

# The DermLep Study I: Results of Prospective Nation-Wide Survey of the Number & Profile of Leprosy Patients seen by Dermatologists in India

## Abstract

**Introduction:** There is evidence to suggest that there is a mismatch between the number of reported cases of leprosy in India and the number of actual cases in the country. One reason could be that many patients are diagnosed and treated outside the NLEP network and dermatologists may be managing some of these patients not captured by official statistics. To estimate these missing numbers, the *DermLep survey* was carried out to study the number and profile of leprosy patients seen by dermatologists and their significance. **Methodology:** The *DermLep* survey was a questionnaire-based study to be filled in by participating dermatologists from all over India, both in private practice and in medical institutions. Participating dermatologists provided information on old and new leprosy patients seen in their clinic over a 3-month period. **Results:** Total of 201 dermatologists from 20 states of India participated in the survey. 3701 leprosy patients (M: F ratio 2.1:1) were seen. Of them 46.62% (n = 1680) were new; 22.89% (n = 825) were under-treatment; and 19.65% (n = 708) were post RFT patients. Children <15 years constituted 4.29%, while elderly >60 years were 22.21%. As per WHO classification, MB were 73.36% and PB 28.46%. Of all patients 30.91% had lepra reactions, with T2R being more frequent. While 23.58% of all patients in the survey had G2D; in new patients 17.79%; and in post RFT patients 37% had G2D. Among the 1680 new cases seen, 59% were reported to NLEP by the dermatologists and 41% remained unreported mainly by the private dermatologists, among whom for 20% of the cases they mentioned “no access to register”. Source of MDT was WHO-MDT in 60.09% of new cases and for rest of 39.91% it was private pharmacies where private dermatologists had no access to MDT blister packs. **Conclusion:** This survey suggests that a good number of new-untreated leprosy patients, treatment defaulters and post RFT cases are managed by dermatologists in India. About 40% of the new patients managed mainly by private dermatologists are not being reported to NLEP for various reasons, and these constitute the “missing numbers” from government statistics. If extrapolated to the large of number of practicing dermatologists in India, these numbers could be very significant. The high percentage of G2D noted in patients surveyed (23.58%) and post RFT patient issues observed need special attention. There is a need to develop access for dermatologists to confidentially report leprosy patients treated at their clinics to the NLEP.

**Keywords:** Dermatologist, DermLep Survey, leprosy, missing numbers

## Introduction

The world health organization (WHO) in its document “Global strategy for leprosy 2016–2020” acknowledges that in the programme “*meaningful engagement of all stakeholders, including private providers is still limited.*” It also suggests that “*partnership with the private sector, including allopathic private provider for case detection/referral, care and/or social support*” of leprosy patients is valuable.<sup>[1]</sup> In India at present the national leprosy statistics are calculated on the basis of the number and details of self-reported

patients registered with health facilities and hospitals affiliated to the NLEP (National Leprosy Eradication Programme) in the country, and the numbers detected through block and district level active leprosy case detection campaigns (LCDC) of NLEP in specified geographic areas in that year. During the past few years, together these accounted for around 130,000 new cases annually. However, the National Sample Survey (2010–2011) and surveys by other Indian leprosy institutes from various states of the country reported a gap between the number of reported cases and the number

**P. Narasimha Rao, Santoshdev Rathod<sup>1</sup>, Sujai Suneetha<sup>2</sup>, Sunil Dogra<sup>3</sup>, Sunil Kumar Gupta<sup>4</sup>, Rita Vora<sup>5</sup>, Shushruth Kamoji<sup>6</sup>, Swagta Tambe<sup>7</sup>**

Department of Dermatology, Bhaskar Medical College, <sup>2</sup>Institute for Specialized Services in Leprosy (INSSIL), Nireekshana ACET, Hyderabad, Telangana, <sup>1</sup>Department of Dermatology, Smt. NHL Municipal Medical College, Ahmedabad, <sup>5</sup>Department of Dermatology, Sree Krishna Hospital, Karamsad, Anand, Gujarat, <sup>3</sup>Department of Dermatology, Venereology and Leprology, Postgraduate Institute of Medical Education and Research, Chandigarh, <sup>4</sup>Department of Dermatology, AIIMS, Gorakhpur, Uttar Pradesh, <sup>6</sup>Department of Dermatology, Belagavi Institute of Medical Sciences, Belagavi, Karnataka, <sup>7</sup>Innovation Skin Clinic, Mumbai, Maharashtra, India

### Address for correspondence:

Prof. P. Narasimha Rao, Department of Dermatology, Bhaskar Medical College, Hyderabad, Telangana, India. E-mail: dermarao@gmail.com

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of actual cases in the community.<sup>[2-4]</sup> One of the reason considered was that many patients are diagnosed and treated outside of organizations where the diagnosis is captured by official statistics and that there is under-diagnosis and reporting but private dermatologists might be filling this gap,<sup>[5]</sup> and this is not being reflected in the data.

