PRELIMINARY REPORT ON THE DATA OF THE CONTROL UNITS OF THE GANDHI MEMORIAL LEPROSY FOUNDATION

R. V. WARDEKAR, B. Sc.; M. D. Secretary, Gandhi Memorial Leprosy Foundation Wardha, India

The Sixth International Congress of Leprology, held at Madrid in October 1953, (2) recommended:

Because of the efficacy of the new medicaments, it is reasonable to assume that these drugs will reduce considerably the period of contagiosity of the lepromatous cases. To investigate this matter, which we regard as of great importance, extensive investigation should be carried out in countries where institutional isolation is impracticable, with the aim of determining if there is any reduction of the incidence of leprosy among the contacts of lepromatous cases.

As if anticipating the recommendation of this congress, the Gandhi Memorial Leprosy Foundation had started its work of control units on similar lines about two years earlier. The work being of an experimental nature, detailed statistical data are being kept in each unit so that at the end of a ten-year period the results can be assessed and the failure or success of the scheme be understood. Considering the need of a new approach and the interest it has evoked, a preliminary report on the method of this work is made here.

Evolution of the work.—The writer started a control unit at Savagram in November 1951, and conducted the work for some months to evolve a method which could be followed by other units of the Foundation. A good deal of time was then spent in preparing the registers for record keeping. Thus 1952 was devoted to these preliminaries, and the work was at this stage when I left India for a study tour abroad. In the meantime, with demands for starting more units a few sites were selected where the work was started in 1953.

From the beginning it was felt that work in the different units would not progress well unless supervised frequently, and in May 1954—a suitable medical person not being available—a well-trained and experienced leprosy social worker was appointed for this purpose. He visits each unit once in three months, and since then the work has progressed well and I am kept in close touch with it.

Since 1952 units have been added each year, and now there are ten of them. The development of the work has progressed gradually. The first two years of each unit has been spent in stabilizing the work, but from now on this preparatory period will be reduced.

Location of the units.—India is a vast country, with variations in diet, habits, mode of living and customs of the people, and perhaps in the type of the disease. Our ten units have been so located that all the variable factors are well represented. The method of work in all the units, under different personnel, is the same; thus we will be judging the results of one common method on all the variable factors that exist in this country.

Method of work.—Details of the method of work of a control unit were published in 1952 and 1955 (3, 4). As the present report concerns the data rather than the method of work, the latter is indicated only summarily.

Area of work of a unit: 3 to 5 miles radius in rural areas.

Population of an area: About 15,000 to 26,000.

Number of clinics: 2 or 3, depending on the density of the population. In any case, they are so located that the patients do not have to walk more than 3 or 4 miles.

Incidence of leprosy: From 1 to 6 per cent.

Staff: A trained medical man, a trained leprosy social worker, one compounder and one peon.

Surveys: House-to-house surveys are made each year, and all registered cases are put on oral DDS.

Segregation: The very birth of the scheme lies in the difficulties of segregation. However, whenever possible segregation is encouraged, either in villages, houses or colonies.

Period of work: Work will be continued in each unit for at least ten years.

Data recorded.—Printed registers are supplied the units for keeping of the day-to-day data, which are then compiled each year in the annual report forms. These forms I then analyze to interprete the findings and recompile the data. The figures cited in this paper are mainly from the Sevagram unit, but for general items the figures of the total work of all units are given. Each item is discussed to indicate its purpose and significance, and also the difficulties of the work. Since the Sevagram unit was the experimental one and 1952 was spent in preliminary work before printed records were available, 1953 has to be considered the first year for certain items. In some places the figures for the three years are available. Those items of the data of 1952, 1953 and 1954 which serve to depict the situation found at the beginning of the work have been added together.

1. Population of the areas selected.—Rural areas are selected for the control work mainly for the following reasons:

(a) Most of the Indian population is in rural areas.

(b) Leprosy, therefore, is primarily a disease of the rural community.

(c) The population not being as floating as in urban areas, the same people can be under study for a longer time.

(d) The people in rural areas are easily approachable and are likely to listen to advice, while in urban areas the people are more educated and are likely to be correspondingly sophisticated.

Although the population in rural areas is more fixed than in urban areas, there are minor but inevitable fluctuations each year. Some of the common reasons are:

New births: In India, in a population of 1,000 there are about 40 births

annually, and although 50 per cent of the new-born children die in the first year there is a small annual increase of the population.

Marriages: Some of the girls leave the village after marrying, and some come in to live for the same reason.

Deaths and migration: Some people die or leave the village for one reason or other, while some come in to stay.

