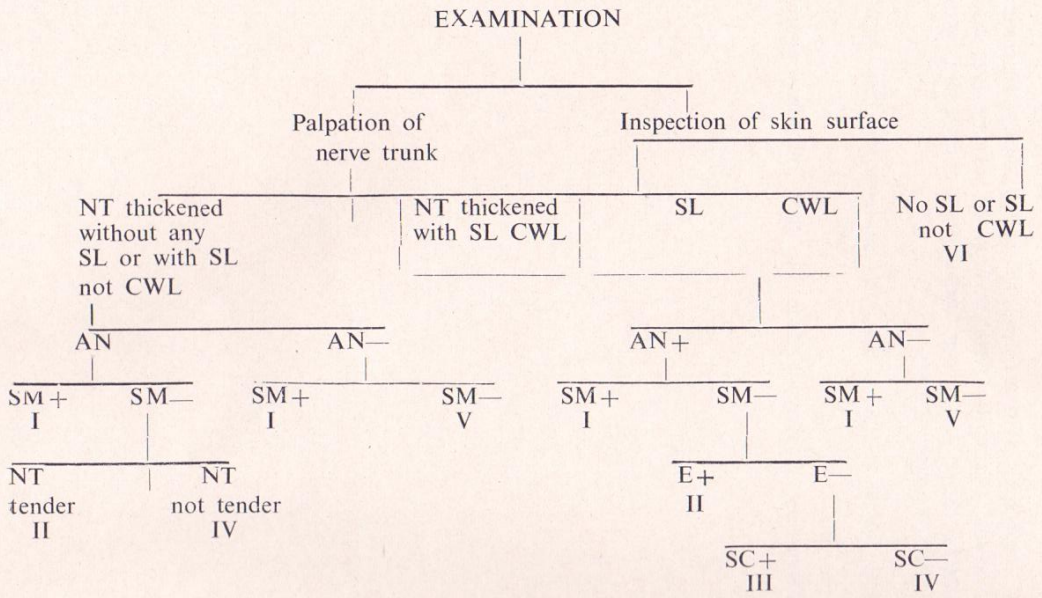
III. **Leprosy inactive :** Scarred anaesthetic skin lesions which would otherwise be compatible with leprosy with AFB negative smears.

IV. **Leprosy-activity status doubtful :** (*a*) Anaesthetic skin lesions compatible with leprosy, with neither erythema, nor infiltration, nor scarring, and with AFB negative smears.

V. **Doubtful leprosy :** (*a*) Non anaesthetic smear negative skin lesions otherwise eompatible with leprosy or (*b*) Nerve trunk thickening with no area of sensory loss and with AFB negative smears or (*c*) Area of sensory loss over apparently normal skin with no nerve trunk thickening and with AFB negative smears.

VI. **No leprosy :** No skin lesion, no nerve thickening, and no sensory loss compatible with leprosy.

A simple key for suspecting/diagnosing leprosy is given in the following chart.



I	Multibacillary leprosy	SL –	Skin lesion
II	Paucibacillary leprosy–active	CWL –	Compatible with leprosy
III	Leprosy–inactive	NT –	Nerve trunk
IV	Leprosy–active doubtful	AN –	Anaesthesia
V	Doubtful leprosy	E –	Erythema
VI	No leprosy	SM –	Skin smear
		SC –	Scarring

APPENDIX—VIII

CLINICAL HISTOPATHOLOGICAL AND IMMUNOLOGICAL FEATURES OF THE FIVE-TYPE CLASSIFICATION OF LEPROSY APPROVED BY THE INDIAN ASSOCIATION OF LEPROLOGISTS

At the outset it is to be emphasized that classification of leprosy lesions should be made only when the diagnosis of leprosy is certain.

The criteria in the description of the different types might appear to be rigid in certain respects, as for example, in the number of skin lesions. This is by no means absolute. Where laboratory and other facilities exist to confirm the classification, a reasonable flexibility would no doubt be permissible. The apparently rigid description is to facilitate the Para Medical Workers in the field, especially for administrative reasons and uniformity of reporting.

