Managing the Patient's Response to TB Treatment

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Has the following disclosures to make:

- No conflict of interests
- No relevant financial relationships with any commercial companies pertaining to this activity

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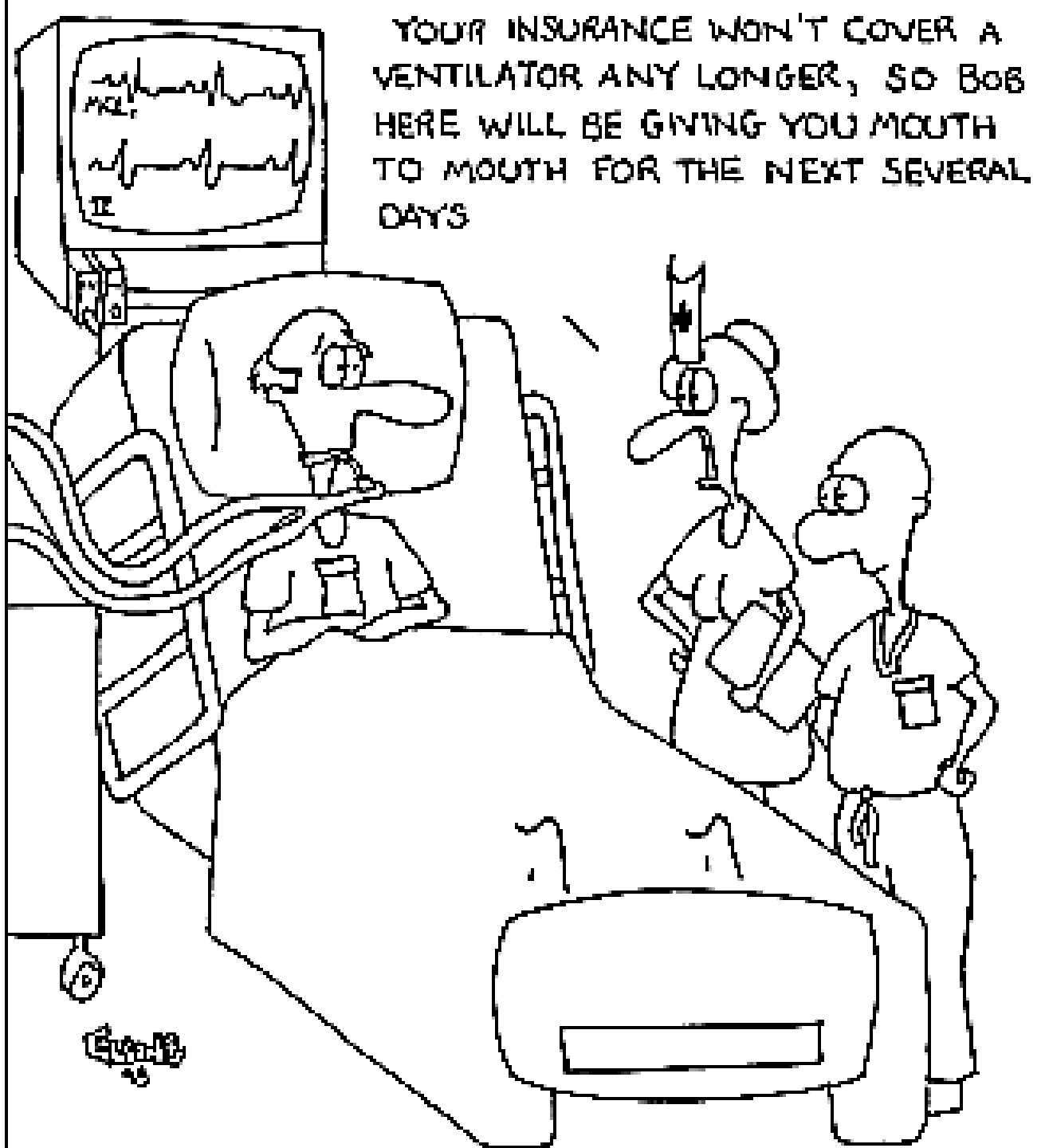
YOUR INSURANCE WON'T COVER A VENTILATOR ANY LONGER, SO BOB HERE WILL BE GIVING YOU MOUTH TO MOUTH FOR THE NEXT SEVERAL DAYS

