DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000

REPLY TO
ATTENTION OF

MCCS

10 SEP 2004

MEMORANDUM FOR

Commanders, MEDCOM Major Subordinate Commands
Commander, 18th MEDCOM

SUBJECT: Guidance for the Management of Suspected Cutaneous Leishmaniasis in Operation Iraqi Freedom and Operation Enduring Freedom

1. References.

a. Memorandum, Office of The Surgeon General, 21 Oct 03, subject: Medical Advisory-Leishmaniasis.

b. Memorandum, Assistant Secretary of Defense for Health Affairs (ASD(HA)), 12 Sep 03, subject: Medical Advisory-Leishmaniasis.

c. Memorandum, DASG-HSZ, 23 Dec 02, subject: Policy for Diagnosis and Treatment of Leishmaniasis sp. Diseases.

d. Leishmaniasis information, DoD Deployment Health Clinical Center website, http://www.pdhealth.mil/leish.asp.

e. Centers for Disease Control and Prevention National Center for Infectious Diseases website, http://www.cdc.gov/ncidod/diseases/submenus/subLeishmania.htm.

2. Since January 2003, over 600 Soldiers deployed to Southwest Asia have been diagnosed with cutaneous leishmaniasis (CL) (Old World leishmaniasis), a parasitic infection of the skin transmitted by the bite of an infected sand fly. Several hundred additional Soldiers may have been infected.

3. This memorandum updates the guidance provided in reference 1.c. above.

a. There are now additional options for evaluation and treatment of suspected CL in addition to referral and evacuation of cases to Walter Reed Army Medical Center. No specific treatment may be warranted. Others may be treated at a military treatment facility close to the Soldier's home or unit.

MCCS
SUBJECT: Guidance for the Management of Suspected Cutaneous Leishmaniasis in Operation Iraqi Freedom and Operation Enduring Freedom

b. Updated clinical management guidance is included in Appendices 1, 2 and 3.

c. Additional information may be obtained from members of the Leishmaniasis Clinical Policy Work Group listed in Appendix 4. In addition, each Regional Medical Command Commander has designated a regional point of contact (POC) identified in Appendix 5.

4. Training. All primary care providers caring for persons who may have been exposed to leishmaniasis must remain alert for signs and symptoms of this disease which can be manifested several weeks to many months after infection. Commanders will ensure that these providers receive training in the management of this disease, which will include a review of the briefings on leishmaniasis available on the pdhealth.mil and afip.org websites.

5. My POC for this memorandum is LTC David Sproat, Tertiary Care Staff Officer, Directorate of Health Policy and Services, (david.sproat@otsg.amedd.army.mil), DSN 761-0102 or commercial (703) 681-0102.

FOR THE COMMANDER:

5 Encls

JOSEPH G. WEBB, JR.
Major General
Chief of Staff

CF:
Director, National Guard Bureau, ATTN: Surgeon, 111 South George Mason Drive, Arlington, VA 22204-1382
Chief, U.S. Army Reserve Command, ATTN: Surgeon, 1401 Deshler Street, South West, Fort McPherson, GA 30330-2000
Commander, U.S. Army Training and Doctrine Command, ATTN: Surgeon, 7 Fenwick Road, Fort Monroe, VA 23651-5000
Commander, U.S. Army Forces Command, ATTN: Surgeon, Fort McPherson, GA 30330-6000
Commander, U.S. Army Materiel Command, ATTN: Surgeon, 9301 Chapek Road, Ft. Belvoir, VA 22060-5527
Commander, U.S. Army Test and Evaluation Command, ATTN: Surgeon, Park Center IV, 4501 Ford Avenue, Alexandria, VA 22333-0001
Commander, U.S. Army Special Operations Command, ATTN: Surgeon, Fort Bragg, NC 28307-5200

APPENDIX 1

Clinical Policy Guidance for the Management of Suspected Cases of Cutaneous Leishmaniasis in Operation Iraqi Freedom and Operation Enduring Freedom

1. General. Guidance for clinicians on suspected cutaneous leishmaniasis (CL). CL typically presents as one or more open skin lesions that develop over weeks to months after a bite by an infected sand fly. While CL is not life threatening, the skin lesions may result in permanent scarring. Health care personnel need to focus on the possibility of leishmaniasis in slowly or non-resolving skin lesions in Soldiers redeploying from Iraq and Afghanistan. No general screening tests are currently available for CL. Diagnosis involves a combination of compatible symptoms, objective signs, and laboratory findings. These recommendations apply to leishmaniasis acquired in the CENTCOM AOR. If a clinician suspects an individual has CL, the following steps should be taken:

