
Feature



Association between HIV and Tuberculosis: Technical Guide¹

The XXXVI Meeting of the Directing Council

Resolves

To urge the Member Countries:

- *To strengthen and assign highest priority to activities under the Tuberculosis Program in coordination with the AIDS Program. (para. 2.c)*

To request the Director:

- *To provide for the framing by the appropriate technical agencies of specific recommendations for the epidemiological surveillance of the association tuberculosis-HIV, primary and secondary chemoprophylaxis procedures, and the diagnosis, treatment, and monitoring of tuberculosis in persons infected with HIV, and to promote the epidemiological and operational research needed for optimal understanding of a new and changing situation. (para. 4.d)*

*Resolution XIV of the XXXVI Meeting of the PAHO Directing Council
Adopted 24 September 1992
in Washington, D.C.*

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1. NATURE, MAGNITUDE, AND TRENDS OF THE ASSOCIATION BETWEEN HIV AND TB

Coinfection with the human immunodeficiency virus (HIV) is a risk factor that aggravates the epidemiologic situation of tuberculosis (TB), particularly in developing countries. This virus induces progressive immunosuppression, which favors the reactivation of TB in persons with a latent tuberculous infection and a progression towards disease in persons with primary tuberculous infection or reinfection. There is also evidence to indicate that tuberculosis exacerbates the course of HIV infection.

The overlapping of HIV-infected populations and populations infected with *M. tuberculosis* favors interaction between the two pathogens. The risk of progression to active TB faced by persons infected with both pathogens is much higher (on average, 8% per year) than that of those infected with *M. tuberculosis* alone (0.2% per year). Persons positive for HIV who contract a primary tuberculous infection are at high risk of suffering from disseminated progressive TB.

There are difficulties in controlling this interaction because of certain characteristics of the association of HIV and TB. Diagnosis of TB can sometimes be difficult, since these patients may present nonspecific and atypical disease, including the appearance of extrapulmonary and disseminated forms, lower positivity from bacteriologic inspection of sputum and sputum culture, disappearance or reduction of the intensity of the skin

reactions to the purified protein derivative of *M. tuberculosis* (PPD), and noncharacteristic radiological findings. In recent investigations of nosocomial outbreaks in the United States of America occasioned by multidrug-resistant strains, it was noted that most of those infected were HIV-infected patients; they developed serious tuberculous infection and mortality was high. The appearance of drug-resistant strains tends to result from the inadequate administration of treatment, demonstrating the importance of strictly supervised therapy.

With regard to the global magnitude of tuberculosis, the World Health Organization (WHO) has estimated that one-third of the world's population is infected with *M. tuberculosis* (1 722 million people), and that annually 8 million new cases of active TB appear and 3 million people die because of the disease. Ninety-five percent of these cases and 98% of the deaths occur in developing countries.

With regard to the global magnitude of HIV infection, WHO estimated that at the end of 1992 the number of HIV-infected persons ranged from 11 to 13 million, of whom 1.7 million had developed AIDS. Seventy-five percent of the cases and deaths occurred in developing countries. In the last 6 months of 1992, one million people became infected with HIV, and by the year 2000 the number of infected persons will rise to 40 million, 90% of whom will live in developing countries.

WHO also estimates that from the beginning of the AIDS epidemic to the end of 1992, the number of people simultaneously infected with HIV and *M. tuberculosis* throughout the world rose to 4.4 million. By 1995 there will be roughly half a million additional cases of active tuberculosis as a result of simultaneous HIV infection, and in the year 2000, nearly one million.

HIV and *M. tuberculosis* Infection in Latin America and the Caribbean

The Pan American Health Organization (PAHO) has estimated that at the end of 1992 the number of HIV-infected persons in Latin America exceeded one million, and the number of persons with *M. tuberculosis* infection stood at 117 million. In addition, the annual number of new cases of active TB was approximately 500 000.

In 1992, 330 000 people suffered from a mixed infection of HIV and *M. tuberculosis* in Latin America and the Caribbean. In some countries, TB is already the most frequent opportunistic infection among AIDS patients.

