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Report on the
NATIONAL LEPROSY SYMPOSIUM 2018
Theme: *Accelerating Towards A Leprosy Free India*
Report prepared by
Special Interest Group (SIG) Leprosy
(IADVL Academy of Dermatology)
Indian Association of Dermatologists, Venereologists & Leprologists (IADVL)

Introduction

Background

1. A 'National Leprosy Symposium' on the theme of *'Accelerating towards a leprosy free India'* was convened on the 24rd of August, 2018 at the Hotel Radisson, Delhi NCR. The symposium was jointly organized by the Indian Association of Leprologists (IAL) and the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) with the Special Interest Group (SIG) Leprosy (IADVL academy of Dermatology) taking an active lead in organizing the symposium. The purpose of this symposium was to discuss a few specific issues of current therapeutic importance that could impact the National leprosy program and play a role in achieving the goal of a *Leprosy-free India*. The Symposium attempted to bring together as many key stakeholders in leprosy in the country to discuss these issues and possibly arrive at a consensus statement/guidelines for implementation.

Objectives of the symposium

2. The symposium had three major objectives with three strategic approaches of therapy, chemoprophylaxis and Immunoprophylaxis:

I. To discuss the efficacy and value of implementation of Uniform-Multidrug Therapy (U-MDT);

II. To examine the efficacy, value, limitations and administrative aspects of administration of Single dose Rifampicin (SDR) as a chemoprophylaxis tool; and

III. To discuss the efficacy, value, availability and implementation of MIP vaccine and other vaccines in the Immunoprophylaxis of leprosy.

Participating Organisations

3. A total of 52 representatives from 19 different national and international organizations / groups participated in the symposium (Annexure-1). These included representatives from the Central leprosy division (CLD), Government of

India, & National Leprosy Elimination Programme (NLEP); Representatives of the World Health Organization, (WHO), South-east Asian region, (SEARO) New Delhi; Indian Association of Leprologists (IAL); Indian Association of Dermatologists, Venereologists and Leprologists (IADVL); IADVL Academy; The Leprosy Mission (TLM); Bombay Leprosy Project (BLP); Central Leprosy Training & Research Institute (CLTRI) Chennai; JALMA Agra; Lepra Society; Foundation for Medical Research (FMR) Mumbai; Talwar Research Foundation; Association for People Affected by Leprosy (APAL); Emmaus Swiss foundation; AIFO; Sivananda Rehabilitation Home (SRH) Hyderabad; SIG leprosy of IADVL; and other organisations working in the field of leprosy.

Opening Remarks

4. Dr. Ramesh Bhat, President of IADVL and Dr. Rathindra Nath Dutta, President of IAL formally inaugurated the symposium and welcomed the participants from all the major stake holders in leprosy in the country. They reiterated the need and timing for such a symposium and expressed their desire to see the objectives achieved. They highlighted the need for co-operation among IADVL, IAL and all agencies working in leprosy to join hands and fulfill the goal of leprosy elimination and a leprosy-free India. Dr Sujai Suneetha read out the names of each participant and the representing organizations.

Structure of the Symposium

5. Dr. P Narasimha Rao, President-Elect, IADVL presented an overview of the goals, objectives and structure of the symposium. He explained that the scope of discussion was focused on three specific topics of 1) Uniform MDT (UMDT); 2) Single Dose Rifampicin (SDR) as chemoprophylaxis; and 3) Use of MIP vaccine as Immunoprophylaxis in leprosy. He mentioned that the design of the symposium was to have a plenary talk on each of the topics, followed by 2-3 short perspectives on the issues. (Annexure-2) This was to be followed by a 30-45 minute open forum discussion on the topic by a panel consisting of the chairpersons, speakers and a few experts with inputs from the floor. The talks and panel discussion would be recorded by rapporteurs who would capture the key points of the discussion. Dr Rao reminded the members to keep the discussion focused and outcome oriented.