2. Diagnostic Procedures.

a. Review the attached information sheet on leishmania biopsy and scraping procedures at Appendix 2 and view the instructional media (available online at pdhealth.mil, and afip.org/hot-topics.html). Questions may be referred to the Army's Dermatology Army Knowledge Online (AKO) telederm site, derm.consult@us.army.mil, for the proper technique for making a skin scraping for the diagnosis of CL. Skin biopsy with touch preps may be preferred if the differential diagnosis includes other skin diseases. However, a properly performed skin scraping may have equal diagnostic yield if the presumptive diagnosis is CL. In order to provide an adequate specimen, the skin scraping must be vigorous. Infiltration of local anesthetic with epinephrine (except where contraindicated) is encouraged to facilitate the deep scraping necessary to get an adequate specimen. Healing, re-epithelialized ulcers should not be scraped or biopsied.

b. Skin scrapings containing only keratinized epithelium are inadequate. Pathology reports (on scrapings) comment on specimen adequacy, i.e., presence of inflammation and or blood, and state whether amastigotes are present. Specimens containing only keratinized epithelial cells should be repeated depending on the clinical situation. The diagnostic yield of the scraping in suspected cases of CL should be 75 percent or higher.

c. Initial diagnosis will be made by MTF pathologists. For those MTFs without a pathologist, smears and polymerase chain reaction (PCR) tubes should be sent through normal military referral channels. If this lab is not an Army lab, the smears and PCR tube should be sent to the nearest Army MEDCEN. After primary examination, all scraping smears (whether read locally as positive or negative), along with the corresponding PCR tube, should be submitted to the Department of Infectious and

Parasitic Disease Pathology of the Armed Forces Institute of Pathology (AFIP) for quality control, confirmation, and inclusion in the AFIP Leishmaniasis Registry. If AFIP confirms a negative smear, the PCR tube will be sent to Walter Reed Army Institute of Research (WRAIR) for PCR analysis. Pathologists at every AMEDD facility with assigned pathologists have completed training on the diagnosis of CL from skin scrapings. This training has included training slide sets. (As experience of MEDDAC/MEDCEN pathologists increases and a quality assurance comparison of results from MEDDAC/MEDCEN pathologists to those at WRAIR and AFIP, the requirement to submit all scrapings or skin biopsies to AFIP will be dropped except when new sites stand up.)

d. A positive PCR, positive skin biopsy, or a positive histopathology on either skin biopsy or scraping, establishes the diagnosis of CL.

3. Treatment Procedures.

a. Patients with small lesions (< 2 cm in diameter) and lesions that are few in number (fewer than 5-10) may warrant no therapy. Even more than lesion size or number, the primary consideration in recommending therapy is the history and appearance of the lesions themselves. Patients with old lesions demonstrating epithelialization (healing) should not be treated in general. Conversely, patients with more recent lesions that are actively ulcerated are better candidates for active treatment. A discussion of therapeutic options with the patient should always include the fact that CL is self-limited although the decision not to treat may prolong the duration of the ulcerations and/or result in more scarring.

b. Cryotherapy with liquid nitrogen has demonstrated efficacy in the treatment of CL, particularly in small lesions. Use of this modality requires two full 30-second applications of cryotherapy in the same setting for efficacy. Cryotherapy should be used sparingly, if at all, in dark-skinned patients with CL because cryotherapy applied aggressively enough to be effective in CL may result in permanent depigmentation. In terms of lesion size and number, the subset of patients with CL in whom cryotherapy is appropriate overlaps with the subset of patients in whom no therapy might also be appropriate. Small lesions and lesions few in number in light-skinned patients may respond to cryotherapy. Providers with extensive experience in the use of cryotherapy (dermatologists primarily) may consider the use of cryotherapy on larger lesions.

c. Heat is the newest modality added to the treatment options available for CL. ThermoMed™ is the device used to apply heat. The Army has obtained ThermoMed™ devices from the manufacturer. This device has been approved by the FDA for a number of applications and initial distribution of these devices will be as follows: ERMC – 2, SERMC – 4, NARMC – 4, GPRMC –3 with one unit as back up. As the efficacy data analysis is completed, additional units will be purchased and distributed based on the results of that analysis. Regional POCs are responsible for positioning ThermoMed™ units within the RMCs for maximal benefit based on the locations where

Soldiers and their units are redeploying. There are currently only four AMEDD providers experienced in the use of ThermoMed™. While the ThermoMed™ device is easy to use, treating one patient with ThermoMed™ under the supervision of someone who has used the device before is the standard for training before independent use. Liberal amounts of local anesthetic are required. ThermoMed™ application may produce bullous lesions in a significant number of cases. Initial use at WRAMC resulted in superficial skin infections in 20 percent of cases and a soft tissue abscess that required incision and drainage in one patient. Gentamicin or Bacitracin ointment and a non-stick, nonocclusive dressing should be used after ThermoMed™ application. Dressing and ointment should be changed twice daily.