As one of the earliest signs of leprosy is a skin lesion, a number of leprosy patients present to dermatologists in institutions and in private clinics voluntarily for diagnosis and management of their disease. They include both new and post-RFT (released from treatment) leprosy patients. However, many of the new patients may not be getting registered with NLEP, reason being the lack of access. This is especially true for private dermatologists who as service providers are not linked to the public health system for registering patients managed by them nor is the sources of these cases and chains of transmission investigated. Consequently, these could comprise the *un-accounted leprosy numbers* of India and it is important that a methodical estimate of these *un-accounted/missing numbers* is conducted. To address this felt need, the *Indian Association of Dermatologists Venereologists and Leprologists (IADVL) Special Interest Group (SIG) leprosy* initiated this systematically planned survey with the objective of ascertaining the number and profile of leprosy patients seen by dermatologists in India and the availability of key leprosy care services.

## Methodology

The study titled *DermLep survey* is primarily a questionnaire-based study to be filled in by practicing Dermatologists from India regarding leprosy patients, both old and new, attending their clinic during a 3-month period. It was designed to get information on the number and profile of each patient examined by them during this study period and the facilities available to manage leprosy at their clinic/hospital. The project was screened and approved by the IADVL academy, the highest academic body of IADVL. Dermatologists nation-wide willing to take part in the survey were contributors to the study and provided information in a fixed format in the survey tool detailed below. The forms once filled were passed on to the principal investigator for compilation and analysis. Ethical clearance for the study was obtained from an independent ethics committee on 7<sup>th</sup> April 2017 and participating institutions also took permission from their respective institutional ethics committees.

## Enrolling participants

All members of IADVL were offered to participate in the survey. National and state executive committee members' of IADVL were consulted and their support taken in enrolling dermatologists for the study. Details of the study was communicated to IADVL members with the help of the member database, through their state associations, directly

through telephone, emails, short message service providers, and social media forums. Both individual dermatology practitioners as well as dermatology departments of medical institutes were invited to take part in the study. Over 6500 dermatologists from all over India were informed at least twice over a period of 9 months. Our initial target was to enroll at least 650 dermatologists from all over the country for the study. Three thousand *DermLep* survey booklets were printed and sent to various state coordinators and other volunteers for distribution to the interested members. Dermatologists were recruited for the study initially from August 2017 to end of December 2017 (6 months). Subsequently the date of recruitment was extended up to the end of April 2018. After recruitment, dermatologists were instructed to record the details of all the leprosy patients seen by them in the survey forms for any chosen consecutive 3-month period at their clinic/hospital. All participants were expected to complete their survey by 31<sup>st</sup> August 2018.

## Administration of the study

The coordinator of SIG-leprosy was the Principal Investigator (PI) for the study. The PI took responsibility for the concept and planning of methodology. The co-PIs were drawn from members of SIG-leprosy and they took responsibility for enrolling dermatologists from their states and zones ensuring coverage of different parts of the country. They also encouraged interested IADVL members from different zones of India to volunteer for this work as coordinators for the implementation of this survey based study. Power point presentations and frequently asked questions and answers (FAQ & A) regarding the survey and its execution were prepared and was made available to all participating dermatologists.

The survey tool: It had two sections. The section one of survey questionnaire to record patient's information had 14 questions. It also included a consent form for each patient to be assented before they are enrolled. Each question was provided with ready response options to be filled by the dermatologist. One survey questionnaire form was to be filled for each leprosy patient seen during the 3-month study period. It was designed to provide information regarding their disease, therapy, and complications, so as to meet the objectives of the study. The fourteen questions were relating to presenting complaint, type of case, clinical and WHO-based therapeutic classification, skin smear examination, type of reaction if present, whether patient was an RFT (released from treatment) case, duration of disease along with the presenting complaint, detail of disability, source of multi-drug therapy (MDT), advise on physiotherapy, if patient was already reported to NLEP before being seen by dermatologist and if not, whether the dermatologist reported the case to NLEP [Annexure 1]. The result of this section will be detailed and discussed in this paper. The Section Two is a brief questionnaire of eleven questions with ready responses, to be filled out by all

participating dermatologists once at the time of enrolment into the survey. It was designed to provide brief details of the dermatologist, their choices for therapy and facilities available for leprosy care, including referral services at their center. The results of section two will be presented separately as part two of the *DermLep* survey.

### Choices for filling the questionnaire

There was an option of using the (a) printed forms for survey, made available as a 20 page *DermLep* survey booklet, sufficient to fill information of 20 leprosy patients or (b) web-based survey option with the same questionnaire to be filled online (<https://docs.google.com/forms>) for each patient seen during study period. The filled in booklets were posted to the coordinator of SIG leprosy at the end of each month. The web-based option was used as a means of knowing how such a reporting system performs in the field and is relevant because the WHO global strategy document for 2016–2020 mentions the “availability of web-based, case- based reporting system” as one of the performance indicator.<sup>[1]</sup>

### Data protection and confidentiality and analysis

All the data obtained were used only for the purpose of the survey and confidentiality of both the patient and the participating dermatologist was maintained. At the end of each month, the data was entered into a database and analyzed statistically. The first draft report was prepared by the PI and circulated to co-PIs and based on their inputs the final version was prepared.

