DPN

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Tuberculosis Treatment

Sobering changes in the epidemiology of tuberculosis across the country have disrupted the national goal of eliminating the disease. Once thought to be under control, tuberculosis has emerged in the 1990s as the world's worst infectious disease, according to the World Health Organization. TB cases in Texas have increased 43% since 1987. In certain areas of the U.S. the proportion of patients with multidrug-resistant (MDR) strains has increased dramatically, and outbreaks of MDR-TB in some hospitals have caused illness and death among health-care workers as well as patients.

Still, the battle against TB can be won. In most cases, TB can be treated effectively, and treatment can stop the spread of the disease. **Therefore, the top priority is to cure patients with active TB.** Prompt diagnosis, appropriate initial treatment, and the provision of HIV-related and social services all improve chances of cure.

This special report provides easy to use diagnosis and treatment guidelines for physicians. Charts are provided that organize the basics of treatment along a timeline, describe doses and toxicities of anti-TB medications, and summarize available evidence on the management of patients with renal insufficiency or TB meningitis, or during pregnancy. The recommendations offered here were developed initially by the New York City Department of Health (NYCDH) based on its evaluation of the current consensus of published and clinical data. As appropriate for Texas, tuberculosis authorities from the Texas Department of Health (TDH) and the Texas Technical Advisory Committee on TB Elimination provided information and modified the recommendations of the NYCDH.

Ten Basics

1 Think TB! Consider the diagnosis of active tuberculosis in any patient with chronic cough and fever, especially if the person has a risk factor for HIV infection or other immunosuppression. Others at increased risk for TB disease include persons with documented PPD skin test conversion within the past two years, persons with medical risk factors known to increase the likelihood of active disease if TB infection has occurred, foreign-born persons from countries where TB is common, alcoholics and injecting drug users, and medically underserved low-income populations. Also at risk are residents of shelters for the homeless and of long-term-care facilities such as correctional and psychiatric institutions, and nursing homes. For TB information call your local health department, the closest TDH regional office, or the TDH state office at the following number:

Information Line
TB Elimination Division
(512) 458-7447
Mon. - Fri. 8 am - 5 pm.

2 Report suspected or confirmed cases of active TB to the Health Department. Prompt reporting is essential for TB control. Doctors who report cases (required by law) are sharing vital information with their colleagues and preventing the spread of TB. Report cases by calling or by mailing a TB400 form to your local health department. Local health departments report to public health regions, which in turn report to TDH. The seven major Texas metropolitan areas report directly to TDH. Health departments begin identifying and examining contacts of confirmed or suspected cases as soon as they are reported.

Texas Department of Health

The TB Elimination Division maintains a registry of patients with active TB, their treatment histories, and their contacts. TDH Laboratory (512/458-7578) maintains the results of patient drug-susceptibility tests. Physicians may obtain the information they need by calling the appropriate office. For questions regarding reporting protocol, call the TB Elimination Division.

3 Always take a careful TB treatment history, and obtain drug-susceptibility studies on all initial TB isolates. Take a complete history of prior anti-TB treatment. For example, has the patient ever taken a medicine (rifampin) that turned their urine and tears orange-red, or gotten shots (streptomycin) for weeks or months? Physicians may call the TB Elimination Division to see if the patient was previously treated for TB in Texas and to find out the results of previous drug-susceptibility studies. Because of the possibility of drug resistance, all initial isolates of *M. tuberculosis* should be tested for drug susceptibility. Such testing is routine for specimens submitted to the TDH lab.

For patients at risk of drug resistant-TB, an expert in the treatment of DR-TB should be consulted.