d. Oral fluconazole may seem an attractive alternative to topical therapy or to the use of Pentostam®, but the speed of resolution and overall success rates are not equal to those of Pentostam®. In this context, the drug should only be considered in infections proven to be due to *L. major.* While easily available, the drug is not FDA approved for this indication and there is no official recommendation for its use. If chosen by the patient after discussion of alternatives, the regimen most widely used has been 200 mg per day for 6 weeks. Initial results in a limited number of patients have been disappointing with some requiring treatment with Pentostam®. Liver function tests must be followed periodically.

e. Pentostam® is used in more severe cases of CL. Pentostam® is available only under a research protocol at Walter Reed Army Medical Center and Brooke Army Medical Center (BAMC). Treatment for CL requires either 10 or 20 days of therapy depending on the protocol used. Beside the time and travel commitment involved in a full course of Pentostam®, a number of Soldiers (10 percent) elect to discontinue treatment before completion of the full course because of side effects. Musculoskeletal side effects are the most frequent. Telephonic consultation with staff at BAMC or WRAMC who are engaged in research with Pentostam® should be performed before patient referral. In some instances, telemedicine consultation should be strongly considered. This medium will allow the Pentostam® investigators to explain the pros and cons of therapy to the Soldier and also afford the investigator the opportunity to see the skin lesions involved. Use of this modality may prevent expenditure of valuable resources as well as patient and provider frustration. For purposes of referral, Soldiers west of the Mississippi will be referred to BAMC and Soldiers east of the Mississippi will be referred to WRAMC. Direct coordination between BAMC and WRAMC is authorized as one center or the other foresees impending capacity or throughput issues. Adjustment in regulating patterns via communication with Global Patient Movement and Regulating Command may be used to shift workload. However, adjustments should be kept to a minimum and historical referral patterns preserved to the maximum extent possible.

f. The outcome of treatment may not be known for 60-90 days. The appearance of new lesions or enlargement of old lesions constitutes treatment failure. Healing of old

lesions and absence of new lesions in the 60-90 days after treatment defines treatment success. The considerations contained in this policy concerning the decision to provide active treatment in the first place are equally relevant to the decision to treat a second or third time. For example recurrence with small lesions or lesions that are few in number may be left untreated or treated with a modality other than Pentostam®.

4. Reporting Procedures.

a. Leishmaniasis Registry. The Armed Forces Institute of Pathology (AFIP) has established a Registry for both cutaneous and visceral leishmaniasis. Maximizing the systematic capture of data regarding the diagnosis and treatment of CL is very important to this overall effort and will shape the evolution of CL treatment for as long as we are engaged in the CENTCOM AOR; initial registry entry is based on a confirmed diagnosis by one of the following criteria: (1) Positive histopathology (skin scraping, biopsy, etc); (2) Positive PCR performed at WRAIR with results forwarded to the AFIP; (3) Positive cultures (performed at WRAIR, results forwarded to AFIP). AFIP is responsible for central data consolidation from WRAIR, USACHPPM, regional MEDDACs and MEDCENs, etc. Web-based questionnaires (both initial entry and follow-up at 6 and 12 months) will be made available on the AFIP website and AKO website. Regional POCs are responsible for ensuring that data from MTF's are entered into the AFIP registry. The AFIP POC is COL Peter McEvoy at 202-782-1850, mcevoy@afip.osd.mil. An alternate contact is Michael Lewin-Smith, MD at 202-782-2836, lewin@afip.osd.mil. Registry summary reports will be made available to OTSG as required. See Appendix 3 for patient data sheets. The AFIP Leishmaniasis Registry Questionnaires are for the newly diagnosed patient (15-R-1), follow-up information 6 months after diagnosis (15-R-2), and follow-up information one year after diagnosis (15-R-3). These forms are to be completed with the assistance of a healthcare provider, and can be found at http://www.afip.org/leishsurvey.html.

b. Disease Reporting.

(1) It is imperative that the Chief of Preventive Medicine designate a POC (and a back-up) from preventive medicine to interface with the clinical staff treating patients with leishmaniasis, so that information on cases is submitted each week to the Army Medical Surveillance Activity through the Reportable Medical Event System (RMES). The comment field in the report should include: (a) date of onset; (b) method of diagnosis (S) for scraping, (B) for biopsy, (P) for PCR, (C) for culture, or (CLIN) for clinical; (c) treatment: Pentostam®, ThermoMed™, cryotherapy, fluconazole, amphotericin, or no treatment, and (d) travel history.

(2) Case definitions are as follows: (These definitions would apply to cutaneous and visceral cases of leishmaniasis; although with visceral leishmaniasis, it is more likely that a biopsy will be done to confirm a clinically compatible case)

(a) **Confirmed case** = Laboratory-confirmed case. A laboratory confirmed case could be parasitologically confirmed by smear (visualization of amastigote) from the scraping or biopsy, by culture (promastigote form, in vitro culture), or by positive PCR.

(b) **Clinically compatible case** = One or more open skin lesions that have an appearance consistent with cutaneous leishmaniasis.

