Managing the Patient's Response to TB Treatment

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Has the following disclosures to make:

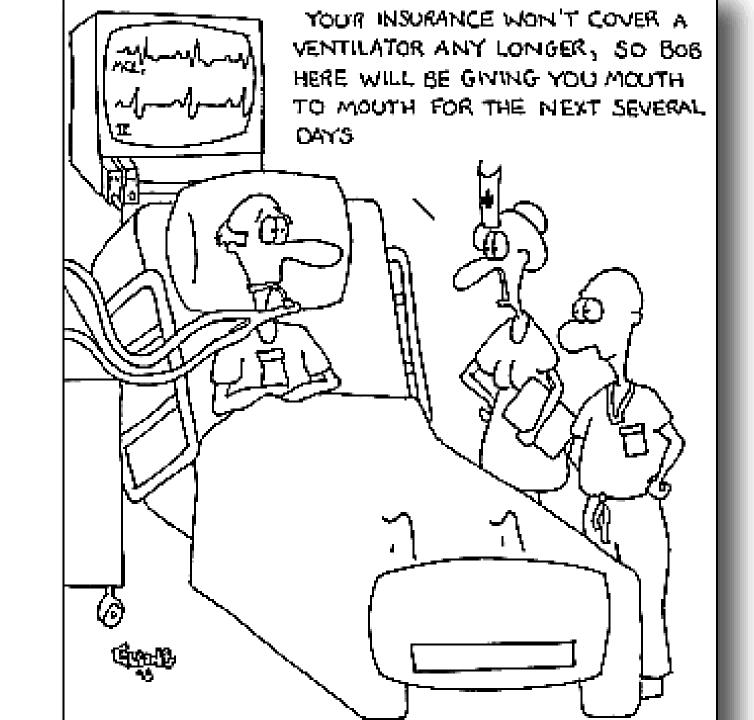
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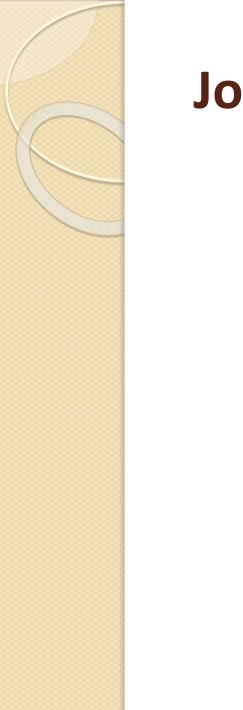
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Joys of Health Care



Objectives

- Identify Components that will determine if the patient is responding to treatment
- How to determine why the patient is NOT responding to treatment
- Determine if the patient is responding to anti-TB therapy via: clinical, bacteriologic, and radiographic responses.

Objectives Continued

• Identify next steps to take when the TB pt is not responding to therapy via: assessing adherence, identifying adverse reactions, drawing serum drug levels, and repeating susceptibility testing if possible.

Goals of TB Treatment

- Cure patient, minimize risk of death/disability, prevent transmission to others
- Provide safest, most effective therapy in shortest period of time (6 months or longer)
- Prescribe multiple drugs to which the organism are susceptible
- Never treat with a single drug or add a single drug to failing therapy
- Ensure adherence and completion of therapy

Develop Treatment and Monitoring Plan

- Plan should include:
 - -Description of treatment regimen
 - -Methods for assessing/ensuring adherence
 - –Methods to monitor for adverse reactions
 - -Methods for evaluating treatment response

TB Case and Suspect Management Plan

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Initial Report Date:

Nurse Case Manager:

Case Management Team:

Directions: Blank boxes indicate week(s) TB service is to be provided. Document date and initials of the provider in the appropriate box when the task is completed. Document comments in progress notes.