4 Begin all patients with active disease who have never been treated for TB before on at least three anti-TB drugs. In Texas all previously untreated TB patients should be started on isoniazid (INH), rifampin (RIF), and pyrazinamide (PZA). If there is any possibility of INH resistance, then ethambutol (EMB) should be included in the initial regimen. If drug susceptibility results indicate sensitivity to INH, then EMB can be dropped. **Do not** use INH and RIF alone unless susceptibility to both has been documented (see Table 2). **Never add a single drug to a failing regimen.** To do so may promote the development of drug resistance. Previous treatment for TB and present or former residence in a community with a history of drug resistant TB are two indicators of high risk for drug resistant TB (DR-TB). For patients at risk of DR-TB, an expert in the treatment of DR-TB should be consulted. For information about multi-drug resistant TB (MDR-TB), see No. 7.

Never add a single drug to a failing regimen.

5 Ongoing care is a complex art. Patients should be evaluated thoroughly at the first visit, and monitored at least monthly (see Table 1). Because immune status is a critical factor in treatment, HIV counseling and confidential testing should be offered. Just as the hypertensive patient should have blood pressure measured regularly, the patient with pulmonary TB should give a sputum sample at every doctor's visit to document smear and culture conversion to negative, and to assure that the culture remains negative during treatment. Patients with drug-susceptible isolates who are compliant with therapy need sputum obtained monthly only until cultures become persistently negative. Determining when culture conversion occurs is critical to monitoring treatment efficacy. In patients with HIV infection or drug-resistant isolates, this information will help determine length of treatment. HIV-seropositive patients with drug-susceptible isolates should continue drug therapy for at least six months after conversion to negative. Suspect drug resistance, non-compliance, or malabsorption if a patient remains smear positive after two months or culture positive after three months of treatment.

6 Focus top priority on complete treatment of all patients with active TB disease. Prompt identification of active cases and completion of appropriate treatment regimens would stop the spread of TB. The time to plan for completion is immediately on diagnosis. Studies demonstrate that adherence to medical regimens is invariably far lower than physicians suspect. Failure to comply with an anti-TB regimen can have serious consequences, not only for the patient, who may develop progressive, drug-resistant disease, but also for the

patient's family and other intimate contacts.

Directly observed therapy (DOT), in which a health-care worker or other person watches the patient take the medicine, is the most reliable and effective way of administering anti-TB medications and assuring treatment completion. Ideally, every TB patient should receive every dose of anti-TB medication within a program of DOT. Health Department staff can provide DOT at a clinic, a patient's home or workplace, drug-treatment centers, or community-based organizations. **For help arranging DOT for your patients, call the TDH TB Information Line.**

An intermittent dosing regimen of twice weekly dosing can be used for patients with drug susceptible TB, **but only via DOT.** (See 4 for recommended treatment regimen.) Patients should remain on daily therapy until drug-susceptibility results are available (a minimum of two to three weeks). EMB should be continued until susceptibility to both INH and RIF has been demonstrated. For HIV-seropositive patients on twice weekly therapy, PZA should be continued until two months have elapsed and their sputum samples are AFB-smear negative. For other patients, PZA may be dropped when they have completed two months of therapy and susceptibility to both INH and RIF is documented. Intermittent dosing is as effective as daily dosing for patients with drug-susceptible organisms.

Physicians can support compliance by structuring all clinical services to be "patient-friendly," and by assuring that the patient's social service needs are met early in treatment. Important support services include HIV-related services, treatment for alcohol and drug addiction, housing, and the provision of Medicaid.

7 Never treat MDR-TB without expert consultation. The treatment of MDR-TB can be as complex as cancer chemotherapy and should not be attempted without consulting a specialist. Always use at least two (preferably three) drugs to which the patient's organism is susceptible and continue treatment for 18 to 24 months after culture conversion to negative. Monitor closely for adverse drug reactions and drug interactions (see Table 3). Assess drug absorption by monitoring serum drug levels, if possible. DOT is essential when treating persons with MDR-TB.

Ideally, every TB patient should receive every dose of anti-TB medication on a program of directly observed therapy (DOT).

8 Isolate hospitalized patients as soon as active TB disease is suspected or confirmed. Prompt diagnosis, effective isolation, appropriate treatment, and realistic plans for treatment completion after hospital discharge are all essential to reducing risk of nosocomial spread of TB. CDC and TDH have published guidelines for preventing transmission in health-care settings (see References 2 and 6).