5. For assistance, Appendix 4 contains a list of the subject matter experts concerning the prevention, diagnosis, and treatment of leishmaniasis. Contact information and specialists who have expertise are provided. Questions regarding this policy may be referred to any member of the Leishmaniasis Clinical Policy Work Group.

APPENDIX 2

Leishmania Scraping & Biopsy Procedures

1. **Criteria for scraping or biopsy**:

- Any patient who has had a non-healing lesion (does not have to be an open, weeping ulcer) for greater than 3 to 4 weeks should to be suspected of having leishmaniasis.
- The patient needs to be placed on a course of oral antibiotic therapy for 7 to 10 days.
- At the conclusion of therapy, the patient should be seen by the same practitioner, to determine if the course of antibiotics was effective. If the lesion has persisted or worsened, a scraping or biopsy should be performed.
- Digital images of the lesion prior to scraping or biopsy should be taken. Submit these photos to AFIP's Telemedicine server (https://www3.afip.org), since this may help in the diagnosis and can be incorporated into the Registry.

2. **Scraping procedure**:

a. Clean area with alcohol pads and allow to dry.

b. Debride any exudate from an open ulcerative lesion.

c. Anesthetize with lidocaine 1% or 2% with epinephrine 1:100,000 (unless the epinephrine is contraindicated due to anatomic site).

d. Two tissue smears are performed by horizontally scraping (lightly enough to elicit an exudate, but not vigorously enough to cause bleeding) the base of the underlying ulceration with a #15 blade (after removal of the overlying crusted debris). The dermal tissue is then thinly applied in a circular fashion to a dime sized area in the center of the slide. Minimize blood, epithelium (keratinocytes), and purulence on the slide.

e. Additionally, material from the scrapings (and even the overlying crusted debris) should be inserted into a small vial of 95-100% ethanol for PCR analysis.

f. Ensure slides are labeled per the format of the affiliated pathology department and submit per the department's protocol. If pathology services are unavailable locally, ship per address below. Work closely with pathologists to verify adequacy of tissue smear samples.

3. **Biopsy/touch prep-impression smear procedure**: (only for submission to WRAIR for PCR analysis, not for pathologist's evaluation).

a. An area of the lesion needs to be cleaned thoroughly with alcohol pads and dried.

b. The anticipated area of biopsy should be anesthetized as described above.

c. A 4 mm sterile disposable punch or sterile scalpel (#15, #11, or #10) should be used to remove a piece of tissue approximately 3 to 4 mm in circumference and approximately 1 mm deep from the edge of the lesion (see photo for preferred area of biopsy). Lesions on the face, anterior of the neck, and near larger vessels and/or nerves need to be biopsied with extreme caution and a simple surface scraping (described above) may be preferred to a true biopsy.

d. The biopsy should be placed on a sterile, clean, dry gauze 2X2, briefly, to absorb excess blood on the tissue that may interfere with the reading of the touch preparations.

e. The tissue should be grasped with forceps and impression smears made on clean slides (4 for each biopsy) by rubbing the tissue gently across the surface of the slide in a circular motion.

f. Dry thoroughly. Fix with methanol if available.

g. The tissue biopsy (after the impression smears are made) should then be placed in a very small amount of ethyl alcohol (just enough to cover the specimen) in a leakproof vial (such as a "nunc" transport tube).

h. The slides and the vial with the tissue should be shipped per local pathology section protocol or via DHL or Federal Express to the address below. The container should be labeled as diagnostic specimens and no shipping permit is required (all MTFs have personnel and resources to ship diagnostic specimens correctly).

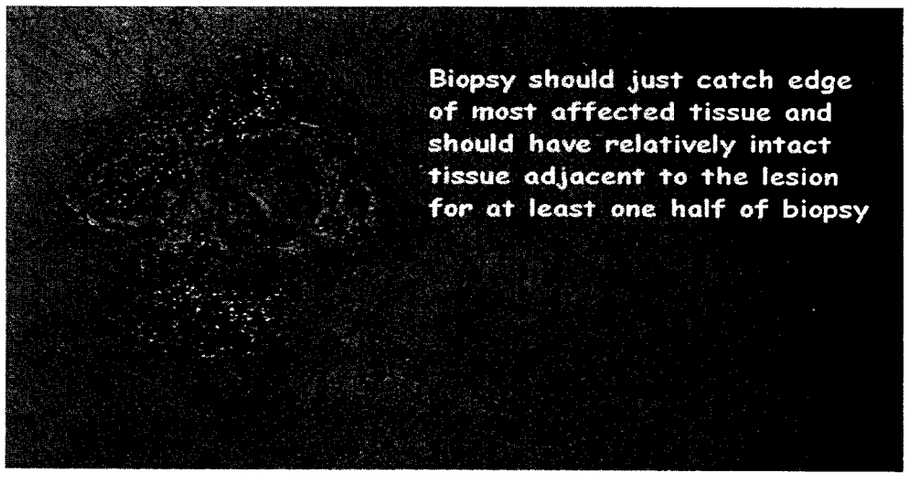
i. Complete the patient information sheet (Appendix 2) and include with the specimen for each patient biopsied.

j. Procedural inquiries should be made to LTC Peter Weina at (301) 319-9956.