## Results

After completion of the time period of the survey a total of 188 dermatologists sent back the filled survey booklets, while 13 members completed it through the web-based survey. A total of 201 dermatologists from 20 states of India took part in the *DermLep* survey. The zone-wise distribution of the dermatologists who took part in this nation-wide survey is depicted in Table 1 and their locations pan-India is depicted as a geo-map in Figure 1.

A total of 3701 leprosy patients were seen by these 201 participating dermatologists over a 3-month period of survey. On an average 18.41 leprosy patients were seen by a dermatologist in a 3-month period and 6.14 patients per month. Of the 201 dermatologists, 100 were working in institutions (48 in government and 45 in private medical

college hospitals and 7 in corporate medical institutions) and 101 were private practitioners. Of the total 3701 patients, 2440 were seen at medical institutes (average of 8.13 patients per month), while 1261 patients were seen at private dermatology clinics (average of 4.16 patients per month).

### Clinical details

The clinical details of the patients is given in Table 2. Of the total 3701 patients, 2517 (68%) were male and 1184 (32%) were female. Children [ $<15$  years] constituted 4.29% ( $n = 159$ ) of the patients, while elderly [ $>60$  years] constituted 22.21% ( $n = 822$ ) of patients. In the patients surveyed, 1640 patients (44.31%) had only a single presenting symptom (monosymptomatic). Of these, the most common presenting symptom was skin patches in 952) patients. Deformity and ulcer were the sole presenting symptoms in 78 and 129 patients, respectively. Rest of the 2061 (55.69%) patients presented with a combination of more than one symptom.

The clinical classification of leprosy was recorded in 3517 of the patients [Table 2]. Of these, borderline tuberculoid (BT) leprosy was the most common clinical type



Figure 1: Representing geo-image locations of pan-India dermatologists who participated in the *DermLep* survey

Table 1: Distribution of participating dermatologists in *DermLep* survey across India

Zone	States	Number of Participating Dermatologists
Western India	Rajasthan, Gujarat, Maharashtra, & Madhya Pradesh	62
Northern India	Delhi, Punjab, Haryana, Uttar Pradesh, Uttarakhand & Himachal Pradesh	20
Eastern India	West Bengal, Bihar, North east states & Odisha	21
Southern India	Andhra Pradesh, Telangana, Karnataka, Tamil Nadu & Kerala	96
Total		201



**Table 2: Age distribution, presenting symptom and the clinical classification of patients**

Age distribution	No. of patients	Presenting symptom	No. of patients	Clinical type	No of patients
Children <15 years	159 (4.29%)	Skin Patches	952 (25.72)	TT	291 (8.27%)
Young adults 16 to 30 years	1044 (28.20%)	Anaesthetic area	307 (8.29%)	BT	1278 (36.33%)
		Neuritis	174 (4.70%)	BB	197 (5.60%)
Middle aged 31 to 59 years	1676 (45.28%)	Deformity	78 (2.10%)	BL	665 (18.90%)
		Ulcer	129 (3.48)	LL	852 (24.22%)
Elderly >60 years	822 (22.21%)	Patients with more than one symptom	2061 (55.69)	PNL	178 (5.06%)
				Indeterminate	56 (1.59%)
Total	3701	Total	3701		3517*

\*Note: In 184 patient details of the clinical type was not recorded by participants

in 36.33% (n = 1278) patients; followed by lepromatous leprosy (LL) in 24.22% (n = 852) and borderline lepromatous leprosy (BL) in 18.9% (n = 665). BL and LL together constituted 43.13% (n = 1527) of the patients. Pure neuritic leprosy (PNL) was seen in 5.06% (n = 178) and indeterminate leprosy in 1.59% (n = 56) of the patients. When grouped under WHO classification for therapeutic purposes (PB leprosy <5 skin lesions and MB leprosy >5 skin lesions), 72.36% (n = 2545) belonged to MB leprosy, while 27.64% (n = 972) belonged to PB leprosy.

### **Skin smear status**

The *DermLep* survey addressed a question about the skin smear (SS) status of patients included in the study [Table 3]. Of the 3701 patients, for 2000 (54.03%) patients it was mentioned that SS was performed. However, bacteriological index (BI) was recorded only for 1017 (27.47%) patients; of these, 376 patients were negative, while in 641 patients the BI was positive, with values ranging from 1+ to 5+.

### **Type of leprosy patients**

Of 3701 patients, in 3603 patients' a clear response with regard to type of case was provided. Of these, 46.62% cases (n = 1680) were new and 22.89% (n = 825) were under-treatment patients with the dermatologist at the time of the survey. In addition, about one-fifth of the cases (19.65% n = 708) were post RFT (Released From Treatment), and 10.99% (n = 396) were partially treated cases (defaulters) seeking further management.

### **Reactions**

The presence or absence of lepra reaction was recorded in 3348 patients in the survey. Lepra reactions were noted in 1035 (30.9%) patients. Of these, type-2 lepra reactions (T2R) were more frequent, observed in 589/1035 (56.92%) patients, while type-1 lepra reaction (T1R) was observed in 442/1035 (42.70%) patients. Features of both reactions were observed in 4 (0.38%) patients.