The result of these changes is that, to a population of 20,000, about 200 to 300 persons are added annually. Some of these persons come from areas unknown to us and are likely to harbor previous infection. There is therefore need of an annual follow-up examination, but in practice that is found to be difficult. However, during the routine annual surveys many of the newcomers will be examined.

2.Surveys and resurveys.—Apart from the difficulties created by the local population due to its prejudices, there are other practical considerations which hamper the survey work. In the first place, after a site is selected it is necessary to find a suitable doctor and a leprosy social worker who speak the regional language. The social workers are usually available, because in each group of lay workers under training there are candidates from different linguistic areas. This is not so in case of doctors. The result is that the social worker starts the work many months before the doctor joins the unit. As far as possible the clinics are not started before then, and the social worker spends his time in doing preliminary work of establishing contact with the people, selecting the sites for clinics, and other such work. Other considerations are the temperament of the workers, their likes and dislikes for certain villages, and the fact that there are convenient communications with some villages but not others.

These factors influence the survey work considerably, but on an average about 72 per cent of the population is surveyed during the first year. With the tendency of the workers to visit some villages more frequently than others it is possible that some population may not be surveyed at all, even in two years, but efforts are made to safeguard against this neglect. It is hoped that at least 90 to 95 per cent of the population will be surveyed at least once in two years. Thus cases will be missed only in about 5 to 10 per cent of the population in the first two years of work. During the subsequent years about 80 per cent of the healthy individuals will be examined at least once in two years. Under this scheme, a majority of the new cases should be detected within one year of their developing the disease, unless they are imported cases.

In Sevagram, a few villages had to be left out of the control area, and in 1952 the population of that area was 17,040. This figure was increased in 1954 by 548, making 17,588; and of that total 16,300, or 92.6 per cent, were examined that year.

3. Broad grouping of cases.-The cases detected during surveys are

divided, on the basis of the clinical examination, into three groups: lepromatous, nonlepromatous, and arrested. Such a broad grouping is necessary for keeping the necessary records.

Lepromatous (L) cases: In case of doubt about the type of cases with lepromatous features, smears are examined at the time of diagnosis. Borderline cases at times create some difficulty, and it is likely that some of the cases may be wrongly diagnosed as lepromatous or tuberculoid, but the percentage error is not great.

Nonlepromatous (N) cases: Active cases not classified clinically either as lepromatous or borderline are grouped together as nonlepromatous.

Arrested cases: In view of the definition of an "arrested" case it is not possible to put a patient in this category unless he has been followed for two years. In practice, cases treated elsewhere but found in the control area with persistent deformities or anesthesia create a problem for typing. In the absence of previous records it is not possible to know whether the lesions are increasing, decreasing or static, so these cases are considered "active." If during two years of observation they do not show signs of activity, they will then be classified as "arrested." In spite of these recommendations some of our control units have labeled a few cases as arrested —only 37 out of 3,220.

4. "Detected" and "registered" cases.—Many of the known cases in the locality come by themselves for diagnosis and treatment, but many others are detected during surveys where only a gross clinical examination is possible. Such patients are requested to attend the clinic but do not always turn up, and so their detailed examination is not made. Therefore, only those who come to the clinic are labeled as "registered" cases. There is thus always a lag between the "detected" and "registered" cases, the latter being normally fewer than the former in any given month. It may happen, however, that in a particular month some of those who have been detected previously turn up for registration, so that the number of registered cases exceeds the number detected in that month. The figures for the Sevagram unit given in Table 1 for 1952-1954 indicate the usual picture. In this instance the totals of detected and registered cases during this period were 499 and 406, respectively.

5. Bacteriological examination.—Initial examination:¹ As the control scheme itself is based on reducing the bacterial content of the skin and mucosa by treatment, the bacteriological examination of every case is essential. Moreover, for assessing the results of the work the total number of cases spreading the infection in the area at the beginning and at the end of the ten-year period should also be known. In spite of the importance of this examination, however, it has not been possible to have it done on every detected or registered case in the first year for several reasons:

¹ The bacteriological examinations are made by the standard slit and smear method.

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(a) Not every case detected in the house-to-house survey comes to the clinic, and making smears in the home is very difficult.

(b) The field of work being in rural areas, it takes a long time to construct or find suitable buildings for the laboratory.

(c) The workers themselves have not yet been able to grasp the importance of making the bacteriological examination, in spite of repeated instructions.