SHIPPING ADDRESS

Armed Forces Institute of Pathology
ATTN: Receiving and Accessions Division (AFIP-RRS)
Room G-071, Building #54
6825 16th Street, N.W.
Washington, DC 20306-6000

Preferred biopsy area:



PART A – SOLDIER **Today's Date:** _____

Patient Name: _____ **SSN:** _____ **Rank:** _____

Weight: _____ **Sex:** ___ **Age:** ____ **DOB:** _____ **Race: White / Black / Asian / Hispanic / Amer. Indian / Other**

Unit: _____ **Email Address:** _____ **Duty Phone:** (___)_____

Home Phone: (___)_____ **Cell Phone:** (___)_____ **Next of Kin Phone:** (___)_____

Date arrived in Theater: _____ **In Iraq:** _____

Places/dates lived in Iraq: (e.g., *FOB Murphy, 10 Jun – 15 Jul 03*) _____

_____

Places/dates lived in Afghanistan: _____

While deployed, did you use insect repellent? Y / N **Medication Allergies:**_____

Date you first noticed lesion: _____ **Date Leishmaniasis suspected by provider:** _____

Has a culture or smear been done? Y / N When? _____

Have you received any other treatment/where? _____

When did you arrive back at your home station? _____

_____

PART B – CLINICAL PROVIDER **Provider name:** _____

5.) Environmental characteristics of region*	**Specify**
a. Terrain (desert, mountain, farmland, etc.)	
b. Work environment (urban, rural)	
c. Near large bodies of water (river, lake, sea)	
d. Near industrial sites (oil, power plant, chemical, other)	

6.) Biting insect exposure	**Y/N**	***If yes, how often ?***
a. Frequent night work		
b. Sleep without mosquito nets		
c. Use of insect repellent		
d. Frequent bites		

7.) Medications *	**Dose**	**From Date**	**To Date**

8.) Clinical observations	**Y/N**	**From Date**	**To Date**
a. Skin lesions/sores			
b. Fevers			
c. Weight loss			
d. Weakness/lethargy			
e. Other symptoms			

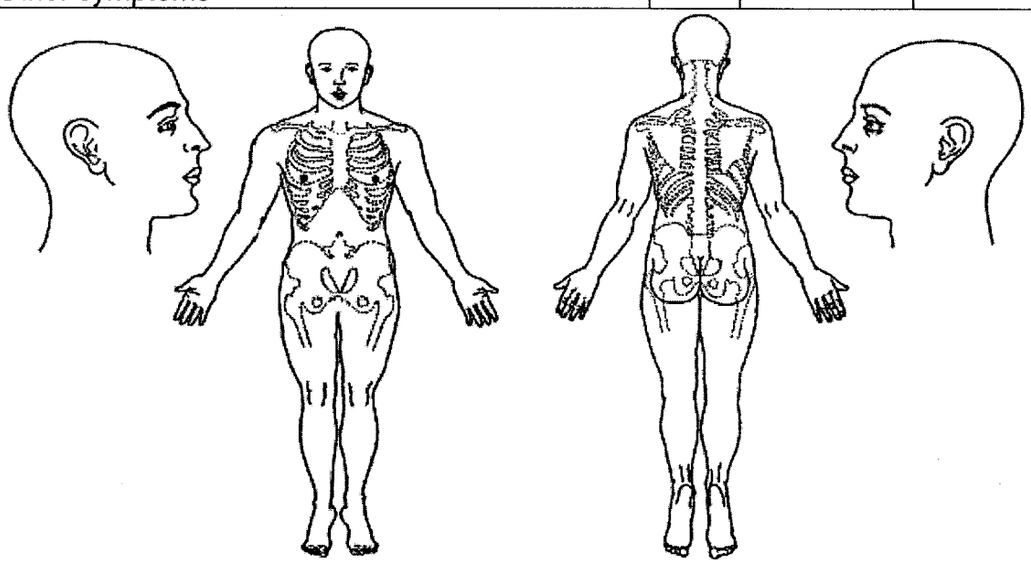


Figure 1.