### **Post RFT patients**

Details of RFT patients seen during this survey are detailed in Table 4. Of the 708 RFT cases who presented to dermatologists, 45.48% (322) presented within the first

year of RFT; 37.98% (269) presented within 5 years of RFT; while 11.01% (78) visited the dermatologist more than ten years after being declared as RFT case. The reason for visit to the dermatologist was elicited in 566 out of the 708 post RFT patients. The most common reason to consult the dermatologist post RFT was lepra reaction or neuritis in 26.1% (n = 148); ulcer or new/increased deformity in 25.6% (n = 145); active skin lesions in 21.2% (n = 120); followed by recurrence of original signs and symptoms in 6.7% (n = 38) of the patients. About 20.3% (n = 115) of the patients came for reassurance.

### **Grade 2 disability**

The presence of grade-2 disability (G2D) was recorded in 873 (23.58%) out of 3701 patients [Table 5]. When presence of G2D was correlated against the type of patient [Table 5], G2D percentage was highest among post RFT group at 37% (262 out of 708). In the group of 1680 new patients, 299 (17.79%) had G2D at the time of examination. G2D was also observed in 32.07% of defaulter group of patients. For 16 patients marked as having G2D, the category of patient was not specified. To the question whether the patients was advised physiotherapy as a part of management, out of responses received for 3683 patients, for 1226 patients (33.28%) physiotherapy was advised.

### **The Source of MDT for new leprosy patients seen by Dermatologists**

Of the 1680 new leprosy patients, specific response was marked for 1601 patients regarding source of MDT. Out of them 60.09% (n = 962) received WHO MDT blister pack (NLEP govt. supply) while 39.91% (n = 639) patients were prescribed MDT from private pharmacies.

### **Reporting of Cases to NLEP/government Agencies by Dermatologists**

One of the objectives of the study was to find out if practicing dermatologists report or register the patients seen by them with government agencies/NLEP. The response was elicited for 3496 patients seen by dermatologists in this study [Table 6]. They affirmed that 32.% (n = 1119) patients were already reported to NLEP before they were seen at the dermatology clinic. Of the remaining, 2337 patients

**Table 3: Skin Smears status of patients enrolled for the study**

Skin smear (SS) examination	No. of patients	BI (-) ve patients	BI (+) ve patients & details
SS Done & BI readings mentioned	1017	376	BI (+) : 641, BI 1+: 125, BI 2+: 109, BI 3+: 138, BI 4+: 147, BI 5+: 122
SS Done, but BI readings not mentioned	983	-	-
Total	2000*		

Note: For rest of 1701 patients skin smears were not done

**Table 4: Duration after RFT and reason for visit to the dermatologist**

Duration after RFT	No. of patients	Reason for visit of RFT patient	No of patients
< 1 year	322	Lepra reaction & Neuritis	148 (66+82)
1-2 years	185	Ulcer or new or increased deformity	145 (78+67)
2-5 years	84	Active skin lesions	120
5-10 years	39	Reassurance	115
More than 10 years	78	Recurrence of original symptoms/signs	38
Total	708		566*

\*Note: Reason for visit post RFT not recorded in 142 patients

**Table 5: Grade 2 disability (G2D) in various categories of patients**

Category of patient	Number of patients	Patients having G2D (%)
New	1680	299 (17.79%)
Partially treated (Defaulter)	396	127 (32.07%)
Post RFT	708	262 (37.00%)
Under treatment	825	169 (20.48%)
Total		857

**Table 6: Reporting of patients to NLEP by dermatologists**

Status of reporting of patients by dermatologist to NLEP	No. of patients
Already reported to NLEP	1119 (32%)
Newly reported	992 (28.37%)
No Access	338 (9.67%)
Not reported	1047 (29.94%)
Total	3496*

Note: For the remaining 205 patients the status was not recorded

in the survey, 992 new patients were reported by the dermatologists to NLEP, while for 338 patients; “no access to register” was selected as the reason for non-reporting with NLEP. The remaining 1047 (29.94%) leprosy patients of various categories were not reported to the NLEP agencies. When this data was analyzed further specifically for 93 participating dermatologists from medical college hospitals, while 79 of them reported all their patients to NLEP, there was partial reporting from 3 (out of 48) government and 11 (out of 45) private medical colleges.

## Discussion

Early detection and treatment of leprosy will lead to reduction in the source of infection in the community, interrupt transmission and result in true elimination of

the disease. This approach is very relevant to India which contributes about 58% of world's new leprosy cases annually.<sup>[6]</sup> A situational analysis of the health indicators of the National leprosy elimination programme (NLEP), reveals that the trend of two important indicators of the program Annual New Case Detection Rate (ANCDR) and Prevalence Rate (PR) has remained almost static from 2006 to 2018. This indicates that a large number of undetected cases are still present in the community and that there is transmission of *M leprae* infection in the community.<sup>[7]</sup> The ANCDR reported by NLEP is directly based on the number of leprosy cases registered by various affiliated government agencies, medical institutions, and non-governmental organizations (NGOs) in a year. What is not taken into consideration is the sizable number of leprosy patients who are treated outside of these registration facilities, mainly by a large pool of dermatologists all over India, and this forms the focus of the present study.