Aware of the severity of this association in the Region, the Directing Council of PAHO urged the Member Governments at its September 1992 meeting to strengthen and assign highest priority to activities under their programs on tuberculosis control in coordination with their programs on AIDS. In addition, it requested the Director of PAHO to arrange for the framing by appropriate technical agencies of specific recommendations for surveillance of the effects of the HIV-TB association.

In order to implement these recommendations, discuss operational aspects, seek agreements, and prepare guides to facilitate this activity, a

Consultation Workshop was held at PAHO Headquarters in November 1992, with participation of a group of professionals with recognized experience in the field.

2. PURPOSE AND OBJECTIVES OF THIS GUIDE

The association between HIV and TB poses problems for diagnosis, chemoprophylaxis, treatment, and surveillance of the patients infected with both pathogens. One of the objectives of the Consultation Workshop was to prepare a simple and appropriate technical guide on the procedures to be followed by health personnel in relation to persons infected with HIV, *M. tuberculosis*, or both. This guide includes guidelines and recommendations for the standardized diagnosis, treatment, and follow-up of tuberculosis associated with HIV infection or AIDS.

Application of these recommendations, which are based on international experience, will be limited by social factors and by the conditions and resources of the countries. In interpreting them, it will be necessary to take into account the epidemiologic situation of tuberculosis and HIV infection in each country. In addition, they will have to be adjusted to the constantly increasing body of knowledge in this field.

This guide represents an attempt to facilitate the work of health personnel in providing effective care to patients infected with HIV and *M. tuberculosis*. Among its specific objectives are the following: to provide effective treatment to persons with active TB who are infected with HIV or have AIDS; to reduce the transmission of *M. tuberculosis* to HIV-positive persons and to the general population; to reduce the incidence of reactivation of latent tuberculous infection in HIV-positive persons; and to reduce the incidence of primary active tuberculosis in HIV-positive persons who are exposed to *M. tuberculosis*.

3. PROCEDURES TO BE FOLLOWED IN PERSONS WITH HIV-POSITIVE SEROLOGY OR AIDS

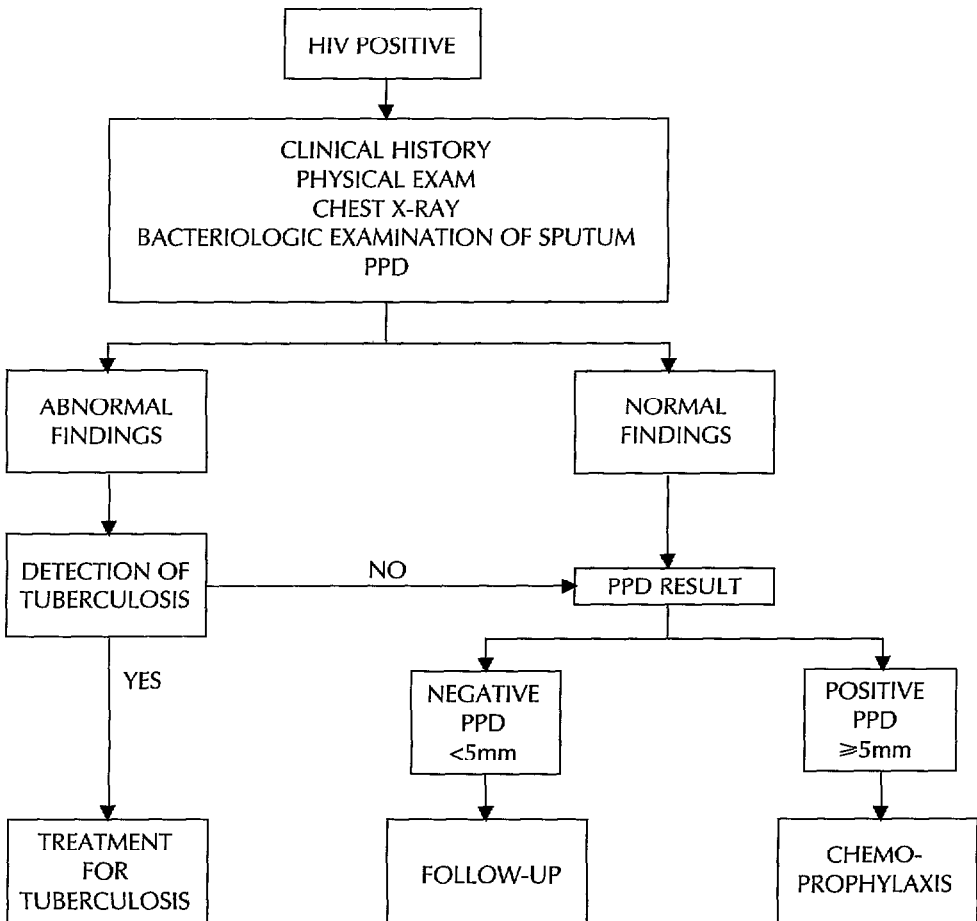
The procedures to be followed to establish a diagnosis of tuberculous infection or disease in persons with HIV-positive serology or AIDS vary according to the risk of tuberculous infection that exists in the area where the suspected case lives. For this reason, two different algorithms were prepared, one for areas of low tuberculosis transmission and another for areas of high transmission. Transmission is considered low when the annual risk of infection (ARI)² is less than or equal to 0.5%, a figure that amounts to an estimated incidence less than or equal to 25 bacilliferous pulmonary cases confirmed by stained sputum smear per 100 000 persons