9 Give preventive therapy when appropriate. The purpose of preventive treatment is to stop latent, asymptomatic infection from progressing to clinical disease and to prevent the recurrence of past disease. Candidates for preventive therapy are persons with a 5mm or greater PPD skin test who
- are HIV infected or at risk for HIV infection but decline testing,
- are close contacts of persons with newly-diagnosed infectious TB, or
- have abnormal chest X-rays that show fibrotic lesions likely to represent old healed tuberculosis; and persons with a 10mm or greater PPD skin test who
- are recent converters with a 6mm increase within a two-year period,
- have medical conditions known to increase the risk of active TB if infection has occurred, or
- are under 35 years of age.

The usual preventive therapy regimen is isoniazid, 10 mg/kg daily for children, up to a maximum adult

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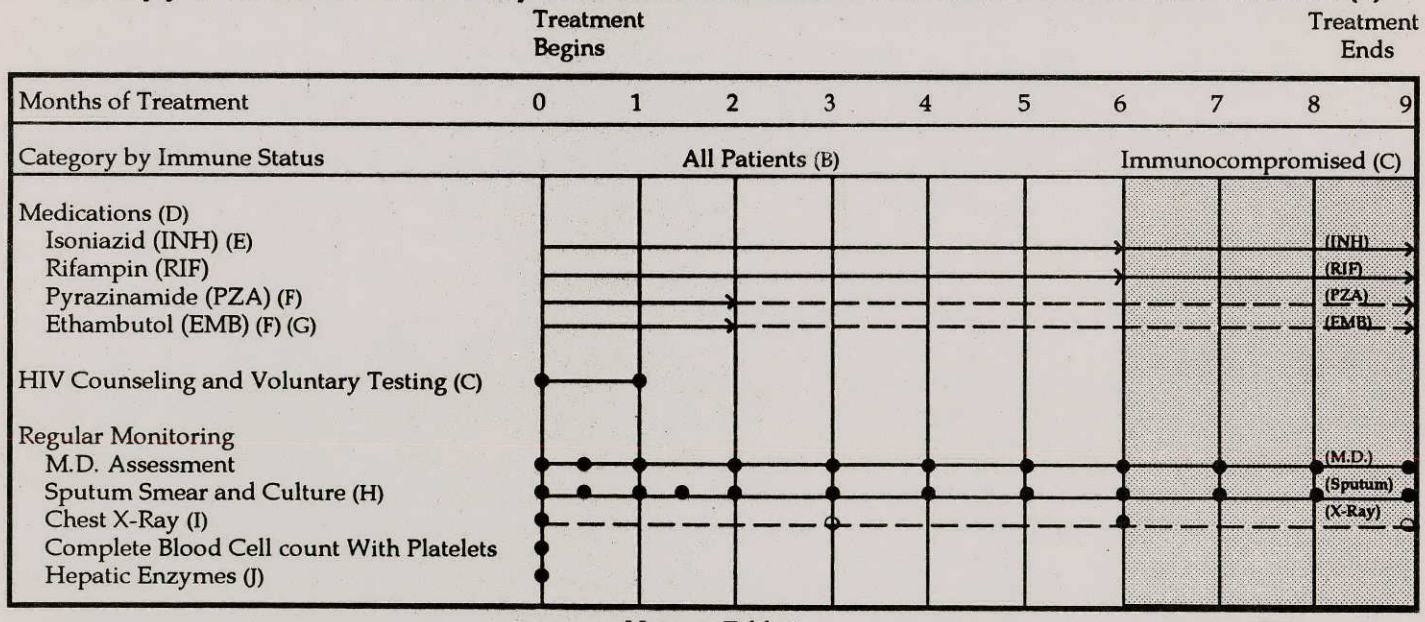
dose of 300 mg daily. The recommended duration of INH preventive treatment is 6 to 12 months; 12 months is recommended for persons with HIV infection or other immunosuppression and those with abnormal chest X-rays consistent with old healed tuberculosis, and six months for all others. Follow-up chest X-rays after an initial negative film are not indicated, unless symptoms of active TB develop. It is essential to rule out active pulmonary or extrapulmonary disease before initiating preventive therapy.

