GUIDELINES FOR THE TREATMENT AND PREVENTION OF CUTANEOUS LEISHMANIASIS IN PAKISTAN

Ministry of Health
The World Health Organization
Health Net International

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Acknowledgements

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Islamabad
14 August 2002
Introduction

Leishmaniasis incidence is influenced by a complex of environmental and socio-economic conditions. The recent outbreaks of Cutaneous Leishmaniasis in the Federally Administered Tribal Area (FATA) (Oct. 2001) adjacent to Afghanistan and in the districts of Dadu and Larkana (Dec. 2001 to Feb. 2002) in the Sindh province have followed droughts (1998-2001) and population displacements (Afghan war and conflicts, 1980-2001) in the region. Considering the size and nature of these outbreaks, WHO mobilized its health emergency response set-up in Pakistan to promptly control these outbreaks. WHO together with the Federal Ministry of Health and provincial health departments responded to these epidemics by first confirming and quantifying the outbreaks and then taking prompt actions to control them.

Although these guidelines for the treatment and prevention of Cutaneous Leishmaniasis have been used in various workshops conducted jointly by WHO and MoH to train the Cutaneous Leishmaniasis treating physicians and public health officials in both NWFP and Sindh, a wider distribution of these guidelines in Pakistan and for that matter in the neighboring countries is highly needed. Given the rising incidence of this disease in the region along with the recent advancement in knowledge of how to manage the various forms of Cutaneous Leishmaniasis cases, the compilation and publication of this concise and up-to-date guide was considered. We are confident that the distribution and usage of this publication will improve Cutaneous Leishmaniasis case management, prevention and epidemic control.

1. LEISHMANIASIS

The Leishmaniases are a group of parasitic diseases caused by morphologically similar parasites in the genus Leishmania (Order Kinetoplastida, Family Trypanosomatidae) and transmitted by the bite of Phlebotomine Sandflies. The disease is transmitted by the bite of infected Phlebotomine Sandfly (about 23 mm long), which becomes infected by taking blood meal from infected mammalian host. A total of about 30 species in Phlebotomus genus (old world) and Lutzomyia genus (new world) have been identified as vectors. Sandflies are relatively weak, noiseless fliers; they rest in dark, moist places, and are typically most active in evening and at night-time hours.

Globally, wide-spread disease with multifaceted clinical manifestations, the Leishmaniases can be broadly separated into two epidemiological categories:

Cutaneous Leishmaniasis cases from Faidabad, Dadu (Jan. 2002)
1) Anthroponotic, with man as the source of infection and transmission occurring mainly in settled communities, or
2) Zoonotic, with domestic or wild animals as the main source of infection. Clinically the disease occurs in several forms, ranging from simple cutaneous ulcers (e.g. caused by *Leishmania major*) through disfiguring mucocutaneous form (caused by *Leishmania braziliensis*) to fatal visceral infection (caused by for example *Leishmania donovani*). Although clinical manifestations in the man had been the principal criterion on which the disease and its epidemiology was studied, with the use of sophisticated biochemical methods for identifying the parasites, it was found that clinical criteria were not always reliable predictors of the infecting parasite and now the key to studying the disease is the accurate identification of the parasites (Lane, 1993). To date, some 21 species of *Leishmania* are known to be pathogenic to humans.

1.1. Disease incidence
Leishmaniasis has been considered to be a serious public health problem in many countries of the world and is responsible for adverse economic and social impact. The disease is documented to be currently prevalent in 88 countries around the world, 72 of which are developing countries. The annual incidence is estimated at some 600 thousand new clinical cases, officially reported, with a global prevalence of 12 million cases and a population at risk of approximately 350 millions (Desjeux, 1992). It is documented that 90% of all visceral Leishmaniasis cases occur in Bangladesh, Brazil, India, Nepal and Sudan; 90% of Cutaneous Leishmaniasis cases occur in Afghanistan, Brazil, Iran, Saudi Arabia, and 90% of all muco-cutaneous Leishmaniasis cases occur in Bolivia, Brazil and Peru.