²Annual risk of infection is defined as the percentage of the population that is infected or reinfected during a calendar year. However, characterization of the epidemiologic situation as high or low risk is done in the conventional manner.

per year. Transmission is considered average or high when the ARI is greater than 0.5%, which amounts to an estimated incidence of more than 25 bacilliferous pulmonary cases confirmed by smear per 100 000 persons per year.

The fundamental difference between the two algorithms is that in an area of high TB transmission, it makes no sense to perform the PPD skin test. In these areas, the probability of being or becoming infected with *M. tuberculosis* is high and, as a result, it is appropriate to prescribe chemoprophylaxis to an HIV-infected person, regardless of the result of the tuberculin PPD test. On the other hand, in an area of low transmission, the probability of being or becoming infected with *M. tuberculosis* is low. Therefore, chemoprophylaxis is indicated only in persons with signs of latent tuberculous infection, such as a positive PPD test.

Algorithm for Areas of Low Transmission of TB



As the foregoing algorithm shows, every person with HIV-positive serology should be interviewed and his/her clinical history written down. A complete physical examination, chest x-ray, and tuberculin PPD test must be done and, when respiratory symptoms exist, sputum samples must be taken to identify the presence of *M. tuberculosis* through bacteriologic examination and culture.

The clinical history should include data on tuberculous disease; previous treatments; contact with tuberculosis patients; previous PPD tests; vaccination with BCG (bacillus Calmette-Guerin), specifying, if possible, the number of doses and the dates they were administered; history of respiratory symptoms; and other manifestations that suggest pulmonary or extrapulmonary TB.

The physical examination must be complete and should be aimed at ruling out the presence of signs suggestive of pulmonary or extrapulmonary tuberculosis. The chest x-ray should be examined carefully in order to identify pathological pleuropulmonary images. The search for *M. tuberculosis* through bacteriologic examination of stained sputum smears and through culture should be carried out in every patient with respiratory symptoms.

When there is any abnormal finding in the clinical history, physical examination, or chest x-ray of an HIV-positive person and repeated sputum examination does not confirm the diagnosis of TB, the diagnostic search should be continued in order to confirm or rule out active tuberculosis, either pulmonary or extrapulmonary. When a pulmonary form is suspected, if necessary an induced sputum sample should be obtained, and when an extrapulmonary form is suspected, bacteriologic and histopathological studies of the affected tissue should be done. If the diagnosis of tuberculous disease is confirmed, appropriate treatment according to these established guidelines (see point 5 of this guide) should be administered. If it is ruled out, the results of the patient's earlier PPD test should be reviewed in order to determine whether he/she is suffering from a latent mycobacterial infection.