I INDETERMINATE TYPE

The indeterminate type represents those cases where leprosy is in the very early stages of evolution. The skin lesions consist of macules. The clinical and histo-pathological characteristics of the lesions are given below :

(*a*) Skin lesions :

Number	:	One to three
Size	:	Small (5 cm. or less in diameter)
Colour	:	Hypopigmented
Elevation	:	Flat and flush with rest of the skin
Margin	:	Ill defined
Surface	:	Smooth, occasionally dry
Sensory changes	:	Impairment of pain or touch sensation.

(*b*) Nerve lesions : Nerve thickening not necessarily present.

(*c*) Skin smears by slit and scrape method : Negative.

(*d*) Lepromin reaction : Negative to doubtful.

(*e*) Histology : A non specific infiltration, mostly with small round cells. The dermal nerve twigs are infiltrated with the above cells. Acid fast bacilli may be demonstrated in the nerves by very careful examination of serial sections.

II. TUBERCULOID TYPE

(*a*) Skin lesions :

Number	:	One to three.
Size	:	Could be of any size.
Colour	:	Hypopigmented or varying shades of erythema.
Elevation	:	Raised or flat. In the raised lesions the entire lesion may be raised or only the edges may be raised.
Margin	:	Well defined. The edges in the raised lesions are abrupt.
Surface	:	Dry, rough, anhydrotic, consistency in raised lesion : firm
Sensory changes	:	Analgesia and/or anaesthesia.

(*b*) Nerve lesions : In cases with raised lesions, cutaneous nerves leading to the skin lesion and regional nerve trunks are often enlarged. In cases with flat lesions such nerve enlargement may not be observed.

(*c*) Skin smear by slit and scrape method : Negative.

(*d*) Lepromin : Positive (1+ to 3+)

(*e*) Histology : In raised lesions, there is a well defined granuloma, consisting of focal collections of epitheliod cells surrounded by lymphocytes. Such a granuloma encroaches upon the subepidermal zone. Nerves are infiltrated and destroyed. Acid fast bacilli are not usually found. In flat lesions, the granuloma is sparse and consists of focal collections of lymphocytes and infiltrated acid fast bacilli are not usually found.

Note : It could thus be seen that the Tuberculoid leprosy could be divided into Polar Tuberculoid (TT) and Macular Tuberculoid (TM).

III. BORDERLINE TYPE

The Borderline type of leprosy represents a clinical spectrum reflecting the immunological gradation from the Tuberculoid at one end to the Lepromatous at the other. Both flat and raised skin lesions are found throughout the spectrum.

(*a*) Skin Lesions :

Number	:	4 or more, sometimes satellite lesions may be observed near the larger ones.
Size	:	Could be of any size.

Colour	:	Hypopigmented or varying shades of erythema.
Elevation	:	Flat or raised. In the raised lesions, the entire lesions may be raised or only the edges may be raised. There could thus be various patterns of lesions e.g. uniformally raised, dome shaped circinate, concentric or irregular.
Margin	:	In the flat lesions, margins may be ill defined, partially defined or well defined. In the raised lesions edges are sloping.
Surface	:	Smooth to different grades of dryness.
Consistency of raised lesions	:	Rubbery to soft.
Sensory changes	:	Modalities of sensation may be lost to varying degrees.

(*b*) Nerve lesions : In cases with raised lesions, cutaneous nerves leading to the skin lesions and regional nerve trunks are often enlarged. In cases with flat lesions, such nerve enlargement may not be observed.

(*c*) Skin smears by slit and scrape method : Moderately positive to negative.

(*d*) Lepromin : Moderately positive to negative.

(*e*) Histology : In flat lesions the granuloma could be non-specific consisting of focal collections of lymphocytes and plasma cells. Occasionally histiocytes and macrophages may be found. The dermal nerves are infiltrated. Acid fast bacilli may be demonstrated in the nerves or macrophages.

In raised lesions, the granuloma is irregular and branched, consisting of macrophages and/or epithelioid cells. Varying proportions of lymphocytes and plasma cells are found. The subepidermal zone is infiltrated. Nerves are infiltrated, showing varying degrees of destruction. Acid fast bacilli in small to moderate numbers may be demonstrated in the nerves or macrophages.