10 Preventive therapy for contacts of MDR-TB cases is complicated. In deciding how to treat patients who may have been infected with MDR-TB, four questions must be answered. First, **How likely is it that a patient is newly TB-infected?** A patient with a documented positive prior PPD skin test is less likely to be newly infected. Second, **How likely is it that the patient is MDR-TB infected?** A PPD-positive infant of a mother with untreated MDR-TB is highly likely to be MDR-TB infected. In contrast, a health-care worker with a positive PPD and no known source case may have a low-intermediate probability of being MDR-TB infected. Third, **How likely is the patient to develop active TB?** Those at highest risk include infants and persons who are HIV-seropositive or otherwise immunosuppressed. Fourth, **What is the drug-susceptibility pattern of the source patient's isolate?** CDC recently published guidelines for the treatment of people exposed to MDR-TB (Reference 3).

Table 1.

Therapy Timeline for Previously Untreated Tuberculosis Patients With Active Disease (A)



Notes to Table 1

(A) All initial isolates of *M. tuberculosis* submitted to the TDH lab will have drug-susceptibility testing performed. **This chart applies only to patients whose isolates are found to be drug susceptible.** The treatment of drug-resistant tuberculosis is complex. If drug resistance is documented, consult a physician who is an expert in its management.

(B) Pending the results of drug susceptibility testing, begin all patients on the three or four anti-TB medication regimens described in No. 4 (10 Basics), unless absolute contra-indications are present. Immunocompetent, HIV-seronegative patients should be treated for six months, and for at least three months beyond documented culture conversion.

(C) Because HIV status is a critical factor in the treatment of tuberculosis, HIV counseling and testing should be encouraged at the first or second clinical visit. Patients known or suspected to be infected with HIV, or otherwise immunocompromised, should be treated for a minimum of nine months, and for at least six months beyond documented culture conversion. Some authorities recommend longer courses of therapy for patients with extrapulmonary disease, and advise the continuation of monitoring with chest X-rays, and sputum smears and cultures for immunocompromised patients.

(D) Ideally, every TB patient should receive every dose of anti-TB medication on a program of directly observed therapy (DOT). This is particularly critical for patients with drug-resistant isolates and those with a history of noncompliance. See Table 3 for doses and toxicities.

(E) Pyridoxine hydrochloride (vitamin B6), 25 mg with each dose of INH, may decrease peripheral neuritis and CNS effects. Pyridoxine should be given with INH to patients who are pregnant, malnourished or who use alcohol.

(F) Continue treatment with PZA until eight weeks have passed and susceptibility to both INH and RIF is documented. For HIV-seropositive pa-

tients, PZA should be continued until eight weeks have passed and their sputum samples are AFB-smear negative. EMB should be continued until susceptibility to both INH and RIF has been demonstrated. **For twice weekly dosing regimens** preceded by a minimum of two weeks of daily therapy, some authorities recommend discontinuing PZA and EMB after two months have passed and susceptibility to both INH and RIF has been demonstrated.
(G) During treatment with EMB, monitor visual acuity and color vision monthly.
(H) Regular monitoring of sputum AFB smears and mycobacteriology cultures is essential. Susceptibility testing should be repeated if cultures remain positive after three months of treatment, or if the patient fails to improve clinically. **Directly observed therapy is critical for patients whose cultures are positive after three months of treatment.** If drug resistance is documented, seek expert consultation.
(I) Sputum examinations are far more useful than chest X-rays for following clinical progress. Obtain chest X-ray after three months to document response to treatment only if initial cultures are negative.
(J) Hepatic enzymes should be monitored monthly if baseline levels are elevated or if there is a history of alcoholism or liver disease. At least 20% of patients will have elevated hepatic enzymes; asymptomatic elevation less than five times the upper limit of normal is not an indication for discontinuing treatment. If patients have jaundice or symptomatic liver disease, discontinue medications immediately and consult a specialist. If baseline hepatic enzymes are normal and there is no history of alcoholism or liver disease, repeat tests are not necessary unless signs or symptoms of liver disease appear. Baseline hepatic enzymes are optional for those under 18 years of age unless they have a history of liver disease.