In northeastern India (particularly the state of Bihar), epidemics of anthroponotic Kala-azar caused by *L. donovani* flared up in the 1970s, probably in part because of cessation of insecticide spraying for malaria, and during some years still generate an estimated 200,000 or more cases. In southern Sudan, which has been affected by civil war, an epidemic of *L. donovani* infection occurred in a remote area not previously considered endemic for Kala azar infection. The epidemic first reported in 1988 continued into the 1990s. According to some estimates the excess mortality has been about 100,000 deaths among about 300,000 people at risk. An epidemic of anthroponotic *L. tropica* infection in another war-affected area, Kabul, Afghanistan, shows that Leishmaniasis is not limited to rural areas and that even Cutaneous Leishmaniasis can occur on a large scale, with hundreds of thousands of cases, and can be personally and socially disruptive. Northeastern Brazil is another example of a region where Leishmaniasis is encroaching on urban areas.
1.2 Leishmaniasis in Pakistan
Three types of Leishmaniasis are prevalent in Pakistan. Zoonotic Cutaneous Leishmaniasis is mainly prevalent in the south-western region, Anthroponotic Cutaneous Leishmaniasis in central region and visceral Leishmaniasis in the north-eastern region. The later is mainly endemic in Northern Areas and Azad Kashmir. The disease status up to 1986 has been reviewed by Munir et al., (1989).

2. DIAGNOSIS
Basically the only diagnostic test available in OPD/clinics is the examination of tissue from the active margin of a lesion with high power microscopy (under oil immersion). Another method is by culturing the parasites on NNN medium and by PCR. But these facilities are available only in the specialized laboratories.

3. THE TREATMENT
3.1 The treatment of Cutaneous Leishmaniasis (CL) is not altogether satisfactory. There is a need for an effective topical oral preparation; a large number of compounds have been tested, but as yet none has proved satisfactory. Therefore, current treatment is confined to the injection of Pentavalent antimony drugs. These have been in use for a long time, although their exact mode of action against Leishmania is not known.

3.2 The 3 equally good antimony preparations available are:

- Glucantime (meglumine antimoniate) made in France, containing 85-mg/ml antimony.
- Pentostam (Sodium Stibogluconate) made in England, containing 100mg/ml antimony.
- Sodium stibogluconate (chemically the same as Pentostam) produced in India, containing 100-mg/ml antimony.

3.3 Ineffective treatment, either due to inadequate dose or poor technique, is positively harmful. It is important to note that partial treatment may cause drug resistance. Since the drug is expensive, it is therefore
necessary to make the right decision regarding the treatment of CL.

3.4 Two questions need to be answered when considering treatment

a) **Should the patient be offered treatment?**

It is sometimes difficult to decide whether to treat or not. The answer will depend on many factors including the wishes of the patient or family, their ability to co-operate, the position, stage and severity of disease and the availability of drugs. In addition, the treatment of a large proportion of cases in an area will reduce the spread of the disease, so there is a public health component to the decisions.

- Lesions that are judged to be inactive (without raised margins) are usually healing spontaneously and should be left alone. This can apply to lesions that still look large and unpleasant. The patient can be reassured, and seen in 1-month time to check that the lesion is healing.
- Safe and effective intra-lesional treatment is sometimes impossible with a strong child who resists. It is usually best to accept defeat early on, and then it should be decided whether to proceed to intramuscular treatment (which is nearly always possible) or to leave the child untreated.
- Early and nodular lesions are often easier to treat intralesionally, and treatment may prevent the development of more severe disease.
- If drugs are in short supply, then cases need to be prioritized for treatment.

Using the above considerations, the following notes can be used as a guide. However, it must be stressed that this is only a guide and a clinical decision must be taken.
i. The cases usually accepted for treatment

- All cases judged to be severe enough to justify systemic treatment.
- Lesions of the face, especially of women.
- Large lesions, which are still active (have a raised edge).
- Early (usually nodular) lesions, where treatment may prevent the lesion enlarging.
- Lesions which are lying over a joint (e.g. wrist, fingers or ankle).
- Lesions, which cause a loss of function (e.g. on the fingers or toes).
- Chronic (Intra-Muscular Lupoid) lesions.

Taking impression smear slide from CL lesion (Faridabad, Dadu, Jan. 2002).

ii. The cases not usually accepted for treatment

- Lesions of the arms or legs which are not causing a problem.
- Lesions with a flat margin which are probably healing.
- Small lesions of more than 6 months duration, especially of the hand or foot or side of face in man.
- A previous reaction or side-effective to treatment.

b) Should the patient have intra-lesional (local) or systemic (i.e) treatment?

i. Again, there are no easy rules and sometimes the decision can be hard. About 90% of cases can be successfully treated intralesionally. Since approximately 10-times more drug is needed for intramuscular treatment, this decision may be partly based on drug availability. Intra-lesional treatment also requires fewer visits to the clinic/hospital and has lower risk of side effects,
although it requires more skill on the part of the doctor.

ii. Basically, patients should have intra-lesional treatment wherever possible, although it is pointless to try intra-lesional treatment for the more severe cases. The following guidelines should help to make the right decision:

a) Patients usually suitable for intra-lesional treatment

- Where lesions are small (<about 3-4-cm. diameter), even if they are multiple.
- Lesions where the surrounding tissue is fairly soft.
- Where the lesion is accessible and the patient is co-operative.

b) Patients usually suitable for intramuscular treatment

- Large (<5cm) diameter lesions.
- A large number of lesions.
- Lesions at the sites that are difficult to inject (e.g. some lesions affecting ears, eyelid, nose)

- Where there is lymphatic spread.
- Children who need treatment but cannot be restrained for intra-lesional treatment.

iii. Lupoid CL should always be treated. Even though the lesions are often large, only the active margin needs to be treated and this can be done intralesionally.