Note : It could thus be seen that borderline leprosy could be divided into macular and infiltrated types. In the hands of experienced workers it would be possible to subdivide it into Borderline on Tuberculoid side (BT) and Borderline on Lepromatous side (BL) both in the raised and flat lesions.

IV. LEPROMATOUS TYPE

(*a*) Skin Lesions : The skin lesions in Lepromatous vary according to the stage of the disease. In the early stages the lesions could be seen as macules which are small, numerous, symmetrically distributed, hypopigmented or coppery red, ill defined, smooth and shining with no sensory loss. As the disease advances, the lesions get infiltrated with a smooth shining surface and with colour varying from coppery red to reddish brown, involving the skin of the entire body except

for certain areas like the axilla, groin and flexures where the lesions are relatively inapparent. In the more advanced stages, papules and nodules appear.

(*b*) Nerve Lesions : Some of the nerve trunks are enlarged on both sides and are soft in consistency. Loss of sensation is found in the distal parts of the limbs.

(*c*) Skin smears by slit and scrape method: positive.

(*d*) Lepromin : Negative.

(*e*) Histology : The skin shows extensive granuloma involving the entire thickness of the dermis, sparing immediate sub-epidermal zone. The predominent cells of the granuloma are macrophages which have a foamy cytoplasm. Plasma cells and small numbers of lymphocytes are diffusely distributed in the granuloma. The nerves are prominent with proliferation of the perineurium. Acid fast bacilli are seen in large numbers in the macrophages, nerves and occasionally in other skin appendages.

V. PURE NEURITIC TYPE

In this type of leprosy, there are no skin lesions. Larger nerve trunks or their branches are enlarged. There is sensory loss in the areas of distribution of the nerves. A single nerve or multiple nerves may be involved. The enlarged nerves are generally firm, but also be soft. Skin smears are negative. Lepromin reaction is generally positive, but sometimes may be doubtful or negative. The histology could be of the Tuberculoid, Borderline or non-specific type.

EQUIVALENTS OF DIFFERENT CLASSIFICATION OF LEPROSY

Other Classification	Current Classification	
	Multibacillary	Paucibacillary
1. Inernational (Madrid 1953)	i. Lepromatous	i. Tuberculoid
	ii. Borderline lepromatous	ii. Indeterminate
	iii. Smear positive indeterminate, tuberculoid and borderline tuberculoid	iii. Borderline tuberculoid
2. Ridley and Jopling	i. BB	i. I
	ii. BL	ii. TT
	iii. LL	iii. BT
3. Indian	i. L	i. T
	ii. N ? L	ii. MA
		iii. P under N
		iv. Early indeterminate under N ? L
4. Indian Association of Leprologists (1983) consensus	i. Lepromatous	i. Indeterminate
	ii. Borderline lepromatous.	ii. Tuberculoid
		iii. Pure neuritic
		iv. Borderline tuberculoid

APPENDIX—IX

THE 'SLIT AND SCRAPE' METHOD

TECHNIQUE

1. Thoroughly clean the selected site with spirit or ether to remove dirt and any saprophytes.

2. Hold the skin pinched up and raised between the thumb and index finger of the left hand. This will squeeze out blood from the part and minimise bleeding when cut is made. If due to thickness of the skin, it is difficult to pinch up the skin, exert lateral compression with the two fingers stretching the bit of skin in between them.

3. With the point of a sterile scalpel make an incision of 5 mm long and 2 mm deep, scrape the bottom and the sides of the slit to obtain sufficient material for a smear.

4. Transfer the material from the point of a scalpel to a clean new glass slide of 1" x 3" and make a uniform and moderately thin smear by spreading the material over a small area of 1 cm. in diameter.

5. Press the out surface of the skin with piece of a cotton wool to stop bleeding and seal the part with tincture benzoin.

6. When the smears are dry, fix it by passing the slide twice or thrice over a flame with surface carrying the smear upper most. Care should be taken to avoid too much heat which will result in cracking or charring the smear. Too little heat may not fix the smear efficiently and it may be washed out during staining and subsequent washing.