A. Session 1 – Uniform MDT (UMDT)

Chairpersons: Dr. Ramesh Bhat, President IADVL & Dr. Anil Kumar, DDG leprosy

Overview of topic: Dr. Kiran Katoch

View point: Dr. E Cooreman of WHO and Dr. MD Gupte

Panel Discussion:

Moderator: Dr. P Narasimha Rao

Panellists: Chairpersons, Speakers, Dr Vanaja Shetty, Dr V Ramesh, and Dr M Ebenezer

Rapporteur: Dr. Joydeepa Darlong

- **Dr. Kiran Katoch** gave an overview of Uniform MDT. She presented data from the UMDT study carried out in India (Manickam et al 2016, 2018) and touched upon other work done on UMDT in other parts of the world.
- She mentioned that the inclusion of clofazimine as a third drug in PB leprosy patients resulted in better short and long term treatment outcomes; beneficial effect in preventing type 1 reactions/neuritis; was acceptable; and that the side effect of pigmentation was reversible and short lived (Katoch K et al 1999).
- In MB leprosy the short period of 5 years follow up with regard to evaluating relapse and both type 1 and type 2 reactions; the non

inclusion of the pure neural group; absence of skin smears or any other lab parameter to assess improvement/relapse; and lack of a control arm in the study were mentioned as a limitation.

- In conclusion, she mentioned that in PB leprosy a 3 drug regimen that included clofazimine was valuable because of the low relapse rates, minimal adverse drug reactions, high adherence, acceptability and operational ease of implementation. In MB patients she concluded that the data is insufficient to say that the MB regimen can be shortened to 6 months.
- She advocated for the inclusion of Clofazimine to the present 2 drug 6-month PB regimen and continuation of the present 3-drug 12 month MB regimen for MB patients in the national programme with a long term follow up strategy that combined clinical and laboratory tools to monitor effectiveness.

Dr E. Cooreman presented the WHO viewpoint on U-MDT. In his introduction he mentioned that in the past, WHO guidelines were drafted by an expert committee but presently, the *GRADE* method is used to develop new treatment guidelines, which is evidence based, transparent and public health oriented. He mentioned that based on a grading of recommendations, assessment, development and evaluation, new WHO guidelines for treatment of leprosy were developed and approved in 2018 (http://www.searo.who.int/entity/global_leprosy_programme/approved-guidelines-leprosy-executives-summary.pdf) which advocates a 3-drug regimen containing clofazimine for both PB and MB leprosy for 6 and 12 months respectively.

- While advocating for a single regimen for all of leprosy he mentioned the pitfalls in differentiating leprosy into PB and MB classes in the present context of limited diagnosing skills in the field. He also cited the higher relapse rate after PB treatment with 2 drugs compared to MB treatment with 3 drugs as another reason to move to a three drug regimen. He gave a detailed view of the outcomes, risk of bias, effects and quality of the various studies on UMDT and concluded that the evidence is not without in consistencies. In addition, he mentioned that the only available randomized control trial (RCT) found a potential association between shorter duration of treatment for MB leprosy and increased risk of relapse. He further mentioned that the use of U-MDT of 6 months for all leprosy patients, probably leads to increased equity; that the acceptability varies; that there is no evidence on its cost-effectiveness; and that the certainty of evidence of efficacy is low.
- He concluded that for PB leprosy, changing to a 3-drug regimen with a duration of 6 months might be associated with improved clinical outcomes and potential advantages with regard to implementation in the field, and for MB leprosy, that there is insufficient evidence to recommend a decrease in the duration of the current 3-drug regimen from 12 to 6 months. He advocated, based on WHO recent recommendations, the use of a 3-drug regimen with Rifampicin, Dapsone and Clofazimine for all patients with leprosy, with a duration of treatment of 6 months for PB leprosy and of 12 months for MB leprosy.

Dr. MD Gupte who was involved in the UMDT study in India also presented a brief viewpoint. He said that since the incidence of smear positivity is low (<5%) in a majority of cases a shorter regimen would be adequate to manage > 95% of the patients. He said that in non RCT clinical trials, the Robins criteria are used and that further data on the UMDT study would soon be available.