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 patient is not responding to therapy by 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.
- 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

Texas Department of State Health Services

TB Case and Suspect Management Plan

Patient's Name: _____ 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		0 Begin	2 Wks	4 Wks	8 Wks	12 Wks	16 Wks	20 Wks	24 Wks	26 Wks
Interval:										
Date:										
Responsibility	Assign nurse case manager; establish team; document in client's record									
Medical Evaluation	Obtain medical history; document on TB-202									
	Obtain release (L-30); request previous medical records									
	MD evaluation									
	RN 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									
Treatment	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									
	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									
Toxicity/ Clinical Assessment	Clinical assessment according to protocol; document (TB-205 and progress note as appropriate)									
	Visual acuity (Snellen) and color discrimination (Ishihara Plates) initially and monthly if on EMB or rifabutin; document (TB-205)									
	Hearing sweep check initially and monthly if on amikacin, capreomycin, kanamycin or streptomycin; document (TB-205)									

TB Case and Suspect Management Plan for Outpatient Care

	Action Interval:	0 Begin	2 Wks	4 Wks	8 Wks	12 Wks	16 Wks	20 Wks	24 Wks	26 Wks
	Date:									
Adherence	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									
Isolation	Conduct site visit to assess living situation.									
	Institute isolation in congregate living situation or home and exclude from work or school, if infectious									
	Discontinue 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									
Education	Appropriate client education provided initially and monthly per protocol; written instructions and monthly review of medication side effects, document on TB-203									
Public Health/ Contact Investigation	Interview case/suspect and contacts; plan contact investigation using the "Concentric Circle" approach									
	Initiate contact investigation within 3 working days; interview and evaluate (skin test/reading, CXR, medical evaluation); document on TB-340									
	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									
	Provide education and counseling for contacts									
Reporting	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									
Quality Assurance Review	Clinical supervisor or TB Program Manager reviews and evaluates contact investigation									
	Team review of client record									
Social Services	Enroll in Medicaid, if eligible; make appropriate referrals to drug/alcohol treatment programs, nutritional support programs, and refer for HIV services, if necessary									

PRINTED NAME:_____ SIGNATURE:_____ INITIALS:_____

PRINTED NAME:_____ SIGNATURE:_____ INITIALS:_____

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TEXAS Department of State Health Services

Case Management

Nursing Management

- Administrative
- Initial Assessment
- **Monitoring**
- Treatment

Texas Department of State Health Services
Tuberculosis Education/Counseling Record

NAME: _____ **D.O.B.:** ____/____/____ **SS#:** ____/____/____

Instructions: 1. Provide appropriate Education/Counseling to ALL TB clients. 2. Each client must have an education/counseling plan based on individual assessment and need. 3. This tool serves as a guideline but education/counseling should not be limited to this information only. 4. Initial each box as education/counseling is performed. 5. The (Y) □ indicates when instruction should occur. 6. Standardized printed materials (in client's preferred language, if available) are provided to client on the initial visit. 7. Staff providing client education must be familiar with reference information listed in the TB standing delegation orders.	**Language used for education/ counseling:** **Interpreter names:** **Comments:**								
	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	✔	✔	✔	✔						
EVALUATION: • 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,	✔	✔	✔							

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

- Keep open communication with their DOT workers
- The DOT worker phones the case manager with concerns
- For concerns that the patient is not ingesting the medication, ask the patient to open their mouth for observation after DOT

Nursing Management

- When a patient is complaining of adverse effects the nurse case manager holds the DOT and advise the patient's provider of concerns.
- The nurse also assess the patient and obtain labs
- Please refer to the DSHS standing orders

(Texas Department of State Health Services Standing Delegation Orders…Fiscal Year 2025)

Nursing management continued

- If there are concerns of hepatoxicity, hold medication.