	Action Interval:	0 Begin	2 Wks	4 Wks	8 Wiks	12 Wks	16 Wks	20 Wks	24 Wks	20 WI
	Date:									
Responsibility	Assign nurse case manager; establish team; document in client's record									
	Obtain medical history; document on TB-202									
	Obtain release (L-30); request previous medical records									
Medical Evaluation	MD evaluation									
	RN evaluation									
Evaluation	Mantoux skin test (if not previously done)									
	Chest X-ray									
	Supervised sputum for AFB smear/culture according to protocol									
	HIV testing, unless patient has knowledge of HIV+ status or has documented negative HIV test result within 14 days of TB diagnosis									
	Nutritional assessment									
	Drug regimen according to protocol or specific order									
	Initiate DOT on all cases/suspects: Daily X2 weeks, 2X/week (Mon/Thurs or Tues/Fri) or 3X/week									
	(Mon/Wed/Fri) until completion of adequate therapy; document DOT on TB-206									
Treatment	Pyrazinamide X2 months and ethambutol X2 months (or until susceptibilities are reported and client's									
	organism is known to be pan sensitive) Vitamin B6 (if pregnant, diabetic, at risk for peripheral neuropathy)									
	Obtain Informed Consent form TB-411 (TB-411A, if Spanish speaking, only) initially and for any drugs added to regimen.									
Consultation	Obtain expert consult for drug resistant cases, complicated adult/pediatric cases or client who remains									
	symptomatic or sputum positive after 2 months therapy; written consult in client record									
	Clinical assessment according to protocol; document (TB-205 and progress note as appropriate)									
Toxicity/ Clinical	Visual acuity (Snellen) and color discrimination (Ishihara Plates) initially and monthly if on EMB or effortion document (CE 205)									
Assessment	rifabutin; document (TB-205) Hearing sweep check initially and monthly if on									
	amikacin, capreomycin, kanamycin or streptomycin; document (TB-205)									

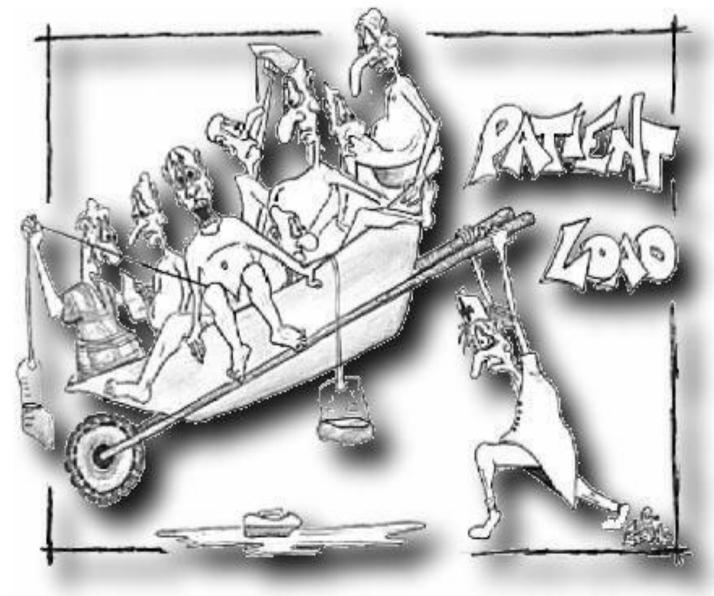
TB-201 TB Case and Suspect Management Plan for Outpatient Care - 04/12 (Continued on Reverse)