Leprosy is an important component of Dermatology curriculum in India and all dermatologists are therefore qualified leprologists. It is known that dermatologists in both public & private sector play a significant role in the diagnosis and management of leprosy in India, which is more true after the integration of leprosy services into the general health care in this country post 2006.<sup>[8]</sup> The National health policy 2017 advocates “a positive and proactive engagement with the private sector for critical gap filling towards achieving national goals”,<sup>[9]</sup> and leprosy is one of them. With increasing health awareness in India linking skin patches with leprosy, dermatologists are the point of first contact for patients with skin lesions. However, to date, there have not been any published studies to evaluate the role of dermatologists in leprosy care in India or on the numbers of leprosy patients treated by them in the country.

A survey is an investigation that uses a structured and systematic gathering of information from a sample of a

population of interest.<sup>[10]</sup> Surveys are designed to obtain specific information about a population and can be conducted once or on a periodic basis. The subjects of a survey can be members of the general public, patients, health-care providers, or organizations. National surveys on infectious disease by interested societies though rare, are known.<sup>[11]</sup> The present study is a survey conducted by IADV L through the participation of nation-wide dermatologists to systematically assess the *number and profile of leprosy patients seen by them* in order to understand and appraise the role of dermatologists in leprosy care in India.

Although 6500 life members of IADV L were approached to participate in the *DermLep* survey, about 700 members took up the survey, out of which only 201 dermatologists sent back their completed patient survey details. Of the 201 dermatologists, only 11 opted for web-based reporting, which reflects a preference for physical forms over a web-based survey format. There is a scope to evaluate the reason for such a preference. The participation of dermatologists was from 20 states all across India, as one can appreciate from Figure 1 making this a truly pan Indian survey. The participation of dermatologists was highest from the four southern states of India, while it was lowest from the northern states, possibly reflective of case load, as well as of presence of dermatologists in these zones. There are many reasons for such a less-than-expected response, the most notable being the apprehension of dermatologists to provide information on patients seen by them who are not being reported to NLEP.

A notifiable disease is one wherein the reporting of certain diseases or health conditions to the local, state or national health authorities is required by law. There is a general impression that leprosy is a notifiable disease all over India, which is not true (Personal communication from Central leprosy Division, Govt of India). In India, health is a state subject. While the central government runs the NLEP and provides directives and inputs, their execution and policies on notification are made at state level. As per state government policies, at present leprosy is a notifiable disease only in certain states of India, for example, the state of Tamil Nadu.<sup>[12]</sup> Many dermatologists informed the investigators off-the-record that the fear of being on the wrong side of law if leprosy were notifiable as the reason for not taking part in the *DermLep* survey. Clarity and wider dissemination of policies on this aspect can allay this apprehension.

In the present study it was observed that dermatologists working in medical institutions were seeing almost double the number of leprosy patients compared to private practitioners. It could be for two reasons. One, leprosy is more common in the lower socioeconomic strata who prefer government health facilities for treatment. Second,

dermatology departments of most hospitals/institutes are routinely supported by NLEP to register patients and provide WHO MDT blister packs. This data highlights the important role that dermatology departments in medical colleges play in diagnosing and treating leprosy in India. On the other hand, it also highlights the equally important role that private dermatologists play in managing leprosy patients in an integrated mode in their private clinics, dispelling the stigma leprosy carries in the society. Further, it points to the need to strengthen the link between private dermatologists treating leprosy patients and the public health system to enable registration of patients managed by them to investigate the sources of these cases and chain of transmission.

### ***Profile of leprosy patients***

According to the NLEP annual report for the year 2017–2018,<sup>[7]</sup> the MB: PB ratio in adults was 1.035:1, while in our survey it was 2.6:1. The higher MB ratio in this study could be due to the self-selected nature of patients seen at dermatology clinics. Nonetheless, there is a concern among leprologists that the percentage of MB cases is increasing in India and the current survey supports this observation. Studies have opined that this could be due to varied reasons including changes in the epidemiological patterns, delay in early diagnosis and reporting of new cases in the community and integration of the program with general health services.<sup>[13-15]</sup> The increased MB numbers may also signify the skill and ability of dermatologists to diagnose and manage leprosy in the community, while such cases may have been missed by other health facilities and general practitioners. These MB patients, especially LL with few obvious skin changes who appear apparently normal are an epidemiologically important form of leprosy who could silently be spreading the infection in the community.<sup>[16]</sup> This also highlights the need for healthcare services to include the participation of specialist dermatologists. Here it is heartening to note that the Central Leprosy Division (CLD), Government of India in the year 2018 has extended its collaboration with IADV L in order to receive technical support from dermatologists who are considered ‘specialized cadre of medical field’ in the context of leprosy in India.<sup>[17]</sup>

With the national program giving up the routine use of slit skin smears, concerns have been raised about the declining interest and ability to perform skin smear (SS) examination correctly among all the persons involved in leprosy work even in the teaching/training institutes.<sup>[18]</sup> The *DermLep* survey showed that SS examination was performed on over half (54.03%) of the patients in the survey and of these, BI reading was available for 50.85% (1017) of smears. One reason why BI status was not available for rest of the SS done could be that although smears were taken at the time of examining the patient and recording in the survey form, their processing and reading was done

much later. Nonetheless, the fact that dermatologists took SS in more than half of the leprosy patients seen by them highlights the value dermatologists continue to place on SS examination as a part of a complete clinical assessment in leprosy, although it is not emphasized any more in the national program.