		19	52			19	53			19	54		Т	otal
Month	Dete	ected	Regis	tered	Dete	ected	Regis	tered	Detected		Regist	ered		1
	L	N	L	Ν	L	N	L	N	L	Ν	L	Ν	Detected	Registered
January February March April May June	18 8 3 5 3 5 3 5	$ \begin{array}{r} 41 \\ 14 \\ 16 \\ 6 \\ 6 \\ 34 \end{array} $	$\begin{array}{c}11\\2\\1\\5\\3\\5\end{array}$	$27 \\ 4 \\ 6 \\ 7 \\ 36 \\ 36$	11111		2 2 2 1 4 1	4 9 3 14 9		$ \begin{array}{c} 18 \\ 3 \\ 11 \\ 2 \\ 1 \\ 3 \end{array} $	2 1 1 -	$\begin{smallmatrix}&13\\&8\\&8\\&4\\&1\\&4\end{smallmatrix}$	79 27 32 13 10 42	59 20 27 21 29 55
July August September October November December	$ \begin{array}{c} 14 \\ 1 \\ 2 \\ 1 \\ 5 \end{array} $	$ \begin{array}{r} 43 \\ 11 \\ 5 \\ 20 \\ 32 \\ 63 \\ \end{array} $	$\begin{array}{c} 13\\3\\-\\2\\1\\1\\1\end{array}$	42 10 4 10 6 7		5422 2		$ \begin{array}{r} 4 \\ 2 \\ 10 \\ 8 \\ 4 \\ 5 \end{array} $		$2 \\ 3 \\ 6 \\ 9 \\ 11 \\ 53$		$ \begin{array}{c} 4 \\ 2 \\ 9 \\ 3 \\ 25 \\ 17 \end{array} $	$59 \\ 15 \\ 17 \\ 35 \\ 46 \\ 124$	63 18 23 23 37 31
TOTAL	66	291 57	47	166 13	-	17	13	78 9	3	122	6	98 4	499	406

TABLE 1.-Cases detected and registered by the Sevagram unit in 1952, 1953 and 1954.

There is another important consideration: With the insistence on examination of every case, there may be a temptation to examine only a few cases and put down the results for all. In order to check against this tendency a "calculated" column has been provided in the annual report form to indicate that if every case is not examined the worker should put down only those examined and also calculate for the rest. This point may be clarified by a hypothetical example.

Let us take a control unit in which, of a population of 20,000, only 75 per cent of the people were examined and 400 cases were detected, 350 of them being registered. Of these 350 registered cases, let us say, only 200 were examined bacteriologically and 40 were found infectious and 160 noninfectious. On the basis of the actual examinations made it is possible to calculate approximately the total number of cases in the whole population, and also the total number of infectious and noninfectious cases in the area. On this basis, in this population of 20,000 there would be 533 leprosy cases, 107 infectious and 426 noninfectious. It must be admitted that such speculative data will give only a very gross picture, its degree of correctness depending on the percentage of total cases examined, and with less than 50 per cent of examinations it would be meaningless to derive any conclusion from the calculated figures. Still, in view of the necessity of having an idea of the prevalence of infectious cases at the outset the "calculated" figures have to be worked out.

In the experience of all our units more than 50 per cent of all the registered cases have been examined bacteriologically. In order to improve the situation a well-trained worker has now been engaged to do the bacteriological examinations of all the units hereafter, in the hope that it will be possible to get at least 80 per cent of the cases examined every year.

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The figures of the Sevagram unit are given in Table 2, which shows that 67 cases were found infectious and 339 noninfectious. The calculated figures there given are based on the 499 cases detected in the 92.6 per cent of the population examined. Extending the actual findings to a 100 per cent examination, it is calculated that a total of 539 cases would have been detected and that 89 would have been found infectious and 450 noninfectious.

C.	Cases Cases		Bacteriological findings							
	ses		tered		tual cases)		ulated cases)			
L	N	L	N	Infectious Noninfectiou		Infectious	Noninfectious			
69 4	430 99	66	340	67 (16.5%)	339 (83.5%)	82	417			

 TABLE 2.—Bacteriological findings in the Sevagram unit in 1952-1954, actual and calculated.

These bacteriological findings are interesting because so few positives were found, and especially because the number of cases classified as nonlepromatous (340) and the number found noninfectious (339) are virtually identical. This latter finding is likely to give rise to various interpretations, and it is necessary to know how the figures are derived.

(a) Of the 66 L cases registered, one was bacteriologically negative at the time of starting treatment. That case had been treated for a number of years in a colony. (b) Of the 340 N cases, only 2 were found positive.