Action Interval:	0 Begin	2 Wks	4 Wks	8 Wks	12 Wks	16 Wks	20 Wks	24 Wks	26 Wk
Date:									
Issue Order to Implement Measures for a Client With Tuberculouis form TB-410 (TB-410A, if Spanish speaking, only) on all cases/suspects									
Follow-up missed appointments within 1 working day; initiate court-ordered management according to TDH policy (see TB Policy Manual, Section 5) and notify Regional office									
Evaluate barriers to treatment									
Conduct site visit to assess living situation. Institute isolation in congregate living situation or									
home and exclude from work or school, if infectious									
return to work/school following at least 2 wks appropriate therapy, 3 consecutive negative smears									
Appropriate client education provided initially and									-
monthly per protocol; written instructions and monthly review of medication side effects, document on TB-203									
Interview case/suspect and contacts; plan contact investigation using the "Concentric Circle" approach									
Initiate contact investigation within 3 working days; interview and evaluate (ikin test/reading, CXR,									
Expand contact investigation according to CDC guidelines and local criteria for expansion.									
Provide second skin test 8-10 weeks after break in contact with the case to all contacts who were skin test negative on the initial test: document on TB-340									
Report suspect/case to state designated case registry within 1 working day of notification									
Submit TB-400A and TB-400B (all data fields complete) within 7 days of diagnosis; submit TB-400B at least quarterly and at the time of closure									
Submit TB-340 within 14 working days of initiating contact investigation and after second testing of negative contacts is complete									
Clinical supervisor or TB Program Manager reviews and evaluates contact investigation									
Team review of client record									
Enroll in Medicaid, if eligible; make appropriate referrals to drug/alcohol treatment programs, nutritional support programs, and refer for HIV services, if necessary									
SIGNATURE:	MINEN.					INI	TIALS:		
SIGNATURE: IN					TIALS				
	Interval: Date: Date: Issue Order to Implement Measures for a Client With Tuberculosis form TB-410 (TB-410A, if Spanish speaking, only) on all cases/suspects Follow-up missed appointments within 1 working day, initiate court-ordered management according to TDH policy (see TB Policy Manual, Section 5) and notify Regional office Evaluate barriers to treatment Conduct site visit to assess living situation. Institute isolation in congregate living situation or home and exclude from work or school, if infectious Discontines congregate setting isolation or allow to return to work/school following at least 2 wks appropriate therapy, 3 consecutive negative smears on different days and an improvement of symptoms Appropriate client education provided initially and monthly review of medication side effects, document on TB-203 Interview case/suppect and contacts; plan contact investigation using the "Concentric Circle" approach Initiate contact investigation according to CDC guidelines and local cristria for expansion. Provide second skin test 8-10 weeks after break in contact with the case to all contacts in test negative on the initial test; document on TB-340 Provide second skin test 8-10 weeks after break in contact with the case to all contacts may test negative on the initial test; document on TB-340 Provide second skin test 8-10 weeks after break in contact with the case to all contacts who were skin test negative on the initial test; document on TB-340 Provide second and Counseling for contacts Report suspect/case to state designated case registry within 1 working day of notification Submit TB-400A and TB-400B (all data fields complete) within 7 days of diagnosi; submit TB-400B at least quarterly and at the time of closure Submit TB-340 within 14 working days of initiating contact investigation and after second testing of negative contacts is complete Clinical supervisor or TB Program Manager reviews and evaluates contact investigation Team review of client record Enroli in Medicaid, if eligible; make appropriate r	Interval: Begin Date:	Interval: Begin Wits Date: Interval: Date: Interval: Interval:	Interval: Begin Wits Wits Date: Image: Imag	Interval: Begin Wits Wits Wits Date: Interval: In	Interval Begin Wits Wits Wits Wits Date: Date: Date:	Interval: Begin Wits Wits Wits Wits Date: Image: Image	Interval: Begin Wits Wits <td>Interval: Begin Wits Wits</td>	Interval: Begin Wits Wits

TB-201 TB Case and Suspect Management Plan for Outpatient Care -04/12



Case Management



Nursing Management

- Administrative
- Initial Assessment
- Monitoring
- Treatment

Texas Department of State Health Services Tuberculosis Education/Counseling Record

Instructions:	Lang	lage us	ed for a	educati	on/ cou	nseling	2:			
 Provide appropriate Education/Counseling to ALL TB clients. Each client must have an education/counseling plan based on individual assessment and need. This tool serves as a guideline but education/counseling should not be limited to this information only. Initial each box as education/counseling is performed. The (Y) □ indicates when instruction should occur. 										
 Standardized printed materials (in client's preferred language, if available) are provided to client on the initial visit. Staff providing client education must be familiar with reference information listed in the TB standing delegation orders. 	Initial Visit	1 Mo Date	2 Mo Date	3 Mo Date	4 Mo Date	5 Mo Date	6 Mo Date	7 Mo Date	8 Mo Date	9 Mo Date
TRANSMISSION/PATHOGENESIS: • Signs/symptoms of TB disease • Airborne disease / Shared airspace • Infectiousness of case • PPD(+) 2-10 weeks after initial infection • TB infection vs. disease	•	•	•	•	>	•	•	•	•	•
 INFECTION CONTROL MEASURES: Proper use of masks and tissues Isolation/return to work after 3 negative smears, clinically improved, DOT for 2 weeks Sputum collection 	•	•	•	•						
• PPD testing/significance, CXR results, other tests	~						~			•
HIGH RISK GROUPS/FACTORS: • Diabetics, Silicosis, HIV+, Gastric resection • Alcohol/drug abuse (IVDU), Underweight • Corticosteroids, TNF-alpha antagonists • Foreign born, Resident of correctional or long term care facility	•	•	•							
 MEDICATION: Possible side effects, actions to take if side effects occur Increased risk of side effects if post-partum, alcohol abuse, kidney or liver disease Benefits = cure of disease or prevention of disease Administration = dosage/frequency, length of treatment, popt 	\$	>	•							