Lesion Locations	Size (cm)	Duration	Photo Y/N	Scraping/Smear

Results of any previous testing: _____

Diagnosis:_____

Treatment: **Observation and Follow-Up** **FU Appt in _____ weeks**

Fluconazole _____

Cryotherapy _____

ThermoMed™ _____ STAMP

Consult to WRAMC for Pentostam® _____

Other _____

Provider signature _____

All personnel returning to the United States, who think that they may have leishmaniasis, or who have a diagnosis of leishmaniasis, are requested to complete this questionnaire with the assistance of a healthcare provider. In addition, we request follow-up information at 6 months and one year to assess treatment outcomes. **PLEASE FAX THIS COMPLETED FORM TO THE ARMED FORCES INSTITUTE OF PATHOLOGY, DEPARTMENT OF INFECTIOUS AND PARASITIC DISEASE PATHOLOGY AT 202-782-9160.**

PRIVACY ACT STATEMENT

Authority for Soliciting the Information: 5 U.S. Code § 301; 10 U.S. Code §§ 131, 3013; Executive Order 9397; DoD Directive 5154.24.

Principal Purposes for Which the Information Will Be Used: To obtain information about leishmaniasis cases in the military. The information will be used for force protection/surveillance and preventive medicine.

Routine Uses that May Be Made of the Information: Any information you provide may be disclosed to members of the Department of Defense who have a need for the information in the performance of their duties. These may include, but are not limited to, personnel in the AFIP, the Office of The Surgeon General, Army, the U.S. Army Center for Health Promotion and Preventive Medicine, and the Walter Reed Army Institute of Research. Other routine uses that may be made of the information are listed in Army Regulation 340-21, Chapter 3.

Scope Of Discretion in Providing the Information (Voluntary or Mandatory): Voluntary.

Effect of Not Providing Information: There will be no adverse effect on you for not providing the information, other than that certain information concerning leishmaniasis might not otherwise be available to military medical personnel for study and treatment of the disease.

1.) NAME			
	(Last)	(First)	(Middle)

2.) DOB		3.) SSN	
	(MM/DD/YYYY)		

4.) Which country/countries were you in? *	Which region?	From Date	To Date

Indicate location(s) of sore(s). State size of largest sore; (largest dimension in centimeters or inches; give unit).

9.) Treatment *	Y/N	From Date	To Date
a. Pentostam®			
b. Oral Fluconazole			
c. Topical (paromomycin/other-specify)			
d. Heat/ThermoMed™			
e. Freezing/Cryotherapy			
f. Other, specify*			
g. None			

10.) Adverse treatment effects	Y/N	Specify
a. Any adverse effects		
b. Any treatment stopped due to adverse effects		

11.) Outcome*	Y/N	Approximate Date
a. Did lesions/sores go away?		
b. Did any lesions/sores come back?		
c. Did new lesions/sores appear?		
d. Did the sore(s) leave a scar?		
e. Did other symptoms (fever, etc.) go away?		
f. Did other symptoms (fever, etc.) come back?		
g. Did new symptoms arise (specify)?		

Additional remarks: (* including continuation for items 4,5,7,9 and 11).

All personnel returning to the United States, who have a diagnosis of leishmaniasis, are requested to complete this questionnaire with the assistance of a healthcare provider 6 months after the date of diagnosis, and a final questionnaire at one year after diagnosis to assess treatment outcomes. **PLEASE FAX THIS COMPLETED FORM TO THE ARMED FORCES INSTITUTE OF PATHOLOGY, DEPARTMENT OF INFECTIOUS AND PARASITIC DISEASE PATHOLOGY AT 202-782-9160.**

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Scope Of Discretion in Providing the Information (Voluntary or Mandatory): Voluntary.

Effect of Not Providing Information: There will be no adverse effect on you for not providing the information, other than that certain information concerning leishmaniasis might not otherwise be available to military medical personnel for study and treatment of the disease.

1.) NAME			
	(Last)	(First)	(Middle)

2.) DOB		3.) SSN	
	(MM/DD/YYYY)		

APPENDIX 3: AFIP Leishmaniasis Registry Questionnaire 2 (of 3)
Follow-up information 6 months after diagnosis

4.) Countries visited in last 6 months? *	**Which region?**	**From Date**	**To Date**

5.) Environmental characteristics of region*	**Specify**
a. Terrain (desert, mountain, farmland, etc.)	
b. Work environment (urban, rural)	
c. Near large bodies of water (river, lake, sea)	
d. Near industrial sites (oil, power plant, chemical, other)	

6.) Biting insect exposure	**Y/N**	***If yes, how often ?***
a. Frequent night work		
b. Sleep without mosquito nets		
c. Use of insect repellent		
d. Frequent bites		

7.) Medications *	**Dose**	**From Date**	**To Date**

8.) Clinical observations	**Y/N**	**From Date**	**To Date**
a. Skin lesions/sores			
b. Fevers			
c. Weight loss			
d. Weakness/lethargy			
e. Other symptoms			

APPENDIX 3: AFIP Leishmaniasis Registry Questionnaire 2 (of 3)
Follow-up information 6 months after diagnosis