These lesions do not respond well to treatment, so up to 10 week intra-lesional treatments can be tried. If the lesion is not better after that, then a 3-week course of systemic treatment could be considered. Following this there seems a little point in giving more treatment.

4. **TREATMENT METHODS**

4.1. **Intralesional Treatment**

i. Intralesional treatment requires patience and skill, it cannot be rushed. The basic aim is to fill the
infected part of the dermis with Pentavalent antimony. This means carefully infiltrating the area around the lesion, including the base of the lesion, with a fine gauge (25g) needle and injecting the drug under pressure as the needle advances.

ii. Clean the skin carefully and mark out the area to be treated with the 'pen test' (above).

iii. It is best to approach the lesion at right angles as shown in the diagram, and to infiltrate in a v-shaped pattern, ending with advancing the needle into the base of the lesion.

The first treatment is usually the most difficult, and on the next visit the lesion is usually softer, making the injection easier.
iv. Treatment should be given every 5 to 7 days, for a total of between 2 and 5 times. If the lesion is not healing after 5 treatments, it should be reviewed in 1 month when a decision about to reverting to intra-muscular treatment should be made.

4.2. Some key point to remember

i. It is very important to inject into the dermis, not in the subcutaneous space. This mistake is very often seen at the treatment centers/clinics. If the drug is injected into the subcutaneous space it is rapidly absorbed and has no effect on the lesion at all.

ii. It is hard to inject into the dermis, the tissue space is small and the pressure on the syringe is high (by contrast, it is very easy to inject into the subcutaneous space). If it is hard to inject, then it is likely that the needle is in the right place! Sometimes the needle strays into the subcutaneous space (often recognized by a loss of pressure on the syringe) or the needle will pierce the skin and spray outwards. If this happens, no harm is done. It simply means that the needle tip is in the wrong place and the intra-dermal space must be found again.

iii. The whole of the lesion, including the base, must be thoroughly injected.

iv. The idea of a 'dose' does not exist in intra-lesional treatment; the amount of drug needed would vary a lot, although this is usually less than 5 ml. The point is to fill the lesion with drug, and the amount required would be determined by the size of the lesion, elasticity (softness) of the skin and the amount of drug that leaks into the subcutaneous space.

v. Sometime sites (especially ears, noses and fingers) can be difficult to inject because the skin is light and relatively inelastic. Often on the second treatment these become easier.

vi. Do not share needles of syringes between patients because potentially fatal infections such as hepatitis B or even HIV (AIDS) can be spread in this way. For the same reason, take due care not to prick yourself with the needle during the treatment.

4.3. Systemic (intra-muscular) treatment

i. The technique here is much simpler. The volume to be injected is relatively large and it is best to
inject into the upper, outer quadrant of the buttock, alternating sides. Injections have to be daily (with a break of one day for a week-end) for 14 days. If the response is poor by the 14th day, the treatment can be continued for a further 7 days.

ii. Below is a table showing the correct doses for Glucantime and Pentostam on a scale based on a simplified formula relating body weight to surface area (after Anabwani & Bryceson) whereby a 20 kg child receives 20 mg/ml of antimony:

<table>
<thead>
<tr>
<th>Nearest weight of patient (Kg.)</th>
<th>Recommended dose Pentostam (ml.)</th>
<th>Recommended dose Glucantime (ml.)</th>
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4.4. Outcome of treatment

i. Ulcerated lesions take some time to heal, particularly for the skin to re-grow. Therefore, complete healing may not be seen within a month of starting treatment, but the lesion should be flat and soft, indicating that healing is progressing (use the 'pen test'). It is important that treatment is not continued just because the healing skin has not yet covered the lesion; this can take several weeks. It is best to see that lesions are flat and soft by the end of treatment, and to review them 1 month later to check complete healing.

<table>
<thead>
<tr>
<th>Healing Cutaneous Leishmaniasis</th>
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<tbody>
<tr>
<td>Lesion observed by WHO-MoH/NIH team during the April 23 2002 visit, Jonani village, Larkana</td>
</tr>
</tbody>
</table>

ii. If after 1 month of finishing treatment an intralesional case has not healed, it may be worth trying 2 or 3 more local injections. If an intramuscular case has not healed, it is likely to be resistant to treatment and there is no point in giving any more treatment.

iii. If there is any doubt about what treatment to give, it is often useful to see patients after one month;
patients feel reassured and it will be possible to see if the lesion is improving or not.