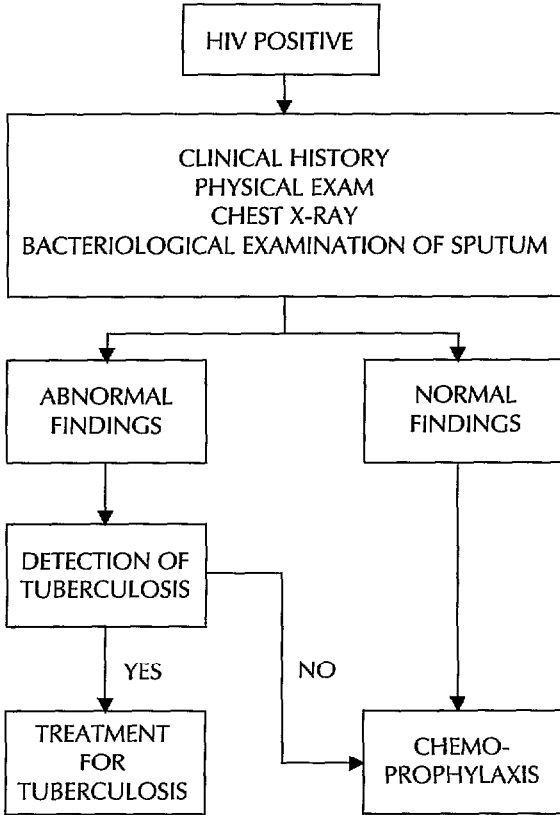
When all findings are normal, namely, when the clinical history data, physical examination, and chest x-ray do not reveal pathological findings and the sputum examination does not confirm the diagnosis of TB, the results of the earlier PPD test should be reviewed in order to determine whether latent mycobacterial infection is present.

If the diameter of induration of the tuberculin PPD test is greater than or equal to 5 mm, it should be considered positive. If the induration is less than 5 mm, the test should be considered negative. This criterion is independent of whether or not the person has a history of BCG vaccination.

If the PPD test is positive, chemoprophylaxis should be started immediately (see point 6 of this guide). If it is negative, the clinical course of the patient should be monitored.

If tuberculosis is ruled out and the pulmonary condition of the patient worsens, other respiratory diseases that can affect such patients (such as *P. carinii* infection) should be considered.

Algorithm for Areas of High Transmission of TB



As the algorithm above illustrates, every person with HIV-positive serology should be interviewed in order to record his/her clinical history. A complete physical examination and chest x-ray must be done, and if the patient has respiratory symptoms or signs, sputum samples must be taken in order to detect the presence of *M. tuberculosis* through bacteriologic examination and culture.

The clinical history should include data on tuberculous disease; previous treatments; contact with tuberculosis patients; previous PPD tests; BCG vaccinations received, specifying, if possible, the number of doses and the date they were administered; and history of respiratory symptoms, as well as other signs that could suggest a diagnosis of pulmonary or extrapulmonary tuberculosis.

The physical examination must be complete and should be aimed at ruling out the presence of signs suggestive of pulmonary or extrapulmonary tuberculosis. The chest x-ray must be carefully examined in order to identify pathological pleuropulmonary images. A bacteriologic examination of sputum and sputum culture should be done on every patient with respiratory symptoms.

If an abnormal finding is discovered in the clinical history, physical examination, or chest x-ray, but repeated examination of sputum does not confirm tuberculosis, diagnostic efforts should continue in order to confirm or rule out active tuberculosis, either pulmonary or extrapulmonary. When a pulmonary form is suspected, if necessary an induced sputum sample should be obtained. When an extrapulmonary form is suspected, bacteriologic and histopathological studies of the affected tissue should be done. If the diagnosis of TB is confirmed, the patient should be treated according to established guidelines (see point 5 of this guide). If it is ruled out, chemoprophylaxis should be initiated immediately (see point 6 of this guide).

In an HIV-positive person who has no pathological findings, chemoprophylaxis should be started immediately (see point 6 of this guide).

If the pulmonary condition of the patient worsens and tuberculosis is ruled out, other respiratory diseases that can affect such patients (such as *P. carinii* infection) should be considered.

4. PROCEDURES TO BE FOLLOWED IN PERSONS WITH TUBERCULOSIS

A serologic examination for the purpose of detecting antibodies to HIV in the blood should be recommended routinely to every person with pulmonary or extrapulmonary tuberculosis. In addition, the risks of associated HIV infection and TB should be explained to the individual, together with the benefits of early diagnosis of HIV infection. Health personnel must explain to the patient that the presence of tuberculosis can indicate an existing HIV infection, since the probability of suffering TB is much higher among persons infected with this virus.