The question arises whether this finding of very few positives in the nonlepromatous group represents the true picture or is due to errors of examination. Admittedly one cannot always vouchsafe the correctness of the bacteriological examination. There are variable factors of which only one is the experience of the examiner. The findings of even welltrained pathologists may not always tally exactly. It is quite likely that experts might have found a few more cases to be positive, but under existing conditions the reports of medical officers who have been trained in leprosy but are not pathologists have to be accepted at face value.

Many of the 340 N cases were either in the early stages or very late stages of the disease. Among the latter, very few had received DDS previously, which excludes the possibility of their having been positive once but made negative by treatment.

The natural conclusion, therefore, is that only about 70 cases have been responsible for giving rise to 400 cases, or that some of the administratively noninfectious cases are also responsible for spreading the infection. The factor of floating population and importation of infection or of cases beclouds the issue. We are dealing with two adjacent large-sized areas, but there is no reason to believe that in the noncontrol area there are large numbers of lepromatous cases which are the sources of infection for the cases in the control area. On the other hand, we have under close observation some bacteriologically negative cases whose contacts have developed the disease. Since the area is an endemic one such findings do not prove that bacteriologically negative cases are infectious, but such instances are sufficiently numerous to raise a doubt regarding the noninfectivity of all negative cases. The problem has to be studied impartially before any conclusion can be reached. If it should be proved that negative cases are infective, that would be a further obstacle to control of leprosy by chemotherapy.

Follow-up examinations: The cases will be followed up to find out when they become bacteriologically negative and whether the negativity continues or whether they relapse. In the Sevagram control unit, of the 46 L cases found positive in 1952 (out of the 47 examined), 8 had died or left the control unit by the end of 1954. At that time, of the remaining 38 cases no less than 19 (50%) had become bacteriologically negative. These findings appear to be very encouraging, but one has to wait for relapses.

A	Year of registration										
Age group (years)	1952	1953	1954	Total							
	1952	1955	1954	No.	. %						
0 - 5	3	2		5	1.2						
6 - 10	10	9	12	31	7.6						
11 - 15	10	9	13	32	7.8						
16 - 20	22	9 9 11	12	45	11.1						
21 - 25	26	9	11	46	11.3						
26 - 30	21	10	16	47	11.6						
31 - 35	27	12 3	16	55 37	13.5						
36 - 40	27	3	7	37	9.1						
41 - 45	12	2 7	4	18	4.4						
46 - 50	22	7		34	8.4						
51 - 55	12	4	2	18	4.4						
56 - 60	15	6	4	25	6.2						
61 - 65	$\begin{array}{c}12\\15\\2\\4\end{array}$	4	1	7	1.7						
Older	4	1	1	6	1.5						
TOTAL	213	89	104	406	99.8						

TABLE 3.—Age grouping of the 406 cases registered by the Sevagram unit in 1952-1954.

6. Age grouping of registered cases.—In view of the need for assessment (see Item 15), the cases are grouped by five-year periods. The data of the Sevagram unit cases are given in Table 3.

7. Attendance and treatment.—First year: Registered patients who come to the clinic for treatment regularly and who tolerate oral DDS

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well are given monthy allowances of the drug. Or, if a patient's relatives or friends come to get it, they are given a week's allowance.

Although it is necessary that all cases should take treatment regularly, not all of them do so. One has, therefore, to insist on treatment of at least those that are important from the point of view of control, i. e., the cases spreading the infection. As has been shown, it is not always possible in the first year to label all infectious cases on the basis of the bacteriological examination, so one has to insist on the treatment of at least every case classified as lepromatous. In order to emphasize this fact the records of attendance of the lepromatous and nonlepromatous cases are kept separately.

The separate recording of attendance has another advantage. The nonlepromatous cases often develop trophic ulcers, and they also have more deformities than the lepromatous cases, and consequently they attend the clinics more regularly.

For example, in a control unit having 400 cases, 100 L and 300 N, the total attendance may be 300, 75 per cent, while in another clinic with a similar number the attendance may be 200, or 50 per cent. On the face of it the attendance of the former is the better, but with respect to attendance of infectious cases it may not be so. It may be that the 300 attendance are 50 L and 250 N, while the 200 may consist of 75 L and 125 N, which is the better. During visits to other centers I have seen that the total attendance data are sometimes misleading when the types are not recorded separately.

The attendance is recorded weekly for each patient for each month. As the purpose is to find out whether each patient takes treatment regularly, those who get their medicine through somebody else are also considered as "attended," although in the records they are marked as "represented." At the end of the year all the data are assembled in an elaborate table, which would be difficult to reproduce here. The basis of this table may, however, be explained by some figures.