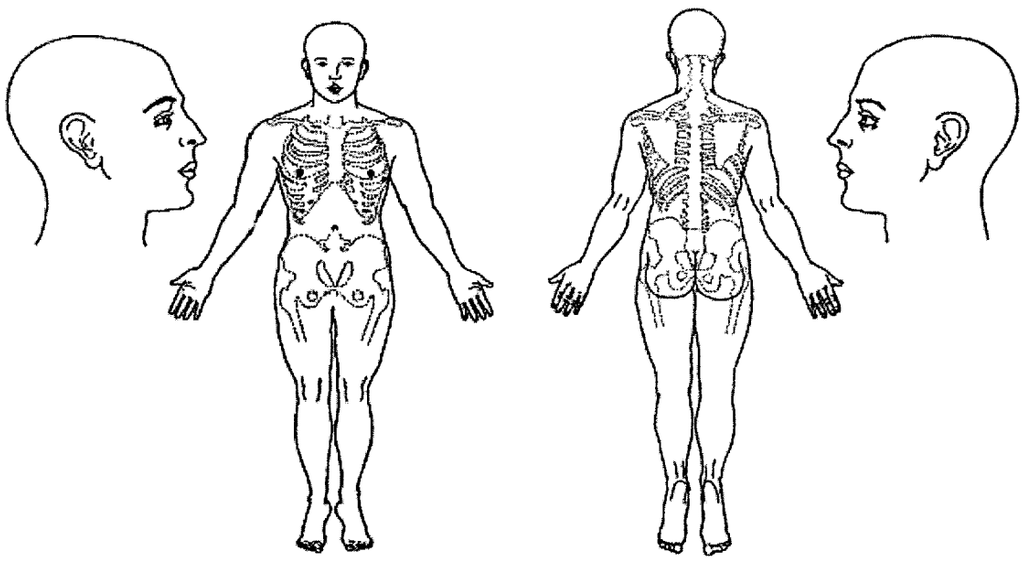

Figure 1.

Indicate location(s) of sore(s).State size of largest sore; (largest dimension in centimeters or inches; give unit). **If sores have left scars please indicate on the diagram and give the largest dimension.**

9.) Treatment*	**Y/N**	**From Date**	**To Date**
a. Pentostam®			
b. Oral Fluconazole			
c. Topical (paromomycin/other-specify)			
d. Heat/ThermoMed™			
e. Freezing/Cryotherapy			
f. Other, specify*			
g. None			

10.) Adverse treatment effects	**Y/N**	**Specify**
a. Any adverse effects		
b. Any treatment stopped due to adverse effects		

11.) Outcome*	**Y/N**	**Approximate Date**
a. Did lesions/sores go away?		
b. Did any lesions/sores come back?		
c. Did new lesions/sores appear?		
d. Did the sore leave a scar?		
e. Did other symptoms (fever, etc.) go away?		
f. Did other symptoms (fever, etc.) come back?		
g. Did new symptoms arise (specify)?		

Additional remarks: (* including continuation for items 4,5,7,9 and 11).

All personnel returning to the United States, who have a diagnosis of leishmaniasis, are

requested to complete this questionnaire with the assistance of a healthcare provider one year after diagnosis to assess treatment outcomes. **PLEASE FAX THIS COMPLETED FORM TO THE ARMED FORCES INSTITUTE OF PATHOLOGY, DEPARTMENT OF INFECTIOUS AND PARASITIC DISEASE PATHOLOGY AT 202-782-9160.**

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1.) NAME			
	(Last)	(First)	(Middle)

2.) DOB		**3.) SSN**	
	(MM/DD/YYYY)		

4.) Countries visited in last 6 months? *	**Which region?**	**From Date**	**To Date**

* If 6 month follow-up questionnaire was **not** completed enter countries visited in last 12 months.

5.) Environmental characteristics of region*	**Specify**
a. Terrain (desert, mountain, farmland, etc.)	
b. Work environment (urban, rural)	
c. Near large bodies of water (river, lake, sea)	
d. Near industrial sites (oil, power plant, chemical, other)	

6.) Biting insect exposure	**Y/N**	***If yes, how often?***
a. Frequent night work		
b. Sleep without mosquito nets		
c. Use of insect repellent		
d. Frequent bites		

7.) Medications	**Dose**	**From Date**	**To Date**

APPENDIX 3: AFIP Leishmaniasis Registry Questionnaire 3 (of 3)
Follow-up information 12 months after diagnosis

8.) Clinical observations	Y/N	From Date	To Date
a. Skin lesions/sores			
b. Fevers			
c. Weight loss			
d. Weakness/lethargy			
e. Other symptoms			