Evaluating Response to Treatment

- Three methods used to assess patient's response to treatment
 - -Clinical Evaluation
 - -Bacteriological examination
 - -Chest radiograph

Monitoring-Clinical

- Perform Clinical Evaluation-Monthly
 - -Identify possible adverse reactions
 - -Assess Adherence
 - -Determine treatment efficacy
 - Keep open line of communication with your DOT worker to assess how your patient is doing in the field

DOT Worker Engagement

- It is imperative that the nurse case manager keep open communication with their DOT workers at least on a weekly basis to ensure that patients receiving DOT in the field are adherent to therapy and are not experiencing adverse effects with their therapy.
- The DOT worker should phone the case manager if a patient complains of s/s of toxicity before providing DOT.
- If there are concerns that the patient is not ingesting the medication, the DOT worker should ask the patient to open their mouth for observation after DOT to ensure that the patient is not holding the meds in their mouth to be spit out later.



Nursing Management

- When a patient is complaining of adverse effects in the field, it is the nurse case manager's responsibility to hold the DOT PRN and advise the pt's MD of the concern. The nurse may also need to bring the patient into the clinic or perform a field visit to obtain labs on the patient to assess health status.
- If there are concerns of hepatoxicity, the DOT should be kept on hold until LFTs come in and are WNL for resuming the pt's DOT.

Monitoring-Clinical

- Is there symptom improvement?
 - Assess symptoms at least monthly
 - Gradual improvement
 - Complete resolving of symptoms
- Symptoms **NOT** improving?
 - After first 2 months
 - Reevaluate for adherence/resistance
 - Symptoms worsening?
 - Reevaluate for adherence issues
 - Development of drug resistance
 - Consider drawing serum drug levels if at 3 months still culture positive (AFB culture positive at 4 months is a treatment failure)

Pulmonary TB Symptoms to Assess--Is there Clinical Improvement in the Following:

- Cough
- Hemoptysis
- Loss of Appetite
- Weight Loss
- Fever/Chills
- Dyspnea
- Chest Pain
- Fatigue
- Night Sweats

Monitoring-Clinical

- Adverse Drug Reaction
 - Type and frequency dependent on meds used and patient's risk
 - Relatively rare but may be severe
 - Educate patient on common side effects

Treating After an Adverse Reaction

- Let reaction resolve (i.e., pt to take Benadryl for itchy rash and don't restart medications until rash resolves)
- Get expert consult
- Start medications one by one "serially" at low doses and build up to full dose on each medication before introducing new medication. Pt must come into clinic to be observed in case of another reaction; have emergency medications for severe allergy/anaphylaxis
- Try to figure out which medication caused the reaction and see if pt could be treated without that medication
- Don't count any of the serial doses until patient has an adequate regimen on board

Texas Depa									
Clinical Assessment fo	r Tube	rculosis	5 Diseas	e Medio	ation T	oxicity			
NAME:			DOP		11		\$\$#.	1	,
+					·'	`		_''	
Adverse Drug Reaction Assessment: Ask <u>questions (1-19) when patient is</u> on first-line drugs and ask que		10) : C			يفيد مد قد قر		D		14. : 4h -
progress notes and notify the physician. Notify physician if a wom	an of child	lbearing age	econd-nneo e indicates t	that she thir	iks she may	be pregna	nt or has sis	en (+) rest ens of preer	ancv.
Results: [+] = If Present [-] = If Denies [NA] = If Not Ap					-				
	Date	Date	Date	Date	Date	Date	Date	Date	Date
Weight									
Temperature									
Blood Pressure									
Do you have any of the following symptoms									
now or since your last clinic appointment?									
1. Loss of Appetite									
2. Nausea/Vomiting									
3. Urine Color Change (Dark)									
4. Skin Rashes/Dry									
5. Sores on Lips or Inside the Mouth									
6. Numbness/Tingling (Hands/Feet, Face/Mouth)									
7. Change in Vision*									
8. Eye Pain/Initation (Redness, Excessive Tears)									
9. Jaundice (Yellow Skin/Eyes)									
10. Flu-like Symptoms									
11. Fatigue									
12. Headaches									
13. Fever									
14. Joint Pains/Swelling									
15. Urine Output‡									
16. Bleeding (Nose Bleeds, Hemoptysis)									
17. Vertigo/Dizziness/Fainting									
Teeter/Fall to Left or Right When Standing									
(With Eyes Closed)									
Weave/Stagger When Walking (Normal Gait)									
18. Hearing Loss/Ears Ringing/Fullness									
19. Nervousness/Giddiness/Restlessness									
20. Increased Gas/Stomach Cramps									
21. Abdominal Pain/Diamhea									
22. Sleep Problems									
23. Mood Changes/Depression									
24. Changein Heart Rate									