Panel discussion:

Dr P Narasimha Rao moderated the panel discussion. He outlined the both the proposals – a) UMDT of three drugs for 6 months for all types of leprosy; b) and three drugs for 6 months in PB and one year in MB leprosy. He mentioned that there is no evidence that the current PB regimen of two drugs is failing, and questioned the need for 3 drugs for PB patients. During the discussion following opinions were expressed.

I. **Dr Anil Kumar**, DDG (Leprosy), GOI, stated that the implementation of 6-month Uniform MDT for all leprosy patients is not being considered currently by NLEP in India. However, due to implementation of U-MDT in Brazil, we must continue research work in India to generate evidence on efficacy and limitation of UMDT should India consider implementation at a later date.

II. The first issue discussed by the expert panel was the safety of clofazimine as a third drug in PB leprosy. Two concerns were raised regarding the safety of clofazimine – one was the skin pigmentation and the second was the concern about its drug interaction with Dapsone resulting in anaemia as seen in a study in Brazil. Since the pigmentation is short lived and reversible it is considered as of lesser concern. Its use in pregnant women causes skin discoloration of babies. Dr. Dharmashaktu cautioned that it could lead to operational concerns in unmarried girls and fair skinned individuals. Dr. Cooreman said that we must look for benefits that outweigh the harm.

III. The second issue discussed was on the value of adding clofazimine in a PB regimen. Based on the observation that relapses were higher with a two drug regimen than with a three drug regimen it was felt that the addition of clofazimine would reduce relapses in PB leprosy. From a transmission point of view it was felt that three drugs would further reduce transmission in PB leprosy.

IV. The value of clofazimine has been established in type 2 reactions (T2R). One of its beneficial roles observed was also in treating and preventing type 1 reactions (T1R) and potential disability. Some members mentioned that it is of some value in mild T1R in general and in persistent T1R in face lesions and neuritis. However, other members argued that there is insufficient evidence of its benefit in T1R from studies and that more work needs to be done to establish its value in T1R. Moreover, it was opined that the immunological basis of a T1R differs from that of a T2R and the value of clofazimine in T1R needs to be established beyond doubt.

V. Concerns were also raised about the clofazimine pigmentation resulting in reduced adherence in PB leprosy. Dr. Cooremen mentioned that there is no such evidence and is therefore of little concern. The aspect of pigmentation revealing the diagnosis of leprosy in an individual and the stigma associated with it was also discussed. Dr. Anil Kumar mentioned that the issue of stigma is being addressed in India through IEC activities and stigma is steadily on a decline.

VI. It was stated that the option of choosing to add/ opt for clofazimine or not in PB leprosy has been included in the new WHO guidelines. Once these guidelines are accepted for implementation, they need to be widely communicated to program managers. Health education and counselling should be an important part of the program to discuss the value and side effects of the third drug in PB leprosy patients and used accordingly.

VII. The next point of discussion was the possible implementation of 6-month UMDT of in MB leprosy. Since this is not in the immediate plan or in active consideration, it was not discussed extensively. The need was felt however to continue to carry out research studies and to gather evidence in favour of or otherwise. There is a split in opinion in Brazil where UMDT has been proposed to be implemented and the WHO is standing in support of the Governments decision and is watching the implementation unfold. Two specific concerns were raised regarding UMDT in MB leprosy - the absence of slit skin smear (SSS) in the diagnosis and management in the Government program and the increased risk of leprosy transmission with a 6 months regimen. Dr Anil Kumar mentioned that SSS would be reintroduced as a part of evaluating MB leprosy patients and relapse patients in NLEP.

Conclusion and recommendation:

a. On the whole, the panel members endorsed the recommendations of WHO to the use of uniform 3 drug regimen for both PB and MB leprosy, but for different durations of 6 and 12 months respectively. It was felt that acceptance of clofazimine by Indian patients by and large is very good. Nonetheless, in special cases, two drug regimens can always be considered for PB patients, who do not accept/ tolerate clofazimine. Shortening of duration of treatment for MB leprosy was not accepted.

b. The panel discussion ended with a brief discussion on the use of alternate drugs like Ofloxacin, Moxifloxacin, Clarithromycin etc. and the need to develop alternate regimens in special populations/needs. Although the recommendation is to use the three mainline drugs it was felt that other drugs can be used on a case to case need. It was felt that IADVL will adhere to NLEP on the use of the mainline drugs but will design studies to study other regimens and develop guidelines for difficult/special situations in leprosy like relapse, drug resistance and high BI patients.

c. The idea of forming a think tank involving IADVL, IAL, ICMR and NLEP to plan future research studies was considered.