7. A minimum of 3 sites should be chosen and at least one should be from the site of active lesion.

TECHNIQUE FOR STAINING SMEARS BY ZIEHL NEELSEN ACID FAST METHOD

(Modified)

The reagents required :

1. The stain

Basic Fuchsin	...	1 gm.
Absolute Alcohol	...	10 cc.
5% Phenol Solution	...	90 cc.

EQUIVALENTS OF DIFFERENT CLASSIFICATION OF LEPROSY

Other Classification	Current Classification	
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	iii. LL	iii. BT
3. Indian	i. L	i. T
	ii. N ? L	ii. MA
		iii. P under N
		iv. Early indeterminate under N ? L
4. Indian Association of Leprologists (1983) consensus	i. Lepromatous	i. Indeterminate
	ii. Borderline lepromatous.	ii. Tuberculoid
		iii. Pure neuritic
		iv. Borderline tuberculoid

2. Decolourising fluid.

Hydrochloric acid (conc)	3 cc.
70% Alcohol.	97 cc.

3. Counterstain

Methylene Blue	1 gm.
Distilled Water	100 ml.

PROCEDURE :

1. Place the slides with fixed smears on a pair of a glass rods kept over a sink or a trough.

2. Pour over the smears requisite quantity of carbol fuchsin through a small funnel fitted with a filter paper. Allow the stain to be in contact with the smears for 20 minutes. If quick staining is desired, heat the stain in a test tube to steaming and pour the heated stain on the smears and leave it there for 5 to 10 minutes.

3. Wash in running tap water.

4. Decolorise with acid-alcohol (10%) for 5 minutes and wash in running tap water.

5. Counterstain with Methylene blue solution for half to one minute.

6. Wash once again in running tap water and let the smear dry in air.

7. Examine under microscope using oil-immersion objective.

The lepra bacilli will be seen as red rods (uniformly stained solid bacilli or more common fragmented rods). The bacilli may be seen in singles, small groups or closely packed bunches called globi. Scattered among the bacilli, irregular blue stained structures are seen, they are the cells of various structures in dermis.

In addition to being able to state whether a given smear is positive or negative, it is also useful to be able to make as quantitative an assessment as possible of a bacterial content in the smears. This is spoken of as 'Bacterial Index'. The assessment of quantity of bacilli in this manner at periodic intervals is a very useful guide, in enabling one to assess the effect of therapy.

For the purpose of such assessment, it is necessary to examine multiple smears. In lepromatous leprosy cases, smears are obtained from several sites of the body and in any case from not less than 3 sites and each of the smears is given a quantitative value. The average of all the smears is the 'Bacterial Index'. There are two methods commonly employed for this purpose.

I. Ridley's logarithmic method.

II. Dharmendra's method.

I. RIDLEY'S METHOD : Grading of bacilli by modified Cochrane method is followed in NLEP.

This method is preferred over that of Dharmendra's as the scale is wide and convenient for assessment of the impact of treatment. As its range extends from the very few to very many, steps of 1+, 2+ etc. are regularly spaced, each additional unit signifying a tenfold increase in the number of bacilli.
Examining the smear under the 1/12 (2mm). oil–immersion objective :–

1+ = 1–10 bacilli on average in 100 microscopic field.

2+ = 1–10 bacilli on average in 10 mic roscopic field.

3+ = 1–10 bacilli on an average 1 microscopic field.

4+ = 10–100 bacilli in an average microscopic field.

5+ = 100–1000 bacilli in average microscopic field.

6+ = many clumps of bacilli in an average microscopic field (more than 1000).

BACTERIAL INDEX : When 3 to 6 smears are examined the average of the values for all the smears is termed as the 'Bacterial Index'.

For example, suppose that 3 smears are taken from

1. R.Ear – 4+
2. L.Fore arm – 2+
3. Rt. Buttock – 2+

BI (Bacterial Index) is obtained by dividing 8 by 3 = 2.67

II. DHARMENDRA'S METHOD :- The positive grades range from one to four, described as under :–

1. 1+ or 'slight'. The bacilli are not found in every microscopic field, but found occasionally. For practical purposes, even one bacillus or a fragment of a bacillus is found in only one field after searching a minimum of 100 fields, it can be graded as 1+.

2. 2+ or 'Moderate' : A few bacilli are found in every field, but not more than 10 in a field, with or without rare globi.