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Styles

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Ishihara Plate #		Red/Gre Deficien				Date								
1	12	12												+
2	8	3												+
3	5	2												
4	29	70												1
5	74	21												
6	7	Х												
7	45	X												
8	2	X												
9	Х	2	2											
10	16	Х												
11	Traceable	Х												
		Protan		Deutan				_	_	-		-	-	
		Strong	Mild	Strong	Mild									
12	35	5	(3) 5	3	3 (5)									
13	96	6	(9) 6	9	9 (6)									
14	Can trace 2 lines	Purple	Purple (Red)	Red	Red (Purple)									
Results														
Initials														+

Visual Acuity: If initial screen was conducted with corrective lenses (glasses or contacts), follow-up screens must be done the same. A change of 1 or more lines from the initial screen in either one or both eyes must be reported to the physician immediately.

Results: [P]=Pass [F]=Fail [U]=Unscreenable Chart Used: [] Letter [] "E" [] Other, Specify:____ Corrective Lenses: []=Yes []=No

Distance	Date								
Acuity									
Right Eye	20/	20/	20/	20/	20/	20/	20/	20/	20/
Left Eye	20/	20/	20/	20/	20/	20/	20/	20/	20/
Both Eyes	20/	20/	20/	20/	20/	20/	20/	20/	20/
Results									
Initials									

Hearing Sweep Check:

When patient is taking amikacin, carreonycin, kanamycin, or streptomycin, for each of the four frequencies listed, record the lowest level in decibals (dB) at which the person responds. Record the findings for both the right and left ear. Refer to an appropriately licensed professional if any two of the four frequencies are recorded as greater than 25 dB in either ear or the same ear or if there is a change of decreased hearing level from baseline. Start with 40 dB, if heard decrease by 10 dB until no response is obtained or until 20 dB is reached. If 20 dB is heard, record as 20 dB. Once no response is obtained, increase the dB level by 5 until a

Adverse Drug Reaction

Caused by	Adverse Reaction	Signs and Symptoms	Significance of reaction
Any drug	Allergic	•Skin rash	May be serious to minor
EMB INH (rare)	Eye damage	Blurred or changed visionChanged color vision	Serious
INH PZA RIF	Hepatic Toxicity	 Abdominal Pain Abnormal liver function test results Dark Urine Fatigue Fever for 3 or more days Flu-like Symptoms Lack of appetite Nausea, vomiting Jaundice 	Serious
INH	Nervous system damage	•Dizziness; tingling or numbness around the mouth	Serious

Adverse Drug Reaction

Caused by	Adverse Reaction	Signs and Symptoms	Significance of reaction
INH	Peripheral neuropathy	•Tingling sensation in hands and feet	Serious
INH (Avoid foods containing tyramines)	Serotonin syndrome	 mild (shivering and diarrhea) severe (muscle rigidity, fever and seizures) Severe serotonin syndrome can cause death 	Serious to minor
PZA	Stomach upset	Stomach UpsetVomitingLack of Appetite	May be serious or minor
PZA	Gout	•Abdominal uric acid level •Joint aches	Serious

RIF	Bleeding problems	Easy bruisingSlow blood clotting	Serious
RIF	Discoloration of body fluids	 Orange urine Permanently stained soft contacts 	Minor
RIF	Drug Interactions	•Interferes with certain medications i.e. BCP, methadone	May be serious or minor
RIF PZA	Sensitivity to the sun	•Frequent sunburn	Minor

Common Adverse Reactions

- Gastrointestinal Problems
 - Nausea
 - Poor appetite
 - Abdominal pain
- Hepatitis
 - Indicated by AST \geq 3 times the upper limit with symptoms
 - Or \geq 5 times the upper limit without symptoms

AST and ALT Level	Levels of Toxicity
AST & ALT <5 times the upper limit of normal	Mild
AST & ALT 5-10 times the normal limit	Moderate
AST or ALT >10 times the normal limit	Severe