Table 2. - Use of Anti-Tuberculous Medications in Special Situations: Pregnancy, Tuberculous Meningitis, and Renal Failure

Medication	Safety in Pregnancy (1)	Central Nervous System Penetration(2) (% of Serum Level)	Dosage in Renal Insufficiency(3)
Isoniazid	Has been used safely(4)	Good (20-100%)	No change
Rifampin	Has been used safely (isolated reports of malformations)	Fair Inflamed meninges (10-20%)	No change
Pyrazinamide	Avoid (limited data on safety)	Good (75%-100%)	Decrease dose/increase interval (use with caution)
Ethambutol	Has been used safely	Inflamed meninges only (4-64%)	Decrease dose/increase interval
Aminoglycosides (Streptomycin, Kanamycin, Amikacin)	Avoid(5) (associated with hearing impairment)	Poor(6)	Decrease dose/increase interval(7)
Capreomycin	Avoid(5) (limited data on safety)	Poor	Decrease dose/increase interval(7)
Ciprofloxacin, Ofloxacin	Do not use (teratogenic in laboratory animals)	Fair (5-10%) Inflamed meninges (50-90%)	Decrease dose/increase interval(8)
Ethionamide	Do not use (premature labor, congenital malformations)	Good (100%)	No change
Cycloserine	Avoid (limited data on safety)	Good (50-100%)	Decrease dose/increase interval
Para-amino-salicylic acid	Has been used safely	Inflamed meninges only (10-50%)	Incomplete data (large sodium load)
Clofazimine	Avoid (limited data on safety)	Unknown	Probably no change

Notes to Table 2

(1) As with all medications given during pregnancy, anti-TB medications should be used with extreme caution. However, the risk of tuberculosis to the fetus far outweighs the risk of adverse reactions to the medications. Patients with active tuberculosis should be treated. For preventive treatment, most authorities recommend beginning isoniazid prophylaxis several months after delivery, unless the woman is at high risk for progression to active tuberculosis (e.g., recent PPD conversion, HIV-seropositive). Limited data are available on the safety of anti-tuberculosis medications during pregnancy. This table presents a consensus of published data and recommendations. Concentrations of anti-TB medications in breast milk are low. Medication present in breast milk is not sufficient to prevent or treat TB in the newborn, and treatment with these medications is not a contraindication to breastfeeding.
(2) Steroid treatment appears to improve outcome in TB meningitis, particularly in patients with altered mental status.
(3) If possible, monitor serum drug levels of patients with renal insufficiency.
(4) Supplement with pyridoxine (vitamin B6) during pregnancy.
(5) If an injectable medication MUST be used during pregnancy, streptomycin is preferred. The risk/benefit of TB treatment must be weighed, however, considering that streptomycin is known to be ototoxic to the fetus at all stages of pregnancy.
(6) Has been used intrathecally; efficacy not documented.
(7) Avoid aminoglycosides and capreomycin in patients with reversible renal damage, if possible.
(8) Ofloxacin may accumulate in renal failure and is poorly removed by dialysis.