B. Session 2 – Single Dose Rifampicin (SDR)

Chairpersons: Dr. Rathindra N Dutta and Dr. Vineet Kumar Chadha

Overview of topic: Dr. Hemanth K Kar

View point: Dr. Anil Kumar and Dr. RR Pemmaraju

Panel Discussion:

Moderator: Dr. Sujai Suneetha

Panellists: Chairpersons, Speakers, Dr Vivek V Pai, Dr. Rashmi Shukla, Dr. Mary Verghese and Dr. Santosh Rathod

Rapporteur: Dr. Mrudula Save

Dr. Hemanth K Kar presented an overview on Single Dose Rifampicin (SDR). He said that Rifampicin is a strongly bactericidal drug and a single dose could kill around 90% of the bacteria. However as it kills only multiplying bacteria, and owing to the long doubling time of *M. leprae,* some of the bacilli may evade the drug and could result in a subclinical infection that may self heal or require a second dose of Rifampicin.

Presenting a few salient points from the study of SDR conducted in Bangladesh he said that a 57% decrease in incidence of leprosy was observed in the first year and that it conferred protection from active leprosy for 2 yrs, beyond which it failed to show significant benefit. Interestingly, better protection was observed in the neighbouring contacts as compared to the close familial contacts.

He also mentioned the study carried out in Indonesia where two doses of SDR were given at 3 months interval to the whole population in an area; which conferred a 50% protection for 2 yrs with no protection from the disease beyond 4-5 years. From these two studies he concluded that SDR could offer only short term protection from leprosy.

Discussing the risk of Rifampicin resistance with SDR he said it was a very low probability in contacts harbouring very few bacilli. However, in those with subclinical infection with a higher bacterial load, repeated doses of Rifampicin, he said could result in drug resistance. In this context he also discussed the pros and cons of use of individual drugs and use of multidrug chemoprophylaxis with higher bactericidal activities. He said that the effects of chemoprophylaxis with ROM and SDR were comparable. As alternative regimens he suggested the use of combination of Rifapentine & Moxifloxacin or Rifamycin & Clarithromycin as Enhanced Post Exposure Prophylaxis (PEP++).

Dr. Anil Kumar, DDG leprosy gave an overview on 'Post exposure prophylaxis under the National Leprosy Eradication Programme. He mentioned that the NLEP recommends the use of Single Dose Rifampicin (SDR) in the chemoprophylaxis of leprosy in contacts of leprosy patients (in adults and in children 2 years of age and above), after excluding leprosy and TB in the contact, and in the absence of other contraindications. This intervention is to be implemented by programmes that can ensure: (i) adequate management of contacts and (ii) consent of the index case to disclose his/her disease.

Outlining the need and basis for chemoprophylaxis in leprosy he said that SDR targets infected individuals during the incubation period and results in preventing leprosy in the contact as well as decrease the load of *M. leprae* in the community. This in turn results in a decrease in the incidence of leprosy in the community in a short span of time. He mentioned the use of SDR in 163 districts in the country where LCDC was conducted in 2016 and the expected benefit in preventing leprosy in the contacts and interrupting transmission. He mentioned that NLEP is considering widespread implementation of SDR as a prophylaxis tool in India.

Dr. Pemmaraju presented the WHO viewpoint on SDR Chemoprophylaxis. He said that SDR has the dual benefit of reducing leprosy and improving contact tracing. He said there is no data contraindicating its use but the social implications of disclosure of disease need to be evaluated. He also outlined the resources required, cost effectiveness and acceptability of SDR in the general population.

Panel discussion:

Dr Sujai Suneetha moderated the panel discussion.