It is well known that reactional states, particularly in the first few years of leprosy treatment, are a major reason for patients to seek medical attention. While the prevalence rate of T1R in leprosy is reported to vary from 8.9 to 35.7% in various prospective and retrospective studies, the prevalence of T2R also has wide geographic variations ranging from 19 to 26%.<sup>[19]</sup> In the present survey, 1035 (30.9%) patients presented with lepra reaction, with T2R being more frequent than T1R. This data shows that almost one out of three patients has the potential to develop lepra reaction and should be monitored closely. Timely detection and medical intervention is needed in both types of reactions since both carry the risk of causing nerve damage and disability, acute damage in type-1 and more chronic damage in type-2 reactions.

### **Post RFT group of patients**

In the national program, a leprosy patient is provided a full course of MDT and then released from treatment (RFT) without much of program cover for a “care after RFT” or a “care after cure”. In the present study a significant number of post-RFT patients (19.1%, n = 708) sought the care of dermatologists. Obviously, they had many concerns physically as well as psychologically that they felt needed to be addressed. Many patients experience post RFT complications, which include lepra reactions, neuritis, neuropathic pain, relapse/reinfection and often a lifelong stigma associated with disabilities left behind. However, the extent of the problem/s, individually and collectively has not been widely studied in the Indian public health set-up, where WHO-recommended regimens are followed, but without much emphasis on post MDT surveillance.<sup>[20]</sup> Presence of active clinical lesions post RFT was noted in 16.94% of the patients in the current study. It is known that the limitations associated with fixed duration MDT is the continued visibility of a clinically active patch in a proportion of patients and continued inflammatory response resulting in persistent clinical activity for up to 12-18 months.<sup>[21]</sup> In our study, 9.32% (n = 66) of post RFT patients visited dermatologists because of lepra reactions, while 11.58% (n = 82) patients presented due to persistent neuritis. In a study from Brazil in RFT patients, it was observed that T1R was most common in 37.1%, followed by T2R in 18.6% and neuritis in 13.9%.<sup>[22]</sup> It was also observed that the number of reactional states were significantly more frequent, severe, and of longer duration during the first 2 years of completion of therapy.<sup>[23]</sup> In a study of RFT patients in Maharashtra, India, 18% patients were detected with

reactional events.<sup>[20]</sup> These observations indicate that reactional events are common in post RFT patients which need appropriate medical management and care to prevent nerve function impairment and disabilities.<sup>[24]</sup> In addition, the fact that about 16% of the post RFT patients visited dermatologists only for reassurance in the present study showcases the need for counselling and *hand-holding* of these patients post MDT. This is needed for many patients as the skin patches and symptoms will not disappear completely post MDT and patients need to be reassured about the adequacy of therapy and slow disappearance of lesions. It is heartening to note that dermatologists are able to provide much needed “care after RFT” or “care after cure” for this group of patients.

A significant proportion of the RFT patients presented within the first year of RFT (45.48%) and a further 26.12% presented in the second year. In other words, about 71.60% of the RFT patients felt the need to consult the dermatologist for various reasons within 2 years of completing their prescribed MDT. This highlights the importance of the first two years post RFT as a period where patients experience most of the post RFT complications mentioned above which need closer monitoring to ensure medical support and POD (prevention of deformity) services from the health system.<sup>[23]</sup> Further it was observed in the present study that there is a graded reduction in proportion of patients presenting after 2 years of RFT. In this study, about 11% of the patients presented to the dermatologists even after >10 years of RFT, emphasizing the need for provision of continued care, monitoring, including reassurance to this group of patients.<sup>[25]</sup>

### **Issue of disability**

Overall disability rates have declined in India following the adoption of MDT as the standard treatment between 1991 and 2005. However, the proportion of G2D increased from 1.8 in 2005-06 to 4.60% in 2015-16 as a result of delay in diagnosis and possibly due to improvements in the quality of disability reporting.<sup>[26,27]</sup> However, it is heartening to note that according to the NLEP report<sup>7</sup> for the year 2018-19 the Grade 2 disability (G2D) is lower among new cases in India at 3.34%. In the present study 17.79% of the *new patients* had G2D at the time of examination. This percentage appears high, but it should be noted this is a self-selected group of patients attending dermatology clinics with varying problems seeking treatment. Nonetheless, it is within the range of 8.6–31.6% reported in previous studies, from India and Brazil.<sup>[28-31]</sup> Even in childhood leprosy the reports of prevalence of deformities in India varies from 0.5% to 40.7%.<sup>[32]</sup> A recent study has found that the G2D has increased in the post elimination era where leprosy has been integrated into the general health services.<sup>[33]</sup> This shows that integration efforts should be matched with awareness and training of health personnel to ensure that early cases are not missed. Only increased awareness about



the disease and reducing stigma will contribute to early reporting of patients and further decline in disability rate in new patients.