Thus, say, in January 1952, 18 L cases and 41 N cases were detected, of whom 11 L cases and 27 N cases were registered. All should attend the clinic for twelve months, but in reality it will be found that attendance will have varied from twelve months to as little as one month. The same thing applies to cases detected and registered in the subsequent months of the year. Data kept in this way give us a pattern of behavior of the patients which may vary from unit to unit.

In Table 4 are to be found figures of attendance at the Sevagram unit.

Subsequent years: To be effective DDS has to be taken regularly for a number of years, but considering human nature and practical difficulties it is likely that the patients may take treatment regularly in the first year and then gradually drop out. It has, therefore, been thought necessary to follow up separately the patients registered each year, during the subsequent years. The data on the Sevagram unit are given in Table 4.

A study of the attendance of cases on this basis in all control units is likely to show the pattern of attendance that the general population would give. If it is found that a materially large proportion of infectious cases stops treatment after two years, or before they have become noninfectious,

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the scheme will fail. The only solution then will be to take the treatment to the patients' homes—or to find a drug which will make the cases noninfectious within one year or so.

8. Classification of cases.—The cases are divided into six types described by Dharmendra and Chatterjee (1). The diagnosis of lepromatous, tuberculoid (T) and maculoanesthetic (MA) cases presents no

		1552 1953 work work					1954 work									
Details; numbers of cases	1952 cases		1952 cases		1953 cases		Total		1952 cases		1953 cases		1954 cases		Total	
	L	N	L	N	\mathbf{L}	Ν	L	N	L	N	L	N	L	N	L	N
Registered ^a	47	166	47	166	13	76	60	242	47	166	13	76	6	98	66	340
Taking treatment over 50 % of period	37	121	31	101	9	47	40	148	29	80	8	24	5	69	42	173
Taking treatment 25-50 % of period	4	19	1	13	2	4	3	17	3	13	1	9	1	7	5	29
Taking treatment less than 25% of period	6	26	4	28	2	25	6	53	7	30	2	18	-	20	9	68
Discontinued, own choice	-		5	18			5	18	1	24	-	13	-	-	1	37
Discontinued, disease arrested b	-		-	-	_	-	-		-		-	-	-	2	-	2
Left control area	-	-	5	5	-	-	5	5	5	14	1	10	-	-	6	24
Deaths	-	-	1	1	-	-	1	1	2	5	1	2		-	3	1 7

TABLE 4.—Follow-up data of the Sevagram unit cases.

a For data on "detected" cases, see Table 1.

b In no case was the treatment discontinued because of reactions.

difficulties, while that of borderline (B) cases has already been mentioned. The remaining two forms need explanation.

The "indeterminate" (I) form is the one which really presents difficulties in field work. In the absence of facilities for making histopathological examinations one has to depend mainly on the history of contact and the clinical and bacteriological examinations. The flat macules which cannot be satisfactorily classified as maculoanesthetic or lepromatous are placed in the indeterminate group. The majority of our indeterminate cases are bacteriologically negative.

With these vague criteria it is quite likely that some of the indeterminate cases may be put down as "suspicious" by our workers. That may affect slightly the figures of the incidence of the disease, but considering the overall figures the error will be almost negligible. It is hoped that as the workers gain more experience such discrepancies will diminish.

Because of the house-to-house surveys in our work, we will come across many cases of this kind. In the initial surveys in all the units, covering a population of 184,758, a total of 2,305 cases have been registered of which 236, or 10.2 per cent, were indeterminate. This small proportion is due to the fact that most of the cases were well developed. With repeated surveys, however, we do not expect to find many advanced cases, and consequently the indeterminate ones may constitute a larger proportion of the total detected from year to year.

A leprologist of my acquaintance claims not to have seen a single case of leprosy without evidence of anesthesia somewhere on the body. Be that as it may, where one has to get the work done through a number of medical men working in rural homes, and where thousands of persons have to be examined, it is not possible to examine the entire body for areas of anesthesia, and thus we cannot place too much dependence on evidence of anesthesia in diagnosing these indeterminate cases.

The "polyneuritic" leprosy cases are those which have no skin lesions but have polyneuritic symptoms due to involvement of peripheral nerves. In some of them the skin has never been involved, while in others skin lesions have been present but have cleared up. The pathological process involving the nerves may be tuberculoid or lepromatous, but the residual lesions do not show distinguishing clinical features, nor are there facilities in our work for testing all such cases with lepromin. We therefore classify all such cases as polyneuritic in a general sense.

Classification of all newly detected cases each year will show how the proportions of various types change.

Figures from the Sevagram unit, given in Table 5, show the proportions of the different classes of leprosy in that particular area.