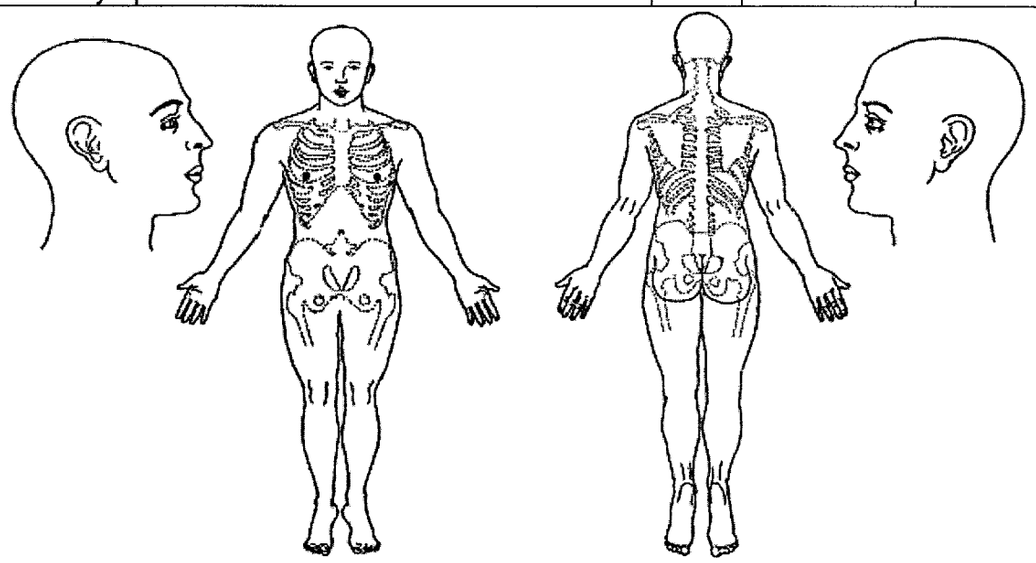

Figure 1.

Indicate location(s) of sore(s). State size of largest sore; (largest dimension in centimeters or inches; give unit). **If sores have left scars please indicate on the diagram and give the largest dimension.**

9.) Treatment*	Y/N	From Date	To Date
a. Pentostam®			
b. Oral Fluconazole			
c. Topical (paromomycin/other-specify)			
d. Heat/ThermoMed™			
e. Freezing/Cryotherapy			
f. Other, specify			
g. None			

10.) Adverse treatment effects	Y/N	Specify
a. Any adverse effects		
b. Any treatment stopped due to adverse effects		

11.) Outcome*	Y/N	Approximate Date
a. Did lesions/sores go away?		
b. Did any lesions/sores come back?		
c. Did new lesions/sores appear?		
d. Did other symptoms (fever, etc.) go away?		
e. Did other symptoms (fever, etc.) come back?		
f. Did new symptoms arise (specify)?		

Additional remarks: (*including continuation for items 4,5,7,9 and 11).

APPENDIX 4

Leishmaniasis Clinical Policy Work Group

1. Walter Reed Army Medical Center

   a. COL Clifton Hawkes (clifton.hawkes@na.amedd.army.mil; 202-782-8696)

   b. LTC Glenn Wortmann (glenn.wortmann@na.amedd.army.mil; 202-782-8684)

   c. COL Naomi Aronson (USUHS) (naronson@usuhs.mil; 202-782-8691)

   d. COL Mark Brissette (mark.brissette@na.amedd.army.mil; 202-782-0773)

   e. COL Dallas Hack (dallas.hack@na.amedd.army.mil; 202-782-3962)

Walter Reed has treated most of the CL to date and collective experience of over 600 cases provides a wealth of experiential knowledge vested in experts (a - c) identified above. COL Brissette is OTSG Consultant in Pathology and is responsible with COL McEvoy for training all MTF pathologists.

2. Walter Reed Army Institute of Research

   a. COL Alan Magill (alan.magill@na.amedd.army.mil; 301-319-9959)

   b. LTC Pete Weina (peter.weina@na.amedd.army.mil; 301-319-9956)

COL Magill and LTC Weina are lynchpins in the Leishmaniasis Diagnostic Laboratory where PCR tests are performed. LTC Weina spent a great deal of the last 18 months in Iraq diagnosing CL and teaching others how to make the diagnosis.

3. Armed Forces Institute of Pathology

   a. COL Peter McEvoy (mcevoy@afip.osd.mil): COL McEvoy is an expert in making the diagnosis of CL in tissue and on smear and assisted in development of the training program for Army pathologists.

4. Brooke Army Medical Center

   a. COL Dave Dooley (david.dooley@amedd.army.mil; 210-916-5554): COL Dooley is OTSG Consultant in Infectious Diseases and also responsible for setting up the second Pentostam site at BAMC.

APPENDIX 5

Regional Points of Contact

Region	Clinical	Preventive Medicine
Europe Regional Medical Command	MAJ Greg Deye	COL Kent Bradley
North Atlantic Regional Medical Command	LTC Glenn Wortmann	COL Dallas Hack
Southeast Regional Medical Command	MAJ Robert Willard	LTC Edward Boland
Great Plains Regional Medical Command	COL David Dooley	COL Forest Oliverson
Western Regional Medical Command	COL Joe Morris	COL Evelyn Barraza
Pacific Regional Medical Command	COL Susan Fraser	COL Glenn Wasserman