3. 3+ or 'Heavy' numerous (more than 10) bacilli in every field with or without globi.

4. 4+ or Massive' : Innumerable bacilli and a large number of globi found in every field.

APPENDIX—X

TABULATION PLANS.

The following tables will be generated using the data collected in the household schedule and the patient card.

1. Age, sex, distribution by type :

Age & Sex		MALE		FEMALE		TOTAL		G. TOTAL
Category		<14	>14	<14	>14	<14	>14	
Cases	PB							
	MB							
	All							
Healthy Population								
Total								

2. Distribution by leprosy status.

Leprosy Status	Population
No history of leprosy.	
Has leprosy & under treatment DDS	
Has leprosy & under treatment MDT	
Has leprosy & not under treatment	
Had leprosy & under surveillance	
Had leprosy & completed surveillance	
Total	

3. Distribution of deformity by type & sex.

Sex		MALE		FEMALE		TOTAL	
Deformity.	Type	MB	PB	MB	PB	MB	PB
Hand							
Foot							
Eye							
Others							
Total							

4. Diagnosis.

SSAU

	Category		Case		Non-case	Not seen	Total
			PB	MB			
NLEP STAFF	Case	PB					
		MB					
	Non-case						
	Not seen						
	Total						

APPENDIX—XI

INDICATORS

The following indicators may be computed from the data collected by the SSAU and the records already available with the local unit. The procedure for calculating the indicators is also given.

1. Case detection rate

$$= \frac{\text{Number of new cases detected by the SSAU}}{\text{Total population examined by the SSAU}} \times 100$$

This has to be compared with the case detection rate of the local unit for the same period. For example, if the SSAU has done the survey in an area in 1987, the case detection rate of the SSAU should be compared with that of the area in question for 1987.

2. Prevalence rate

$$= \frac{\text{Total number of cases detected by SSAU}}{\text{Total population examined by the SSAU}} \times 1000$$

Compare it with the rate of the local unit.

3. Proportion of cases detected by voluntary mode

$$= \frac{\text{Number of cases detected by voluntary mode}}{\text{Total number of cases detected by all modes}}$$

This information should be gathered from the existing records.

4. Proportion of cases with deformities among newly detected cases

$$= \frac{\text{Number of new cases with deformity detected by SSAU}}{\text{Total number of new cases detected by SSAU}}$$

Compare this rate with that arrived at by the local unit

5. Proportion of MB cases among the total new cases detected

$$= \frac{\text{Number of new MB cases detected by SSAU}}{\text{Total number of new cases detected by SSAU}}$$

This rate should be compared with that of the local unit.

6. **Proportion of children among newly detected cases**

$$= \frac{\text{Number of children (0–14 years) among newly detected cases}}{\text{Total number of new cases detected}}$$

This rate should be compared with the rate arrived at by the local unit.

7. **Clinical surveillance rate**

$$= \frac{\text{Number of cases on surveillance examined clinically during the year}}{\text{Number of cases on surveillance.}}$$

8. **Bacteriological surveillance rate (MB)**

$$= \frac{\text{Number of cases (MB) on surveillance examined bacteriologically during the year}}{\text{Number of cases (MB) on surveillance}}$$

Information on surveillance of those cases identified during the survey by the SSAU team is compared with that in the records at the local unit.

9. **Sensitivity and Specificity of diagnosis :**

Diagnosis by SSAU

Diagnosis by NLEP STAFF	Case	Non Case	Total
Case	A	B	A+B
Non-Case	C	D	C+D
Total	A+C	B+D	A+B+C+D

Sensitivity = (A/A+C) X 100

Taking SSAU as the standard, it refers to the ability to detect a case as a case.

Specificity = (D/B+D) X 100

Refers to the ability to identify a non-case as a non-case. Ideally sensitivity & specificity should be equal to 100 but practically it is not. A high sensitivity and a low specificity would mean a propensity for **under diagnosis** (the team is likely to miss cases) which is bad and a low specificity and a high sensitivity would mean **over diagnosis** (all persons with least suspicious patch are dubbed to be cases).

Concordance rate = (A+D / A+B+C+D) X 100

Concordance rate refers to the extent to which the SSAU & the service team agree on their diagnoses (of both case and non-case).