Table 3. - Medications Used in the Treatment of Tuberculosis: Doses, Toxicities, and Recommended Regular Monitoring

	Daily Dose (Should be given as single daily dose, if possible)		Intermittent Dosing(1) Twice Weekly Dose (Directly-Observed Therapy Only)	
Medication	**Children**	**Adults (Usual)**	**Children**	**Adults**
Isoniazid (3)	10 mg/kg PO or IM Max. 300 mg	300 mg PO or IM	20-40 mg/kg Max. 900 mg	15 mg/kg Max. 900 mg
Rifampin(3)	10-20 mg/kg PO or IV Max. 600 mg	600mg PO or IV	10-20 mg/kg Max. 600 mg	600 mg
Pyrazinamide	20-30 mg/kg PO	1.5 g (<50kg) 2.0 g (51-74 kg) 2.5 g (75+kg) PO	40-50 mg/kg	2.5 g (<50 kg) 3.0 g (51-74 kg) 3.5 g (75+kg)
Ethambutol	15-25 mg/kg PO	15-25 mg/kg PO Max 2.5g	30-50 mg/kg	50 mg/kg
Streptomycin (4), (5)	20-40 mg/kg IM	15 mg/kg IM	25-30 mg/kg	25-30 mg/kg
SECOND-LINE MEDICATIONS - USE ONLY IN CONSULTATION WITH A PHYSICIAN EXPERT IN THE MANAGEMENT OF DRUG-RESISTANT TB (6)				
Ciprofloxacin (7), (8)		750-1500 mg PO		
Ofloxacin (7), (8)		600-800 mg PO		
Kanamycin,(4) Amikacin(7)	15-30 mg/kg IM/IV	15 mg/kg IM/IV		
Capreomycin (4)	15-30 mg/kg IM	15 mg/kg IM		
Ethionamide	15-20 mg/kg PO Divided doses	500-1000 mg PO Divided doses		
Cycloserine	15-20 mg/kg PO Divided doses	250-1000 mg PO Divided doses		
Para-amino-salicylic acid (5)	150 mg/kg PO Divided doses	8-12 g PO Divided doses		
Clofazimine(7)	50-200 mg PO	100-300 mg PO		

Notes to Table 3

(1) Ideally, every patient with active TB should receive every dose of anti-TB medication on a program of directly observed therapy. Intermittent therapy, which should always be directly observed, can be used only in some clinical situations.

(2) Not all toxicities are listed. Check package insert or pharmacology text for further information. Use of brand names does not imply endorsement of any product by TDH.

(3) Isoniazid and rifampin are available as a combination capsule (Rifamate) containing 150 mg of isoniazid and 300 mg of rifampin. TDH recommends using this drug instead of isoniazid and rifampin whenever feasible to improve patient compliance and reduce the risk of developing drug resistance.

Table 3. - Medications Used in the Treatment of Tuberculosis: Doses, Toxicities, and Recommended Regular Monitoring (cont.)