It is also important to note that in the present study, in the post RFT group 37% of the patients had G2D, indicating that disabilities can develop and persist long after completion of MDT. In fact, in 20% of the post RFT patients, presence of either ulcer or increased deformity was the principal reason for consulting the dermatologist. Similarly, G2D were also high (32.07%) in defaulter patients who visited the dermatologists. It has been observed that nerve function impairment (NFI) once acquired worsens with time, especially in MB patients<sup>[34]</sup> and neuritis/new deformities continue to develop in certain forms of leprosy even after RFT.<sup>[35,36]</sup>

The possible progression of existing NFI should always be kept in mind while dealing with issues of post RFT patients. Recognizing that disability is a major determinant of social stigma, there is a need to identify events such as reactions and neuritis early in leprosy patients to reduce the occurrence of disabilities. A major reason for risk of disability among adult leprosy patients is the delay of more than 3 months in seeking medical help from the time of noticing the first symptom.<sup>[37]</sup> Hence, participation of all health care providers working for leprosy, including dermatologists is needed to facilitate early diagnosis and treatment of leprosy in the community and through it the prevention of disabilities.

### **MDT supply and registration of patients**

The midterm Evaluation of the NLEP, a joint initiative of WHO and DGHS, India in 2014 indicated that the disease burden in the community was higher than the cases being reported. It mentioned that<sup>[38]</sup> ‘*there is presumptive and scientific evidence that the number of cases detected is less than the number that occur. The exact magnitude of the gap cannot however be known*’. This survey highlights some of these ‘un accounted/missing numbers’ of leprosy patients. It was observed during this survey that out of 3496 patients for whom data was available, 1119 (32%) were *already reported* to NLEP before they were seen by the dermatologists [Table 6]. In addition, 59% of the new cases (992 out of 1680) seen were *registered* with NLEP by the dermatologists. The rest of the 41% (688) of the patients managed by them, however, were not registered with NLEP and these represent the ‘missing numbers’, as they will not be reflected in the national count of leprosy patients. While planning the study, one of the key hypotheses was that a significant numbers of leprosy patients in India are seen and treated by dermatologists. One of the objectives therefore was to arrive at an estimate of these numbers. The 201 participating dermatologists saw 1680 *new* leprosy patients during a 3-month period. If this survey was for a year then these dermatologists would have seen about 6720 *new* leprosy patients. There

are over 10,000 dermatologists in India and presuming that about 50% of these dermatologists are in clinical practice and manage leprosy patients, and the data of 201 dermatologists is extrapolated to 5,000 dermatologists in the country, the number of new leprosy patients seen by this group would be more than 150 thousand. Even if a proportion of them are not reported to NLEP, as noted in this study, then they would account significantly to the “missing numbers” of leprosy patients in the country.

Here it relevant to note that dermatologists in this survey gave “*no access to register*” as the reason for non-registration of 338 patients, drawing attention to the need to make the patient registration process with govt agencies simpler and user friendly for all health care providers. For the ease of reporting and data management of registered leprosy cases, NLEP has launched “*Nikusth*” a web-based reporting system in India.<sup>[14]</sup> At present *Nikusth* is used for patient information collection using the leprosy assessment form, through District Health Information Software 2 (DHIS2) platform. The data of leprosy patients is entered at the block level fortnightly or monthly by NLEP leprosy officers.<sup>[39]</sup> A similar and simpler portal for registration of patients outside of NLEP will be ideal.

Under the national programme, WHO MDT blister packs are provided free of cost to the patients for the entire duration of the fixed duration therapy. In the present study a significant number of institutions/dermatologists had access to MDT blister packs and were able to provide it to about 60% of new patients. The remaining 40% of new patients did not have access to MDT blister packs and were prescribed MDT from outside. Availability of MDT blister packs to private practitioners and dermatologists would enable patients treated by them to have free MDT as well as motivate the dermatologists to take an active part in the leprosy program. This is also because Dapsone is very difficult to procure in the private sector as very few companies manufacture it, probably due to the low profit margins. More recently India faced an acute shortage of Clofazimine and patients had extreme difficulty procuring it from private pharmacies.<sup>[40]</sup> Given this situation access to government supported free WHO MDT blister packs will go a long way in ensuring availability of MDT, and treatment compliance/completion rates, as well as improve the public-private partnership in leprosy control.