I. The first issue discussed was on the efficacy of SDR as a chemoprophylactic agent.

   The COLEP study which is the largest study on the use of SDR was discussed and some of the points highlighted were:

   i. The overall protection afforded with SDR ranges from 50 - 60%;
   ii. The effect lasts for 2 years beyond which it drops to 30% in 5 years;
   iii. It mainly protects against PB and not against MB leprosy;
   iv. It does not protect children or the immediate family contacts and neighbours;
   v. It protects distant social contacts; and
   vi. Repeat doses may be required for long term protection.

Other general points raised were:

i. Rifampicin kills about 90% of *M leprae* with a single dose;

ii. It only kills actively multiplying bacteria (so dormant bacteria evade killing);

iii. At any given time only about 30% of the bacteria are actively multiplying;

iv. In other words, 90% of the 30% actively multiplying bacteria are killed.

v. SDR in effect may result in a delay in the onset of leprosy.

vi. The cost effectiveness of SDR should be worked out in an Indian context - single dose, repeated doses, in contacts alone and also blanket implementation in high-endemic areas.

II. The second issue discussed was whether SDR could induce drug resistance. Some of the points discussed were:

i. In general, the risk of drug resistance with a single dose of Rifampicin is low.

ii. Repeated doses of SDR could lead to development of resistance especially in high endemic pockets.

iii. In the likelihood of subclinical infection with tuberculosis (or leprosy) the risk of resistance is higher if it repeated. Screening of contacts with skin smears and for TB prior to SDR could be an option.

iv. Early diagnosis and treatment of the index case coupled with proper contacts tracing and characterisation of contacts before administering SDR can effectively prevent leprosy and circumvent the development of resistance.

v. Rifampicin once a month (for 6 doses) is being used along with Dapsone in treating PB leprosy all over world with no reports of MDR. The sporadic cases of Rifampicin resistance has more to do with issues such as compliance.

III. The drug quality of Rifampicin was discussed as an important issue for the success of SDR chemoprophylaxis and that it should be strictly monitored. States can procure it from the centre i.e. WHO/NLEP who can ensure stringent quality control. Centralising supply to a single company like Novartis can be an option.

IV. The social implications of SDR were discussed.

i. It was felt that with the identification of the index case in the community and use of SDR in contacts could potentially lead to stigma and discrimination by the extended family, neighbours and the community. This should be kept in mind and handled carefully.

ii. Consent of the index case and his/her contacts is considered important and should be obtained before administering SDR prophylaxis to the contacts. DDG (Leprosy) mentioned that NLEP is following these precautions already.

iii. Better awareness about the disease could also address this concern.

Conclusion and recommendation:

I. The incidence of leprosy in India is occurring in pockets with multiple cases occurring in a single household and in the surrounding community. SDR has the potential to prevent leprosy in the contacts and interrupt transmission.

II. An additional benefit is that household contacts of leprosy patients who are at highest risk of developing leprosy can be examined for leprosy. This is a good public

health intervention where new cases can be identified and treated early.

III. There is concern that SDR protects against only some forms of leprosy (PB only); that it unlikely to interrupt transmission; that it affords significant protection only for 2 years after which it has very little effect; that it may result in a delayed diagnosis of the disease; and that it could induce drug resistance.

IV. Although drug resistance with SDR is not considered a major concern, its use in people who may have concurrent latent or fully manifest TB infections should be with caution.

V. Confidentiality of the index case and his/her family is a key concern and should be closely guarded to prevent issues of stigma and discrimination.

VI. Availability and stringent quality assurance of Rifampicin is paramount for the success of the strategy.

VII. Very stringent surveillance protocols and carefully planned outcome indicators are required to generate meaningful data on the short and long term value of SDR strategy.