10. Concordance rate for diagnosis of type

a. PB

b. MB

This can be computed using the same table as given in the item number 9 with the exception that instead of 'Noncase' use non PB for 10(*a*) and non MB for 10(*b*)

11. Regularity of treatment

a For DDS monotherapy

b. For MDT of MB cases

c. For MDT of PB cases

For a & b regularity could be taken as the receipt of 2/3 of the recommended number of doses of prescribed drug during a year.

Proportion completing treatment among registered PB cases expected to complete during the year could be used as an indirect measure of regularity of treatment of PB cases on MDT (for 10.c.)

This information could be obtained by examining 10% of records of MB cases and 5% of records of PB cases registered by the local unit.

APPENDIX—XII

USE OF THE RECORDS OF CENSUS, & URBAN FRAME SURVEY

A. URBAN FRAME SURVEY

National Sample Survey Organisation (N S S O) Department of Statistics, Govt. of India, conducts every year, on a continuous basis, a National Sample Survey, covering the whole of India, on various socio-economic aspects for the purpose of planning. To facilitate selection of sample blocks of around 700 population in urban areas the field operations Division of the NSSO conducts Urban Frame Survey (UFS) in all the towns and cities classified by local authorities or Registrar General of India or contonment authorities as urban areas are taken up for this survey and are updated quinquennially. Trained staff from the Organisation survey the town and make convenient, identifiable blocks of around 700 population each. These blocks are called UFS blocks and are physically identifiable in the field. Map of the town is drawn clearly demarcating the UFS blocks formed. The maps and the list of UFS blocks for town prepared by NSSO (FOD.) are available with the regional/sub - regional offices of the NSSO (FOD) and may be obtained with the permission of the Chief Executive Officer, NSSO, Department of statistics, Govt. of India.

NSSO (FOD) adopts the census approach of Urban Agglomeration and covers together with the nucleus city its extension also but keeping them as separate units (Investigator Units). Since under the LCU set-up these extension areas are likely to have been included under the jurisdiction of LCUs, the UFS maps for these sub-urban areas may also be used for selecting a cluster of size 900 if their size is large.

CENSUS HOUSE-LIST

Registrar General of India, Ministry of Home Affairs conduct decennial census and as a part of 1981 census, a census house-list has been prepared by them for each revenue village wherein all the structures and population residing in them are listed. During that operation, a census house number (in black paint) is given to each structure. This number is permanent till the commencement of the next census. With this number it is very easy to identify the houses. This house-list c n be obtained with the permission of RGI, Govt. of India from the office of the Deputy Directors of census operations at State Headquarters.

APPENDIX—XIII

ILLUSTRATIVE EXAMPLE FOR THE SAMPLE SELECTION

Assume that the state has 16 districts and 2 SSAUs. It is decided to survey the entire state in two years. Table–1 gives the distribution of the state population over the 16 districts arranged contiguously.

TABLE–I

Dist	Population (Million)	Zone	Sample size	Year of coverage
D1	3.28	Z1	29,000	
D2	3.62	P = 11.31 m	30,000	1
D3	4.41		39,000	
D4	4.20		36,000	
D5	2.00	Z2	17,000	
D6	3.44	P = 11.71 m	29,000	1
D7	2.07		18,000	
D8	3.06		26,000	
D9	0.63	Z3	5,500	
D10	4.54	P = 11.84 m	38,000	2
D11	3.61		30,500	
D12	4.06		30,000	
D13	1.16	Z4	9,000	
D14	3.33	P = 13.54 m	25,000	2
D15	3.57		26,000	
D16	1.42		10,000	
State	48.40	48.40 m	400,000	

I. Since we have to cover the entire stage in 2 years and there are 2 SSAUs, we have to form 4 zones, two of which will be taken up for the survey in the first year and the other 2, in the second year. Since the total population of the State is 48.4 millions, we may form zones of contiguous districts consisting of around 12 million population each. We form these zones Z1, Z2, Z3, & Z4 as indicated in Table I. Zone Z1 & Z2 can be covered in the first year and Z3 & Z4 in the second year.