It is extremely beneficial for the patient to know if he/she is truly HIV-infected. This knowledge makes it possible to follow closely the evolution of his/her clinical symptoms, facilitates the diagnosis and timely treatment of the diseases associated with HIV and adverse reactions to tuberculosis drugs, and can reduce early mortality from tuberculosis. In addition, the patient who knows that he/she is HIV-infected can notify his/her sexual partners and thus avoid spreading the virus.

Counseling should be provided to the patient in at least two sessions: one before the test to detect HIV antibodies and the other afterward. The test should be conducted in a strictly confidential manner and only after the informed consent of the patient is obtained.

The recommendations of WHO for the selection and use of diagnostic tests for HIV infection should be followed. Every serum that is reactive in the first test will undergo a second test based on another principle or carried out with a different antigen. If this second test is also positive, a supplementary diagnostic test will then be conducted. Although measures to ensure the confidentiality of diagnostic test results should be improved, anonymity of samples is not recommended, since it prevents beneficial action from being taken for the patients and their sexual partners. The

proper performance of these serologic tests requires increased availability of resources and greater interaction between national AIDS and TB programs.

5. TUBERCULOSIS TREATMENT

Tuberculosis patients who are HIV-positive should receive the best available tuberculosis treatment. This treatment is no different from the treatment administered to a tuberculosis patient who is not HIV-infected.

Treatment of tuberculosis consists of two phases and lasts a total of 6 months. The duration of the first phase is 2 months and the second, 4 months. However, what is important is not the time elapsed on the calendar but the number of doses administered effectively.

Treatment programs should be short and must be based on the following drugs: rifampicin, isoniazid, pyrazinamide, and ethambutol. These drugs make it possible to administer a short course of highly effective treatment. Ethambutol is preferable to streptomycin because it is administered in a way (orally instead of by injection) that is safer for the immunodeficient patient and carries less biosafety risk for health personnel. Thiacetazone should not be included because of its great number of serious adverse side-effects in the HIV-positive patient.

Treatment of tuberculosis in the HIV-positive patient should be administered under strict supervision. In the first phase, the four drugs (rifampicin, isoniazid, pyrazinamide, and ethambutol) should be administered daily and simultaneously, up to a total of 60 doses of each. In the second phase, a dose of rifampicin and one of isoniazid should be administered simultaneously twice per week, up to 40 doses. In persons who weigh less than 45 kilograms (100 pounds), the daily dose should be adjusted according to the person's weight. This regimen is summarized below:

First phase:

Rifampicin + isoniazid + pyrazinamide + ethambutol.
1 simultaneous dose of each drug every day.
To complete this phase, 60 doses must be administered.

Second phase:

Rifampicin + isoniazid.
1 simultaneous dose of each drug twice per week.
To complete this phase, 40 doses must be administered.

Treatment of HIV-positive tuberculosis patients who are readmitted because they have abandoned treatment or suffered a relapse should be strengthened (secondary resistance may be suspected in the latter patients, although it occurs in a small proportion of cases). For this purpose, treatment must be started with the administration of five drugs—rifampicin + isoniazid + pyrazinamide + ethambutol + streptomycin—during the first phase, the duration of which should be 2 to 3 months; this is followed by administration of three drugs—rifampicin + isoniazid + pyrazinam-

ide—during the second phase, the duration of which can range from 5 to 6 months. The total duration of treatment should be 8 months. Whenever possible, existing epidemiologic information regarding secondary resistance in the area should be used, in order to provide effective treatment. Studies on the drug susceptibility of *M. tuberculosis* should be done in those patients in whom secondary resistance is suspected, that is, only in the case of therapeutic failure or in chronic patients with suspected multiple resistance.