C. Session 3 – Immunotherapy & Immunoprophylaxis of Leprosy

Chairpersons: Dr. VM Katoch and Dr. Umashankar Nagaraju

Invited Talk: Dr. GP Talwar

Overview of topic: Dr. Archana Singal

View point: Dr. Utpal Sengupta and Dr. MD Gupte

Panel Discussion:

Moderator: Dr. Tarun Narang

Panellists: Chairpersons, Speakers, Dr. Kiran Katoch, Dr. Loretta Das & Dr. Aparna A

Rapporteur: Dr. Santhosh Rathod

- **Dr. GP Talwar** gave a special invited talk titled 'Immunoprophylaxis with *Mycobacterium indicus pranii* (MIP)'. The summary is as follows:
- Formerly named *Mycobacterium w*, MIP is a non pathogenic environmental mycobacteria, undescribed taxonomically in the past but now given the name and patented as *'Mycobacterium indicus pranii (MIP)'* attributing credit to Dr Pran Talwar who carried out extensive work on it. MIP has received approval from the Drug Controller General of India (DCGI) and internationally from the USFDA. MIP is an injectable immunomodulatory agent which has been found in studies to convert lepromin negative individuals to lepromin positivity. It has also been found to produce a quick fall in BI in skin smears and in skin biopsies in MB leprosy patients. In a study in household contacts of leprosy patients it produced lepromin conversion of 82% of the contacts with the first dose and with 98.5% of them converting with a second dose. MIP has also found value as a immunotherapeutic agent in Category II tuberculosis where it produced better cure and a reduction in relapse. Dr Talwar in conclusion outlined the following benefits of MIP vaccination and recommended its inclusion in the national strategy to address leprosy in India:

  i. Lepromin conversion from negative to positive (enhancing CMI);

  ii. Faster bacterial clearance;

  iii. Quicker granuloma clearance;

  iv. Shorter recovery time;

  v. Reducing lepra reactions (severity & frequency); and

  vi. Quicker cure in slow responders.

- **Dr. Archana Singhal** gave an overview of Immunoprophylaxis in leprosy. As an introduction she highlighted the inadequacies of using only a chemotherapeutic approach:
    i. MDT has had little effect on reducing the annual incidence of new cases as it does not confer long term immunity;
    ii. Relapse rates of 16 to 39% among MB pts with high BIs are appearing 4 to 10 years after 2-yrs MDT;
    iii. Relative long duration of treatment schedules;
    iv. Poor adherence to treatment regimens;
    v. Persistence of disease activity after stoppage of therapy;
    vi. Occurrence of reactions and nerve damage during and after therapy; and
    vii. The problem of persister organisms and slow clearance of disease.

While advocating for a vaccine strategy she enumerated the benefits of a vaccine strategy:

Used in a Prophylactic (pre-exposure) role

i. It produces a relatively long-lived immunological memory conferring recipients immediate as well as extended protection from infection;
ii. Protects against both drug-susceptible and drug-resistant strains, helping curb the emergence of drug resistance

Used in a Immunotherapeutic role it could improve a patient's response to multidrug therapy

iii. By hastening a cure
iv. Reducing the incidence and severity of the infection and of lepra reactions;
v. Reducing the incidence of relapse through killing of persister organisms;
vi. Expedite clearance of dead bacilli;
vii. Induce cellular responses even in patients with high BI without exacerbating disease; and
viii. Interrupts transmission of disease in the community.

Dr. Singhal also described the other vaccines studied in leprosy and briefly outlined their role. These included *Mycobacterium bovis* (BCG); killed *M leprae*; BCG + killed *M. leprae;* ICRC bacillus; and *Mycobacterium vaccae.* In conclusion she said that in view of the several advantages of MIP and as it has been approved by the DCGI, the Government can take it up as a vaccine in a well-defined high risk group of close contacts of an index case as a priority. Considering its value as an Immuno-therapeutic agent it can be used to supplement MDT in all newly diagnosed cases in the country while ensuring its availability. She also added that it may not be cost-effective if applied universally to stop transmission, as leprosy is a low incidence disease.

Dr. Utpal Sengupta presented a perspective on the 'Immunoprophylaxis in leprosy' in which he explained the immunological basis for a vaccine in leprosy. He outlined the value of a primary approach using vaccines to create active immunity in the population to prevent leprosy, over a secondary approach of treatment alone. He gave an overview of the various vaccines available but went on to say that at present we do not have a vaccine that is specific for *M. leprae*. He mentioned that the Phase I human clinical trial of a new vaccine 'LepVax', a leprosy-specific vaccine is beginning this year (which is funded by various health agencies of USA including TLM) and may reveal if it is a better candidate vaccine than BCG, killed *M leprae* or *MIP*.