II In each Zone, a sample of 100,000 will be taken for the survey. The sample size will be allocated to the districts in the zone on the basis of the total population content of the district. In the case of District D1, in the Zone Z1, the allocation would be (1,00,000 x 3.28) / 11.31 = 29,000. The allocations worked out on this basis for the 16 districts of the State are indicated in Table–I.

III Let us consider the District D2. What follows is applicable for any district of this State.

The district will be divided into 2 Sectors : 1) Rural – consisting of all the areas under the LCUs/SETs, and 2) Urban – areas under ULCs, and the sample size will be allocated to these sectors in proportion to the population content. As per the data available with the Census, the rural –urban population of the district D2 is 2.21 million and 1.41 million respectively. But all the urban areas as declared by the Census might not be covered by the ULC set up, and some of these areas will be under LCUs/SETs. Hence the population covered under LCUs and ULCs should be determined after properly ascertaining the jurisdiction of these two setups Assume that it is 2.81 million and 0.81 million respectively. Then the sample sizes to be covered in the rural and urban sectors of the district D2 will be 32,000 x 2.81/3.62 (= 24,800) & 32,000 x 0.81/3.62 (= 7,200) respectively.

IV Let us take up the rural sector.

We have to form strata and further allocate the sample size to each stratum. As per the design, each LCU/SET is to be considered as a separate stratum. In a district voluntary organizations and research Institutions may be operating in a specific area. If the area is small, it may be clubbed with the nearest LCU/SET to form a stratum. If the area has a population of around 3,00,000, it may be considered as a separate stratum itself.

The number of LCUs/SETs and the villages under their jurisdiction should be determined. This is shown in Table–II. Control areas under the jurisdiction of 3 agencies functioning outside the LCU/SET set up are also shown as A1, A2, A3.

TABLE II

LCU	No.of Village	Stratum	Rural Population (lakhs)	population to be sampled	No. of cluster
L1	270	S1	3.52	3100	3
L2	232	S2	3.70	3300	4
L3	140	S3	2.92	2600	3
L4	93	S4	3.60	3200	4
A1	60	S4			
L5	179	S5	4.40	3900	4
A2	50	S5			
L6	243	S6	3.31	2900	3
L7	294	S7	3.16	2800	3
A3	308	S8	3.49	3000	3

Each LCU is kept as a stratum. Since the Agency A3 is covering a population of more than 3 lakhs, it is retained as a separate stratum. A1 & A2 are clubbed with the nearest LCUs as shown in Table – II.

V Selection of Clusters will be done as per the procedures explained first by grouping the villages in the stratum into 1) Villages enumerated by LCU staff within a year, and 2) other Villages, and then selecting the required villages (in the case of Stratum S2, 4) randomly but ensuring at least 1/3-rd representation for the first group. (In the case of S2,1)

VI The population covered under ULC set up is 8.1 lakh, which is distributed over 5 towns. Each of these 5 towns is now considered as a separate stratum. The sample size to be covered in the urban sector, 7,200, is distributed over the 5 strata in proportion to the population content as demonstrated for the rural sector. Here the clusters are not villages, but UFS blocks formed in these towns by NSSO.

APPENDIX—XIV

MONTHLY PROGRESS REPORT

MONTH :

(1) State :

(2) SSAU particulars :

(3) Districts of operation :

(4) **Survey done during the month** :

District	Village	Period of survey	Pop. Enu		Pop. Exam		Cases detected			
							MB		PB	
			C	A	C	A	C	A	C	A