• Rash

– May be minor, limited area, or manifested as itching

• Drug Fever

Monitoring-Bacteriology

- Obtain 3 sputum specimens
 - 8-24 hours apart
 - Prior to treatment
 - At least 1 early morning specimen (Observed)
- Extrapulmonary
 - Collect 3 specimens
- At least every 2 weeks-collect 2-3 sputum specimens until three consecutive smears are negative
- Monthly-collect at least 1 specimen for culture until 2 consecutive specimens (at least one month apart) are negative on culture and there are not further positive cultures

Bacteriologic Status

- Positive sputum cultures prior to treatment
 - Obtain specimens at least monthly until negative in two separate months
 - Perform monthly sputum AFB smears and cultures on MDR patients for entire course of treatment
 - A repeat CXR after 2 months of treatment is helpful to determine pt improvement

Bacteriologic Status-Cont.

- Negative sputum cultures prior to treatment
 - Repeat CXR at intervals based on clinical circumstances and differential diagnosis
 - If radiograph does not improve after patient has received 2 months of treatment, abnormality may be due to
 - Previous disease
 - Another reason



Important Reminder:

• At times, a patient with negative sputum AFB cultures will produce a positive AFB sputum smear. This smear's culture should be monitored to ensure that it is negative. If the culture is negative, this random positive AFB sputum smear is due to dead TB bacteria and as a result does not culture out MTB.

Bacteriologic Status-Cont.

- Cultures have **not** become negative after 3 months of therapy
 - Reevaluate for
 - Potential drug-resistant TB
 - Potential failure to adhere (pt cheeking or vomiting medications after DOT)
 - Possible low serum drug levels

Bacteriologic Status-Cont.

- Cultures are still positive after 4 months of treatment
 - Consider as having failed treatment and manage accordingly
 - TB therapy will need to be extended since pt was culture positive after 2 months of therapy

Monitoring X-Rays

- Initial Chest radiograph at onset of treatment
 - Children <6 receive AP/Lat views
 - Anterior/Posterior and Lateral Views recommended for <18
 - Dr. Seaworth/Armitigerequest PA/Lat CXRs for all pts.
 - Pregnant
 - Abdomen shield



Radiographs

- Extra-pulmonary TB
 - Get baseline CXR to assess pulmonary involvement
- Culture negative
 - Repeat in 2 months for comparison to initial CXR
- Culture positive
 - Repeat at 2 months is useful
 - At completion of therapy and anytime during treatment as recommended by clinician



Radiographs

• Important to remember that sometimes chest x-rays get worse before they improve. This will probably worry the patient that they are not getting better. It is important to assure them that radiographs are just one measure of improvement, but there is also symptom and bacteriologic improvement.

Re-evaluating patients not responding to treatment

- Re-evaluating means repeating –Clinical assessment
 - Symptoms not improving
 - Symptoms worsening
 - -Susceptibility test
 - -CXR

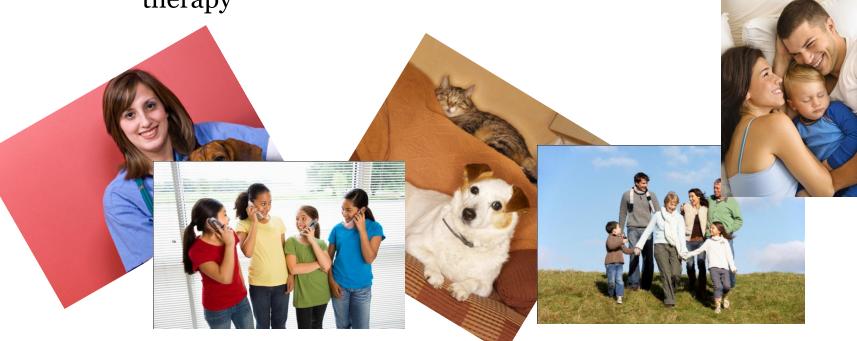


Serum Drug Levels

 Each health department should contact their State health department for further instructions for serum drug levels



- Important for patient to have the support needed
 - Has proven effective in having a positive response to therapy



Summary

- Three methods to determine response
 - Clinical: gradual improvement \rightarrow NO symptoms
 - Bacteriological: collected every month until conversion to negative; re-evaluate patient if sputum positive after 2 months or if sputum is positive after being negative
 - Radiographic

*NEVER add one drug at a time to a failing regimen

Summary

- TST or IGRA cannot be used to determine if patient is responding to treatment
- Treatment completion is defined by the number of doses taken within a specific time frame
- Length of treatment depends on drug susceptibility test results, site of disease, and response to therapy



References:

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