Panel discussion:

The panel discussion was moderated by Dr. Tarun Narang. The first topic discussed was whether there was a need for a vaccine in leprosy.

I. The panellists agreed that there was a definite need for a vaccine both for Immunoprophylaxis and for immunotherapy in leprosy and advocated the inclusion of MIP in the national program.

II. Dr. Anil Kumar suggested that it could be implemented as a 'blanket approach' in a pre-identified high endemic area to establish its efficacy.

III. Some of the members, however, felt that there is no further need to study the efficacy of MIP again and that it should be implemented as early as possible and if implemented it could prevent 2/3rd of future cases and prevent disabilities due to leprosy.

IV. The members expressed the need to identify 'Biomarkers' to assess the efficacy of the vaccine. It was recommended that institutions in the country should conduct studies to evaluate the identified Biomarkers of other immunological tools/parameter to assess the efficacy of MIP vaccine.

The second issue was on what the ideal dosing schedule of the vaccine should be.

V. It was felt that the need of the hour is to standardize the dose, duration and interval of vaccination.

VI. The dosing schedule suggested was the use of one booster dose after 5 years at least.

VII. The issue of cost and availability of vaccine was discussed by the panel. There were concerns raised by many members that the vaccine is not available in the open market although Cadila Pharma is manufacturing it in India and marketing it at present. Assurance was sought by some of the panellists and members from health authorities to make it available for a wider use.

VIII. Concerns were also raised about the high cost of the presently available Immuvac (MiP) vaccine in India. The vaccine is now available at very high price as it is being almost exclusively prescribed for use in malignant conditions like myeloma and lung cancers. The members opined that for its use in leprosy it should be reasonably priced by requesting the manufacturer to lower the price.

The aspects of side effects of the vaccine were discussed.

IX. Concerns were raise that there is an increased incidence of T1R with MIP. Members expressed that there is more adverse effects observed with BCG than with MIP vaccine and there was no increase in Type 2 Lepra Reactions and also no increased nerve damage due to MIP.

Conclusion and recommendation

I. All panellists agreed on the need of MIP Immunoprophylaxis to be included in the national program at the earliest. Dr. Anil Kumar, DDGI suggested to implement its use as a 'blanket approach' in a pre-identified high endemic area to know its efficacy.

II. All experts felt and strongly opined that there is no further need to study its efficacy again and it should be implemented as early as possible. It was opined that immune-prophylaxis implemented now can prevent 2/3rd of future cases and deformities.

III. Dosing: Experts advocated use of one booster dose after 5 years at least.

IV. Adverse effects: Experts opined that increased incidence of T1R is more with BCG than MIP vaccine with no increase in Type 2 Lepra Reactions. There also no increased nerve damage due to MIP.

V. Cost and availability of the vaccine: Experts suggested that cost of Immuvac (MIP) vaccine available for use in India at present is very high and felt the need to make it more economical/less costly for wider use in leprosy. Most experts expressed difficulty in procuring MIP vaccine as well. The need to work on these areas was suggested.

VI. Research priorities:

a. Need to identify Biomarkers of Efficacy: Experts strongly urged the institutions in country to conduct studies for evaluation of Biomarker tool/parameter to assess the efficacy of various interventions.

b. Panel also urged IADVL, IAL and other NGOs to support the current aggressive strategy of Government to tackle Leprosy by complementing with conduction of required research work.

c. An Idea was mooted to conduct a study on use at MIP vaccine at 'Lakshadweep' island which has high prevalence of leprosy, both to patients and contacts and plan for a long term follow-up of the whole population. Both IADVL and IAL volunteered to be part of the proposed study, if it is to be taken up by NLEP. Dr Anil Kumar DDG (Leprosy) agreed in principle to the Idea and stated that a proper format has to be designed first to pursue it further.