Group	L^a	т	MA	в	I	Р	Total
Males	47	54	51	_	27	14	193
Females	16	39	52	-	27	11	145
Children	3	30	12	-	21	2	68
Total	66	123	115		75	27	406
Percentages	16.3	30.3	28.3		18.5	6.6	100.0

 TABLE 5.—Classification of the 406 cases registered at the Sevagram unit, 1952-1954, by sex for adults and in total for children.

a Lepromatous cases: males, 24.4%; females, 11.0%; children, 4.4%.

9. Subclassification of lepromatous cases.—The lepromatous cases are grouped in four different but broad groups. The following are the figures for the Sevagram cases.

Macular,	12	cases,	18.1%;	
Diffuse,	2	cases,	3.0%;	
Infiltrative,	27	cases,	40.9%;	
Nodular,	25	cases,	38.0%;	
Total	66	cases,	100.0%.	
		2	1 - Contraction of the second	

Grouping in this way all newly-detected cases each year will help to find out how useful the work will prove to be in detecting cases before they reach advanced stages. 10. Involvement of nerves.—All the cases, regardless of the clinical typing, are divided into four groups according to externally visible deformities and involvement of the nerves.

(a) In some cases, with or without anesthesia, the nerves may not show any thickening on clinical examination.

(b) In some the nerves may be thickened, but if they are not on the face or extremities they will not lead to any deformity. For example, an intercostal nerve on the back supplying a tuberculoid macule may be thickened, palpable and tender but it will not give rise to a deformity which can be noticed externally.

(c) Some cases may have thickened and tender nerves, not associated with any visible deformities at the time of examination. Ultimately, when the lesions heal, they may very likely lead to deformities, as in case of nerves supplying the face or extremities. Classification of cases of this group will depend on the judgment of the worker.

(d) Cases showing deformities at the time of examination, irrespective of whether the nerves still continue to show thickening or are fibrosed. Some of these cases will be "polyneuritic" and some "arrested."

Such an analysis of the cases of each year may show changing proportions of the different groups. It will also show the percentages of cases showing deformity at the beginning of work and at the end of the ten-year period.

These data, although they do not indicate anything regarding control of the disease, will definitely show the usefulness of the work in prevention of deformities, which are ultimately responsible not only for physical disability but also for ostracism of the patient.

The cases of the Sevagram control unit, classified according to involvement of nerves, are shown in Table 6.

		Total						
Condition of nerves	L	т	MA	в	I	Р	No.	%
. No clinical thickening	34	81	55	-	71	-	241	59.3
2. Thickening, deformities unlikely	2	12	18	-	4	-	36	8.9
3. Thickening, deformities likely	21	22	28	-	-	8	79	19.5
. Deformities present	9	8	14	-	-	19	50	12.3
Total	66	123	115	-	75	27	406	100.0

TABLE 6.-Condition of the nerves in the 406 cases registered at the Sevagram unit.

11. Degree of skin involvement.—There has been much emphasis on detecting leprosy case in an early stage, the word "early" being used mainly in the chronological sense. Leaving apart all other considerations of prognostic value (type of lesion, age at onset, etc.), consideration merely of chronological time of detection of a case is not sufficient to indicate the seriousness of the lesions.

For example, let us compare two cases. One has a single tuberculoid, bacteriologically-negative macule, $3'' \ge 2''$ in size, detected 1-1/2 years after onset. The other has three widely distributed (arm, back and leg), maculoanesthetic, bacteriologically-negative macules each $1/2'' \ge 1/2''$, detected 6 months after onset. Now, the latter of these cases has certainly been detected chronologically in an earlier stage as compared with the former, but the seriousness of the two is not the same. In fact, the one detected in the earlier stage is more serious than the other because it shows a wide dissemination of the infection.

There are, therefore, three factors to be considered in evaluating the seriousness of the lesions in a nonlepromatous case: (a) duration of the disease; (b) size of the macules; and (c) number of the macules.

For a field worker dealing with many cases it is not possible to record all these variable factors in every case. It was, therefore, necessary to select only one of them of which detailed data could be kept. The most significant one is the number of lesions, because that indicates the degree of spread of the infection, so it was decided to keep records of that point in all nonlepromatous cases.

All such cases are classified into five groups, depending on the number of macules—one, two, three, four, or more than four. Such data kept from year to year will show how the proportions of the cases in the different groups change, and whether the survey work helps in detecting the cases in early stages and preventing their progress by treatment.

Taking together the tuberculoid, maculoanesthetic, and indeterminate cases at the Sevagram unit, 48 per cent had only one patch, 16 per cent had two patches each, 6 per cent had three, 3.5 per cent four, and 26 per cent more than four. The differences in the corresponding percentages in the three clinical forms were not as great as might perhaps be expected.