These patients should be rigorously monitored during treatment, and an effort should be made to identify adverse side effects of the drugs, diagnose related diseases, and, above all, avoid the abandonment of treatment. In every tuberculosis patient, and more often in the HIV positive patient, irregularities in taking the drugs and the tendency to abandon treatment are impediments to effective cure and favor the appearance of drug-resistant strains. Treatment of these patients must be supervised by specially trained, skilled health professionals who are aware of their responsibility. To a large degree, adherence to treatment depends on them. Medical check-ups should be as frequent as necessary and should always involve at least one monthly visit.

Finally, every HIV-positive tuberculosis patient who has been discharged has the option of continuing chemoprophylaxis with isoniazid (for a minimum of 6 months), in order to reduce the risk of reactivation or exogenous infection. However, at the moment, data that clearly indicate the proper duration of this chemoprophylaxis are unavailable.

Treatment for extrapulmonary tuberculosis is identical to that recommended for pulmonary tuberculosis. However, it should be noted that short-course schedules are more efficient against extrapulmonary than pulmonary TB because, in general, extrapulmonary locations have fewer tubercle bacilli. Prolonged treatment of extrapulmonary tuberculosis is not justified.

The recommended dosages for the drugs used in the first and second phases of treatment are given below:

Recommended daily doses for the first-phase treatment of TB

Drug	Daily dose		Daily maximum dose, adults and children
	adults	children	
Rifampicin	10 mg/kg	10–20 mg/kg	600 mg
Isoniazid	5 mg/kg	5–10 mg/kg	300 mg
Pyrazinamide	15–30 mg/kg	15–30 mg/kg	1.5–2 g
Ethambutol	15–25 mg/kg	15–25 mg/kg	2.5 g
Streptomycin	15 mg/kg	20–40 mg/kg	1 g ^a

^aIn persons over the age of 45, 0.75 g and in persons over 60, 0.5 g.

Recommended intermittent doses for the second phase treatment of TB

Drug	Intermittent daily dose	Intermittent maximum daily dose
Rifampicin	10 mg/kg	600 mg
Isoniazid	15 mg/kg	750 mg
Pyrazinamide	50 mg/kg	3.5 g
Ethambutol	40 mg/kg	2.5 g
Streptomycin	15 mg/kg	1 g ^a

^aIn persons over the age of 45, 0.75 g and in persons over 60, 0.5 g.

6. TUBERCULOSIS CHEMOPROPHYLAXIS

HIV-positive persons who do not have TB may need chemoprophylaxis in order to avoid developing secondary tuberculosis due to endogenous reactivation, primary tuberculous infection, or reinfection.

In an area of low transmission, an HIV-infected person with a diameter of induration equal to or greater than 5 mm in the PPD test should be considered infected and receive chemoprophylaxis with 5 mg/kg/day of isoniazid for 6 to 12 months. However, the appropriate duration of this treatment is still under study. If the diameter of induration is less than 5 mm, the person either has never been infected with *M. tuberculosis* or is infected but is suffering from anergy secondary to HIV infection. This phenomenon is seen particularly in patients who suffer from advanced HIV infection, which is either clinically evident (i.e., previous opportunistic infection) or shown by laboratory data (i.e., a count of CD4 lymphocytes under 200/mm³ or a count of total lymphocytes under 1 000/mm³). These patients must be kept under medical observation and periodic check-ups must be provided, including a PPD test once or twice a year.

Chemoprophylaxis of the HIV-infected person is the same regardless of whether the individual has asymptomatic HIV infection or AIDS.

In areas where the transmission of TB is high, every HIV-positive person or AIDS patient who does not have TB should receive chemoprophylaxis for a minimum of 6 to 12 months, regardless of the results of the PPD test (persons with a negative reaction to the PPD may be either anergic or truly not be infected). The possibility that a PPD test with a diameter of induration less than 5 mm reflects the existence of tuberculous infection in an immunosuppressed patient is higher than in a low-transmission area. In addition, if the person has never been infected, the risk of primary infection is high, and an HIV-positive person runs a greater risk of developing active tuberculosis. In the latter case, primary chemoprophylaxis adequately protects the patient.