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Annexure: 1

List of Participants

1. **IADVL**
   - Dr. Ramesh Bhat, President
   - Dr. P Narasimha Rao, President Elect
   - Dr. Yogesh Marfatia, Past President
   - Dr. Mukesh Girdhar, Vice President IADVL
   - Dr. Uma Shankar Nagaraju, Secretary General
   - Dr. Shashi Kumar, Treasurer

2. **IAL**
   - Dr. Rathindra Nath Dutta, President
   - Dr. Sunil Dogra, Vice President
   - Dr. Mrudula Save, General Secretary
   - Dr. Swapan Samantha, Past President, West Bengal

3. **NLEP (CLD)**
   - Dr. Anil Kumar, DDG Leprosy Government of India
   - Dr Rupali Roy, DADG (Leprosy)
   - Dr. Sunil D. Khaparde, Advisor, DGHS, Govt of India

4. **WHO (South-East Asian region)**
   - Dr. E Coorman, Team Leader, Global Leprosy Programme, Delhi
   - Dr. RR Pemmaraju, WHO Delhi

5. **The Leprosy Mission**
   - Dr. Mary Verghese, Director
   - Dr. Joydeepa Dorlong, Research Coordinator
   - Dr. Lorretta Das, TLM, Naini
   - Dr. Utpal Sengupta, Director SBL Labs

6. **Bombay Leprosy Project (BLP)**
   - Dr. V.V Pai, Director

7. **Foundation for Medical Research, Mumbai (FMR)**
   - Dr. Vanaja Shetty, Director

8. **LEPRA Society**
   - Dr. Aparna B, Head of Research, LEPRA Society, Hyderabad
   - Mr. Sathiraju, Senior NMA
   - Dr. Rajni Kant Singh, State Coordinator, Lepra Society, Delhi

9. **National JALMA Inst for Leprosy & OMD (ICMR), AGRA**
   - Dr. VM Katoch, Former Director JALMA and Former Director General ICMR & Secretary Department of Health Research, MoHFW, Govt of India
   - Dr. Kiran Katoch, Former Director, National JALMA Institute (NJIL & OMD)
   - Dr. UD Gupta, Former Director-in Charge, NJIL & OMD, Agra
   - Dr. Beenu Joshi, Scientist G, NJIL & OMD, Agra

10. **CLTRI**
    - Dr. Vineet Kumar Chadha, Director CLTRI
    - Dr. T. Pugazhenthan, Medical Officer

11. **Sivananda Rehabilitation Home, Hyderabad**
    - Dr. Ananth Reddy, Chief Medical Officer

12. **GP Talwar Research Foundation**
    - Dr. GP Talwar, Director

13. Association for People Affected by Leprosy (APAL)

Mr. Narsappa, President, APAL

14. GLRA

Mr. Vivek Srivastava, Chief Executive Officer

15. National institution of Epidemiology

Dr. MD Gupte, ICMR Chair in Epidemiology, Pune

16. IADVL Academy of Dermatology

Dr. KA Seetharam, Chairperson, IADVL Academy

Dr. Deepika Pandhi, Convenor, IADVL Academy

Dr. Sujai Suneetha, Coordinator, SIG leprosy

Dr. Santosh Rathod, Convenor SIG Leprosy

Dr. Vikas Shankar, Member, SIG leprosy

17. Senior Faculty of Medical Colleges

Dr. VK Sharma, AIIMS, New Delhi

Dr. Tarun Narang, PGIMER, Chandigarh

Dr. V Ramesh, Safdarjung Hospital, New Delhi

Dr. Hemant K Kar, New Delhi

Dr. Archana Singal, UCMS, New Delhi

Dr. Rashmi Sarkar, Maulana Azad Medical College, New Delhi

Dr. Neena Khanna, AIIMS, New Delhi

Dr. Binod Khaitan, AIIMS, New Delhi

Dr. Pushpendra Singh, University of Baroda

18. Swiss Emmaus India

Dr. John Kurian George

19. Special Invitees

Dr. Mannam Ebenezer, Former Director, SLTRC Karigiri

Dr. Dharmshaktu, Former DDGL, Govt. of India