12. Study of contacts.—In the annual surveys the majority of contacts will be examined every year as a matter of routine, but to study the infectivity of different types of cases it is planned to study some contacts more thoroughly. A few cases belonging to each of the two broad types, lepromatous and nonlepromatous, are selected and divided into three groups based on the bacteriological findings—lepromatous (all of them infectious), infectious nonlepromatous, and noninfectious nonlepromatous —and their contacts are examined.

A study of contacts made in the Sevagram unit is given in Table 7. The figures are interesting and raise a number of questions, although no conclusions can be drawn from so small and short a study.

Among the contacts of the 32 lepromatous cases only 5 new cases were found, although 106 persons were exposed. This is in contrast to the situation discussed in Item 5, from which it would seem that 70 lepromatous cases had given rise to about 400 other cases. It is likely that the 101 contacts who had not yet developed the disease at the time of

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study may yet do so later. Still, it does not seem probable that the number of cases thus produced will be of the proportion of 400:70. If only the lepromatous cases are responsible for the spread of infection, there must be considered the possibility of a good deal of extrafamilial contact, ordinarily less "close and prolonged" than in intrafamilial contact. This would raise doubt about the role of close and prolonged contact in transmission.

			Findings in contacts			
Nature of leprosy cases	No. of cases	No. of contacts	Leprous	Healthy		
Lepromatous	32	106	5	101		
Infective nonlepromatous	2	12	1 <u></u>	12		
Noninfective nonlepromatous	157	500	5	495		
Total	191	618	10	608		

TABLE 7.—Findings among the contacts of cases registered at the Sevagram unit.

The significance of 5 cases among the 500 contacts of noninfectious nonlepromatous cases has already been discussed (Item 5). It may be noted that when there is so much possibility of extrafamilial infection it can work either way. In other words, if the contacts of noninfectious nonlepromatous cases can be infected by extrafamilial cases, the noninfectious nonlepromatous cases, if they are at all infective, can also act as extrafamilial infectors; and that may explain the small number of cases amongst their own contacts.

To recapitulate, the study so far gives sufficient indication of the relatively high infectivity of lepromatous cases, but it raises doubts regarding complete noninfectivity of nonlepromatous cases and also regarding the necessity of close and prolonged contact. Furthermore, it suggests that there may be a good deal of extrafamilial infection. However, these figures are not large enough nor is the period of study long enough to permit the drawing of any conclusions. A similar study is being conducted in other units.

It is proposed also to ascertain if the cases under treatment are gradually getting less infectious. For this the three types of cases will have to be grouped separately according to the period of regular treatment, the bacteriological examination of every case will have to be made every year, and all the children born after each one-year period of treatment will have to be followed separately for 20 to 25 years to cover the latent period of the disease. The question of extrafamilial contact will remain as before, but since the whole area will be under chemotherapy the rate of diminution of infectivity will apply to all cases in or outside the family.

13. "Suspicious" and "interesting" cases.—In each unit a number of cases present difficulty in diagnosis as to whether or not they have leprosy.

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All such cases are labeled as "suspicious" and are kept under observation.

In addition to these suspicious cases, which have a close resemblance to leprosy, sometimes there are other types of lesions which create a doubt whether they will ultimately develop cardinal signs of leprosy. For example, in one of our units there are many persons without skin lesions or anesthesia who nevertheless have thickened nerves which are not tender. Such cases are labeled "interesting" ones and are kept under observation to see whether we are dealing with some aberrant or hitherto undescribed form of the disease. The diet of the people in this area is very deficient in vitamins, and the thickening may perhaps be due to that factor. Some of these "interesting" cases are given daily vitamins while others are kept as a control to see whether the nerve thickening can be reversed by that medication.

Suspicious cases are followed separately. Those who develop definitely leprous lesions are put on treatment, while the rest are merely followed. It may be that those in whom the lesions have cleared may develop new lesions later, so all these will be followed. The findings in the follow-up of suspicious cases of the Sevagram unit in 1953-54 are given in Table 8.

m. 1 1 1		Follow-up through 1954						
Time when detected	No. of cases	Lesions cleared	Leprosy developed	Remaining suspicious				
1953, first half	15	2	-	13				
1953, second half	8	2	3	3				
1954, first half	7	4	1	2				
1954, second half	18	1	2	15				
Total	48	9	6	33				

TABLE 8.—Occurence and follow-up of suspicious cases in the Sevagram unit.