### **Conclusion**

The results of the *DermLep* survey have thrown up the following conclusions. There are significant numbers of un-registered leprosy patients or *missing leprosy numbers* in India, managed by dermatologists, outside of NLEP registers. The survey has also shown that leprosy patients generally identify dermatologist as a leprosy specialist, and dermatologists provide their services through various medical college hospitals and other institutions which work in tandem with NLEP. In addition leprosy patients



also seek dermatologists consultation in good numbers in private practice outside of NLEP network in India.

While about 40% of *new patients* seen by Indian dermatologists are not being reported to NLEP for various reasons, nonetheless it should be noted that all these leprosy patients are getting adequate drug therapy and care from these specialists as they are also qualified leprologists. Due to fear and stigma associated with leprosy, some patients prefer treatment in a private dermatology set up where their diagnosis can be kept confidential. There is an urgent need to develop an easier mechanism for dermatologists to diagnose and confidentially report on leprosy patients treated at their centers to NLEP.

Post RFT patients are important group of *persons affected by leprosy* who consult dermatologists for “care after cure”. The survey results highlight the need for improved attention of post RFT leprosy patients by the national program. This study observed that the G2D are significantly high, both in new and old patients across the country. Although this observation is from a study of self-selected group of patients, it deserves special attention at it points to the delay in early diagnosis of leprosy in the community and the improvement needed in POD services of post RFT care.

In the present context of integration of leprosy into the general health services dermatologist needs to fulfil the role of a “leprosy specialist” with responsibility. In addition, they will have to play a leadership role and serve as fulcrum of excellence in standards of leprosy care, teaching and research. At this juncture it is heartening to note that IADVL has become an official partner of NLEP, Govt of India in the year 2018 and with it the association and its members are now in a better position to work effectively for the national program. Importantly the interest in leprosy is very much alive among young dermatologists.<sup>[41]</sup> There is merit and necessity of involving dermatologists at all levels of planning and implementation of the leprosy program in India.

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### Conflicts of interest

There are no conflicts of interest.

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## Annexure 1 : Questionnaire of patient survey

<p>1. Presenting symptom: Skin patches <input type="checkbox"/> Anesthetic area <input type="checkbox"/> Neuritis <input type="checkbox"/> Deformity <input type="checkbox"/> Ulcer <input type="checkbox"/></p> <p>2. Type of case: New <input type="checkbox"/> Partially treated <input type="checkbox"/> Post RFT <input type="checkbox"/> Undertreatment <input type="checkbox"/></p> <p>3. If it is a treated case, when was he/she declared RFT: &lt;1 year <input type="checkbox"/> &gt; 1 year <input type="checkbox"/> &gt; 2 years <input type="checkbox"/> &gt; 5 years <input type="checkbox"/> &gt; 10 years <input type="checkbox"/></p> <p>4. Clinical classification: Indeterminate <input type="checkbox"/> TT <input type="checkbox"/> BT <input type="checkbox"/> BB <input type="checkbox"/> BL <input type="checkbox"/> LL <input type="checkbox"/> PNL <input type="checkbox"/></p> <p>5. Therapeutic classification: PB leprosy &lt; 5 lesions <input type="checkbox"/> MB leprosy &gt; 5 lesions <input type="checkbox"/></p> <p>6. Skin smear exam: Done <input type="checkbox"/> Not done <input type="checkbox"/> If done BI:</p> <p>7. Type of reaction: Absent <input type="checkbox"/> Present <input type="checkbox"/> If present: Type 1 <input type="checkbox"/> Type 2 <input type="checkbox"/></p> <p>8. Presence of Grade 2 disability (deformity, ulcers or paralysis) at the time of first examination: Yes <input type="checkbox"/> NO <input type="checkbox"/> Any other <input type="checkbox"/></p> <p>9. If the patient is already under treatment elsewhere the reason for coming to you: Reaction <input type="checkbox"/> Active lesions <input type="checkbox"/> Neuritis <input type="checkbox"/> New or increased deformity <input type="checkbox"/> Ulcer <input type="checkbox"/> Not happy with present treatment <input type="checkbox"/> N/A <input type="checkbox"/></p> <p>10. If the patient is a RFT case, reason for his/ her visit: Reaction <input type="checkbox"/> Active lesions <input type="checkbox"/> Neuritis <input type="checkbox"/> New or increased deformity <input type="checkbox"/> Ulcer <input type="checkbox"/> Recurrence of original symptoms &amp; signs <input type="checkbox"/> Reassurance <input type="checkbox"/> N/A <input type="checkbox"/></p> <p>11. If the patient is new, what is the source of MDT? MDT blister packs of Government supply <input type="checkbox"/> Prescribe MDT from outside <input type="checkbox"/></p> <p>12. Did you advise physiotherapy for this patient: Yes <input type="checkbox"/> NO <input type="checkbox"/> N/A <input type="checkbox"/></p> <p>13. Is this case reported to NLEP before seen at your clinic (Tip: Yes for all those treated with MDT blister packs): Yes <input type="checkbox"/> NO <input type="checkbox"/> Not sure <input type="checkbox"/></p> <p>14. Did you report this case to NLEP/ Government agencies: Yes <input type="checkbox"/> NO <input type="checkbox"/> No access <input type="checkbox"/></p>
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