4.5 Side Effects

In spite of what is written in some old textbooks, Pentavalent antimony is generally a safe drug. However, it can occasionally cause side effect, which should present no serious problem as long as they are correctly recognized and properly managed.

- There may be an anaphylactic response, and this can occur at any time during treatment. The signs are faintness, bradycardia, hypotension and wheezing. Sometimes there is an urticarial rash. If any of these occur the patient should be laid flat and given proper treatment. All clinics should have a kit of resuscitation drugs readily at hand. A patient who has had an anaphylactic reaction to pantavalent antimony should not be administered this drug any more.

- Pentavalent antimony can also cause renal or occasionally hepatic side-effects. If there is evidence of these either before or during treatment, the treatment should be stopped however, no special monitoring is required.

- Pentavalent antimony is mildly immunosuppressive. If the patient has a febrile illness, especially pulmonary TB, should not be treated.

5. CLINIC RECORDS

i. Good treatment requires maintaining of proper records; otherwise it is impossible to know the effect of treatment on the patient, or how the treatment centre/clinic as a whole is performing.

ii. The purpose of good records falls into 3 categories:

- To monitor the progress of individual patients.
- To monitor the general performance of the treatment centre/clinic.
- To provide reports of CL cases to public health authorities.
iii. Just as good clinical records are needed for individual patient care, so regular and accurate reports on cases treated are needed to plan health services and preventive strategies.

iv. For these reasons all treatment centres/clinics/OPD of hospitals should be provided with proper forms and records should be a valued part of the daily work.

6. **PREVENTION OF CL**

i. Prevention of ACL is very similar to malaria prevention, as sandflies bite at night and indoor (endophilic). Sandflies are generally more sensitive than mosquitoes to insecticides. So the main means of preventing ACL are residual spraying of indoor rooms, use of repellants and the use of impregnated bed nets.

ii. Treatment can have a preventive effect if enough cases are treated in an area, especially if they are treated early in the disease, because this would reduce reservoir of infection.

iii. Prevention of ZCL is quite different. Here the Sandfly vector (*P. papatasi*) tends to bite outdoors, so the use of insecticide is unlikely to work. The reservoir of infection is found amongst the burrowing rodents in areas around human habitation, and so the most effective strategy is the control of rodent reservoir.

7. **PROTECTIVE MEASURES AGAINST SANDFLY BITES**

1. Apply repellents on uncovered skin and under the ends of sleeves and pant legs.
   - Most effective repellents are those that contain 30-35% DEET (*N,N – Diethyl-3-tolumide*).
   - Repellents are effective for 4-6 hours.
   - Repellents with DEET should be used sparingly on children who are 2-6 years old.
   - Repellents should not be used on children less than 2 years old.

2. When out side, wear long sleeved shirts and ankle long pants/pajamas etc. and socks.

3. Tuck shirt under the pants.

4. Screening windows and doors.

5. Use Insecticides Treated Bed Nets (ITNs)
8. **FURTHER READINGS**


### LEISHMANIASIS RECORD O.P.D REGISTER

| Date | s.no | Full name | Age | Sex | No.of Leision | Clinical | Permanent | Present | Durati | Treate | Prov | Dis | Vill | Dis | Vill | IL | IM |
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|      |      |           |     |     |              |          |           |         |         |      |       |     |     |      |     |      |    |    |

S= 0-5 cm.  M= 6-14 cm  L= above 14 cm.

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### LEISHMANIASIS MICROSCOPY RESULTS

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<table>
<thead>
<tr>
<th>S. No</th>
<th>Reg. No</th>
<th>Date of enrollment</th>
<th>Age</th>
<th>Sex</th>
<th># of Lesions</th>
<th>Size of Lesions</th>
<th>Duration Of Lesions</th>
<th>Treatment given (IM.IL)</th>
<th># Of Injections</th>
<th>Date of follow up treatment</th>
<th>Follow up treatment</th>
<th># of follow Injections</th>
<th>Total of follow ups</th>
<th>Remarks</th>
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In case of more than one lesion, please write size of the largest lesion in cm.
In case of more than one lesion, please write duration of the oldest lesions in months.
If the patient received more than one follow up treatments, please specify whether he/she got IM or IL injections and write it down in remarks column.
## DAILY REPORT OF THE NEW PATIENTS

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<th>Sex &amp; Age</th>
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<th>15+</th>
<th>Sub Total</th>
<th>Total</th>
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## OPD/CLINIC ACTIVITY

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