14. Segregation of cases.—The very reason for starting this experiment in leprosy control by field work was the difficulty of institutional segregation of all infectious cases. Still, the Foundation did not completely rule out other methods of segregation if they could be effected. In spite of our attempts to encourage village or home segregation, only an occasional case has been isolated in any such way. However, a study of those cases has revealed interesting features. Many infectious cases stay in society during the infectious stage, but later, with development of gross disfigurement and mutilations, society forces them to leave the village. By that time, if the other members of the patient's family are well settled in life, he does not object to staying on a farm in isolation. But in many instances this isolation is adopted at a time when the patient is no longer in the administrative noninfectious stage.

In order to find out how many such noninfectious cases are isolated,

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we group the cases thus segregated as infectious or noninfectious. So far only a negligible fraction of the infectious cases has been segregated, and thus for practical purposes one need not consider the effect of segregation in assessing the results of the work.

15. Other data.—A few other details like cases in reaction in each month, and alternative treatment for those who do not tolerate DDS, are kept. Apart from recalling that in the Sevagram unit no case has discontinued treatment because of reactions (Table 4), these data need not be discussed here.

Other data kept relate to the workers. The doctor and the social worker of each unit have to submit a fortnightly and a monthly diary, and also information regarding the days spent each year for clinics, surveys, home visits, office work, etc. This was found to be necessary because the units are located far from headquarters. These and the quarterly inspection reports of each unit have greatly added to the efficiency of the work and record keeping.

16. Criteria for assessment.—To judge whether leprosy is being controlled or not, various criteria have been laid down. It is recognized that more knowledge, particularly about the epidemiology of the disease, is necessary before we can decide upon dependable criteria. This is particularly so when the results of a method have to be assessed after so short an experimental period as ten years. Only two aspects are discussed, to find out if they can help in assessing the results, or at least in showing the trend of the disease.

Reduction in the total number of infectious cases in the area: In the present state of knowledge of the epidemiology of leprosy it is impossible to say definitely if, under a given set of conditions of living, its spread varies in direct proportion to the number of infective cases existing in the area. Neither do we know whether the usual law of conditions necessary for a decline of an epidemic holds good for leprosy. Nevertheless, leprosy being a communicable disease it is not unreasonable to expect that a reduction in the number of infective cases will expose fewer people to infection and consequently will give rise to fewer new cases. Therefore, if a planned use of chemotherapy without segregation reduces the number of infectious cases, and if cases do not relapse 100 per cent, it should certainly help in controlling leprosy. In other words, if we find a reduction in the number of infective cases we can safely conclude that the method has helped. To what extent it does so may not be decided easily.

Decline in incidence among children: In view of the often long latent period of leprosy, it will be difficult to judge the result of control work at the end of only a ten-year period of work. However, as some contacts do develop the disease within ten years of exposure, we may study the cases occurring among children to see if there is any difference in frequency of cases at the beginning and the end of that period. As has been shown, the cases in all the units are being classified in five-year age groups, and if the figures are statistically sufficient we may be able to judge at the end whether or not there is a tendency for decline of the disease.

SUMMARY

1. The evolution and nature of the work of the Gandhi Memorial Leprosy Foundation in the control of leprosy by chemotherapy are given.

2. Details about the variety of data kept in each control unit, with their purpose and significance, and the difficulties involved are given.

3. Certain questions about our present views of infectivity are raised, but no conclusions are drawn. Need for further study is emphasized.

4. Although village or home segregation of the cases found is recommended, hardly any case has been so segregated.

5. The criteria which are likely to help in deciding whether leprosy has been controlled are discussed.

6. An attempt is being made to conduct this experiment of the control of leprosy by chemotherapy on scientific lines, and the work does not consist merely of distributing DDS.

RESUMEN

1. Expónense la evolución y la naturaleza de la labor realizada por la Fundación Conmemorativa Gandhi contra la Lepra en la lucha antileprosa con la quimioterapia.

 Se ofrecen pormenores acerca de la gran variedad de los datos conservados en cada unidad superior, con su propósito e importancia, y las dificultades encontradas.
 Se suscitan ciertos puntos relativos a nuestros actuales conceptos de la

infectividad, pero sin sacar conclusiones. Recálcase la necesidad de estudios ulteriores. 4. Aunque se recomienda la segregación en aldeas u hogares de los casos des-

cubiertos, apenas se ha segregado ningún caso hasta ahora.

5. Discútense las pautas que probablemente ayudarán a decidir si se ha dominado la lepra.

6. Se trata de llevar a cabo este experimento del dominio de la lepra con la quimioterapia a base científica, y la obra no consiste meramente en distribuir SDD (p'p'-sulfonildianilina).

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