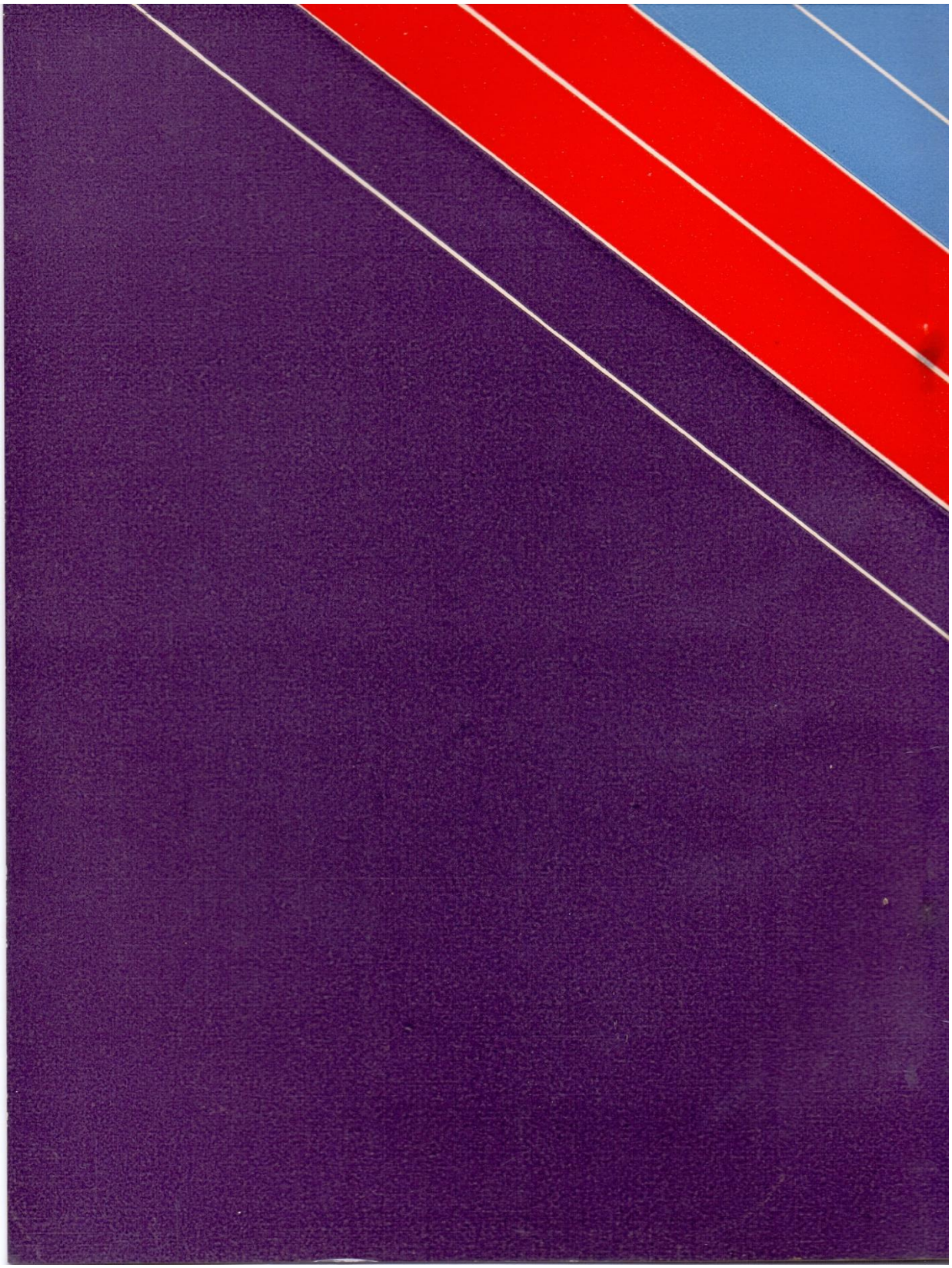
C – Child A – Adult

(5) **Diagnosis :**

District	Village	(i)	(ii)	(iii)	(iv)	(v)	(vi)	(vii)	(viii)

(i) No. of Registered MB cases confirmed as MB by SSAU
(ii) No. of Registered MB cases confirmed as PB by SSAU
(iii) No. of Registered PB cases confirmed as PB by SSAU
(iv) No. of Registered PB cases confirmed as MB by SSAU
(v) No. of Registered cases declared as non - case by SSAU
(vi) No. of people delcared as non cases by NLEP set up but diagnosed as cases by SSAU
(vii) No. of Registered cases not seen by SSAU
(viii) No. of cases of people identified as having leprosy by SSAU but not seen by the NLEP staff

(6) **Bacteriological Examination :**
No. of smears taken :
No. of smears examined :

(7) **Referral service :**
No. of cases referred for examination :
No. of confirmed cases :

XXXXXXXXXX