7. ADDITIONAL RECOMMENDATIONS

- Strengthen the capacity, efficiency, effectiveness, coordination, and availability of resources of AIDS programs and tuberculosis programs in all countries of Latin America and the Caribbean.
- Introduce into national programs regulatory provisions that, based on the conditions or characteristics of the country, ensure diagnosis of people simultaneously infected with *M. tuberculosis* and HIV and clearly set forth instructions for chemoprophylaxis and treatment, according to the case and in agreement with this technical guide.
- Strengthen interaction between AIDS and tuberculosis programs by means of periodic meetings for an epidemiologic analysis of the magnitude of and trends in both diseases. Joint analysis will make it possible to acquire knowledge about the situation and to apply measures aimed at preventing infection or postponing the appearance of disease.
- Provide broad training for health personnel in the AIDS and TB programs, as well as in the general health services, supplying information on both diseases, transmission control mechanisms, psychosocial aspects, and, in particular, matters related to biosafety.

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9. LIST OF PARTICIPANTS AND SECRETARIAT

Participants

Dr. Kenneth G. Castro, Centers for Disease Control and Prevention, Center for Infectious Diseases, Atlanta, Georgia 30333, USA

Dr. Donald Enarson, Union Internationale contre la Tuberculose, 68 Boulevard Saint Michel, 75006 Paris, France

Dr. Victorino Farga, Universidad de Chile, Facultad de Medicina, Avenida Suecia 2202, Santiago 9, Chile

Dr. Julio González Montaner, AIDS Research Program and Infectious Diseases, 1033 Davie Street, Room 200, Vancouver BC, V6E 1M7, Canada

Dr. Philip C. Hopewell, San Francisco General Hospital, 1001 Potrero Avenue, San Francisco, California 94110, USA

Dr. Afranio L. Kritski, Universidade Federal de Rio de Janeiro, Carlos Seide 813, Rio de Janeiro 20931, Brazil

Dr. Elsa Palou, Instituto Nacional del Tórax, Colonia Lara, Tegucigalpa, Honduras

Dr. Mario Raviglione, World Health Organization, Division of Communicable Diseases/Tuberculosis, 20 Avenue Appia, 1211 Geneva 27, Switzerland

Dr. Sergio Rodríguez Filigrana, Instituto Nacional de Enfermedades Respiratorias, Servicio de Neumología, Calzada de Tlalpam 4502, Mexico City 14080, Mexico

Secretariat

Dr. Claude Betts, Pan American Health Organization. Regional Program on AIDS and STD, Washington, DC, USA

Dr. David Brandling-Bennett, Pan American Health Organization, Division of Communicable Disease Prevention and Control, Washington, DC, USA

Dr. Paloma Cuchí, Pan American Health Organization, Regional Program on AIDS and STD, Washington, DC, USA

Dr. Gabriel Schmunis, Pan American Health Organization, Program on Communicable Diseases, Washington, DC, USA

Dr. Mercedes Weissenbacher, Pan American Health Organization, Regional Program on AIDS and STD, Washington, DC, USA

Dr. Alvaro Yáñez, Pan American Health Organization, Program on Communicable Diseases/Tuberculosis, Washington, DC, USA

Dr. Fernando Zacarías, Pan American Health Organization, Regional Program on AIDS and STD, Washington, DC, USA

Suggestions on how to improve the guide would be appreciated. Please use the questionnaire presented below.

QUESTIONNAIRE ON "ASSOCIATION BETWEEN HIV AND TB: TECHNICAL GUIDE"

1. Are the recommendations of this guide consistent with national program policies on tuberculosis and AIDS in your country?

Yes, with both programs

No, with neither of the programs

Yes, with the TB program

Yes, with the AIDS program

Comments: _____

2. Do you think that your capacity in terms of resources and materials permits the use of this guide in your country?

Yes

No

Comments: _____

3. Are there other points related to the association between HIV and tuberculosis that should be covered in this guide?

Yes

No

Comments: _____

4. Is this guide practical?

Yes

No

Comments: _____

5. Is it easy to read and understand?

Yes

No

Comments: _____

6. Would you like to make a basic suggestion to improve it?

Yes

No

Comments: _____

Submitted by: _____

Postal address: _____

Return to:

Pan American Health Organization
Regional Program on AIDS and STD (HPC)
AIDS Research Unit
525 Twenty-third Street, N.W. - Room 417
Washington, D.C. 20037, U.S.A.