Medication	Major Adverse Reactions(2)	Regular Monitoring	Comments
Isoniazid (3)	Hepatic enzyme elevation, peripheral neuropathy, hepatitis, increased phenytoin (Dilantin) levels, interaction with disulfiram (Antabuse), CNS effects.	Hepatic enzymes (if baseline abnormal).	Overdose may be fatal. Aluminum-containing antacids reduce absorption. Pyridoxine hydrochloride (vitamin B6) may decrease peripheral neuritis and CNS effects.
Rifampin(3)	Orange discoloration of secretions, urine, tears, and contact lenses. Hepatitis, fever, thrombocytopenia, flu-like syndrome. Reduces levels of many drugs, including methadone, warfarin, birth control pills, theophylline, dapsone, and ketoconazole.	Hepatic enzymes (if baseline abnormal).	Single doses on empty stomach (2 hrs. before or after meals). Patients on methadone will need an increased dose of methadone (average 50%) to avoid opiate withdrawal. Interaction with ketoconazole leads to decreased levels of one or both. May make glucose control more difficult in diabetics.
Pyrazinamide	GI upset, hepatic enzyme elevation, rash, arthralgias, hyperuricemia.	Hepatic enzymes (if baseline abnormal).	May complicate management of diabetes mellitus. Hyperuricemia can be used as an indicator of compliance. Treat increased uric acid only if symptomatic.
Ethambutol	Optic neuritis (decreased red-green color discrimination), decreased visual acuity, skin rash.	Check color vision and visual acuity monthly.	Optic neuritis may be unilateral; check each eye separately. If possible, avoid in children too young to undergo vision testing.
Streptomycin (4), (5)	Ototoxicity, nephrotoxicity, hypokalemia, hypomagnesemia.	Audiometry and renal function.	Ultrasound and warm compresses to injection site may reduce pain and induration.
SECOND-LINE MEDICATIONS - USE ONLY IN CONSULTATION WITH A PHYSICIAN EXPERT IN THE MANAGEMENT OF DRUG-RESISTANT TB (6)			
Ciprofloxacin (7), (8)	Abdominal cramps, GI upset, tremulousness, insomnia, headache, photosensitivity. Drug interactions with warfarin and theophylline.		Variable absorption; check serum levels if possible. Antacids/sucralfate reduce absorption. Caffeine effects may be increased.
Ofloxacin (7), (8)	Probably similar to ciprofloxacin; possibly fewer drug interactions.		Similar to ciprofloxacin.
Kanamycin,(4) Amikacin(7)	Auditory and renal toxicity, rare vestibular toxicity, hypokalemia, hypomagnesemia.	Audiometry and renal function.	Ultrasound and warm compresses to injection site may reduce pain and induration.
Capreomycin (4)	Auditory, vestibular, and renal toxicity, eosinophilia, hypokalemia, hypomagnesemia.	Audiometry and renal function.	Ultrasound and warm compresses to injection site may reduce pain and induration.
Ethionamide	GI upset, bloating, hepatic enzyme elevation, metallic taste, hypothyroidism (esp. if patient is on para-aminosalicylic acid).	Hepatic enzymes (if baseline abnormal).	Antacids/anti-emetics and lying flat for 20 minutes after doses may help tolerance. Start with 250 mg daily and increase as tolerated.
Cycloserine	Psychosis, depression, seizures, rash, headache, increased phenytoin (Dilantin) levels.	Assessment of mental status.	Increase gradually, checking serum levels. Pyridoxine hydrochloride (vitamin B6), 50 mg with each 250 mg, may decrease CNS effects. Monitor weekly blood levels until stable if possible.
Para-amino-salicylic acid (5)	GI upset, hepatic enzyme elevation, sodium load, decreased digoxin, increased phenytoin (Dilantin) levels, hypersensitivity. Levels decreased by diphenhydramine (Benadryl).	Assessment of volume status.	Begin with 1-2 g TID and increase as tolerated. Monitor cardiac patients for sodium overload. May cause hemolytic anemia in patients with G6PD deficiency.
Clofazimine(7)	Orange-brown skin discoloration. GI complaints. Rare visual disturbances.		Efficacy unproven.

(4) In persons older than 60, the daily dose of streptomycin should be limited to 10 mg/kg with a maximum dose of 750 mg. For patients with drug-resistant isolates, injectable medications are generally given 5 days per week for several months, then reduced to 2-3 times per week, preferably after sputum cultures have become negative.

(5) Available through the Centers for Disease Control: Call (404) 639-3670 (Streptomycin), and (404) 639-2530 (PAS).

(6) Intermittent dosing of oral second-line medications is not recommended. See footnote (4) about injectable medications.

(7) Not FDA-approved for the treatment of tuberculosis.

(8) Not recommended for children.

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A Note About the Charts

The tables provide TB treatment recommendations for Texas based on national guidelines and the best current consensus of clinical and published data. (See references above.) Table 1 charts the treatment of patients with drug susceptible TB. Table 2 reviews the best available evidence on the management of patients in pregnancy, or with TB meningitis or renal insufficiency. Table 3 provides guidance on the use of individual anti-TB medications. All the recommendations presented here have been developed to guide, but not to substitute for, the best judgment of the physician in specific clinical situations. Because the data on which some recommendations are based are limited and because these recommendations will, therefore, continue to change, **expert consultation is often essential,** particularly in special situations (see Table 2) and in the treatment of drug-resistant TB. Consult manufacturers' product information whenever medications are prescribed.