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 which can be ordered earlier. For additional information see - https://www.dshs.texas.gov/sites/default/files/LIDS-TB/forms/TherapeuticDrugMonitoringProcess.pdf

Texas DSHS Considerations for Using Therapeutic Drug Monitoring

Criteria* for Collecting Serum Drug Levels

Bacteriological Criteria (consider at 8 weeks of therapy)	**Medical Criteria** (consider at 2-4 weeks of therapy)	**Clinical Criteria** (consider at 8 weeks of therapy)	**Criteria based on TB Diagnosis****
Slow response to adequate therapy at **8 weeks** of treatment, evidenced by the following: • Patient remains AFB sputum smear positive 2+ or greater (unless easily explained) And/or • Sputum smear results not decreasing as expected (4+ to 3+, 2+, etc.)	• TB/poorly controlled diabetes comorbidity • Mal-absorption due to chronic or acute co-morbidity • Chronic or excessive vomiting or diarrhea • HIV infection and CD-4 count <100** • Low or high body mass index (>10% above or below ideal body weight)	• No improvement of TB symptoms (i.e., no weight gain, no reduction in cough, etc.) at 8 weeks • Worsening CXR anytime during course of adequate therapy • New clinical deterioration, likely related to TB (i.e., new evaluation for TB relapse or concern for drug resistance**)	• Patient Relapse: When signs and symptoms of TB return within two years of a prior episode of disease and there was a good possibility that relapse was due to low drug levels (exclude previous poor adherence, missed doses, or N/V) • When second line drugs need monitoring, as per consult recommendations • TB meningitis

* **Therapeutic Drug Monitoring should be reserved for patients who are not responding to adequate therapy,** and not necessarily for patients who meet some of the stated criteria and are otherwise doing well.
** Consultation recommended by a DSHS-recognized TB medical consultant, see list here: dshs.texas.gov/idcu/disease/tb/consultants/

https://www.dshs.texas.gov/sites/default/files/LIDS-TB/forms/TherapeuticDrugMonitoringProcess.pdf

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
- Get expert consult
- Start medications one by one “serially”
- Try to figure out which medication caused the reaction
- Don’t count any of the serial doses (DSHS SDO Attachment 7).

Texas Department of State Health Services
Clinical Assessment for Tuberculosis Disease Medication Toxicity

NAME: _____ **D.O.B.:** ____/____/____ **SS#:** ____/___/_____

Adverse Drug Reaction Assessment:
Ask questions (1-19) when patient is on first-line drugs and ask questions (1-29) if any second-line drugs are added to patient's regimen. Document [+] results in the progress notes and notify the physician. Notify physician if a woman of childbearing age indicates that she thinks she may be pregnant or has signs of pregnancy.
Results: [+] = If Present [-] = If Denies [NA] = If Not Applicable

	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/Irritation (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/Diarrhea									
22. Sleep Problems									
23. Mood Changes/Depression									
24. Change in Heart Rate									

Red/Green Color Discrimination:
The (X) mark indicates the plate cannot be read. Screen all 14 plates. Client must pass 10 of the first 11 plates for the test to be regarded as normal. Refer for evaluation if ≤ 7 plates are read as normal.
Results: [N] = Normal [A] = Abnormal

Ishihara Plate #	Normal Reading	Red/Green Deficiency				Date	Date	Date	Date	Date	Date	Date	Date	Date
1	12	12												
2	8	3												
3	5	2												
4	29	70												
5	74	21												
6	7	X												
7	45	X												
8	2	X												
9	X	2												
10	16	X												
11	Traceable	X												
		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 Acuity	Date	Date	Date	Date	Date	Date	Date	Date	Date
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, capreomycin, kanamycin, or streptomycin, for each of the four frequencies listed, record the lowest level in decibels (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 vision ●Changed 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 Upset ●Vomiting ●Lack of Appetite	May be serious or minor
PZA	Gout	●Abdominal uric acid level ●Joint aches	Serious

Adverse Drug Reaction

RIF	Bleeding problems	●Easy bruising ●Slow 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 ≥ 3 times the upper limit with symptoms
  - Or ≥ 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

- See DSHS SDO Attachment 6 for additional guidance on sputum collection.

Bacteriologic Status

- Positive sputum cultures prior to treatment
  - Obtain specimens at least monthly
  - Perform monthly sputum acid fast bacilli (AFB) smears and cultures, on patients with drug resistance, for entire course of treatment
  - Repeat CXR after 2 months of treatment

Bacteriologic Status-Cont.

- Negative sputum cultures prior to treatment
  - Repeat CXR
  - If radiograph does not improve after patient has received 2 months of treatment, abnormality may be due to
    - Previous disease
    - Another reason

Important Reminder:

- A patient with negative sputum AFB cultures may produce a positive AFB sputum smear.

Bacteriologic Status-Cont.

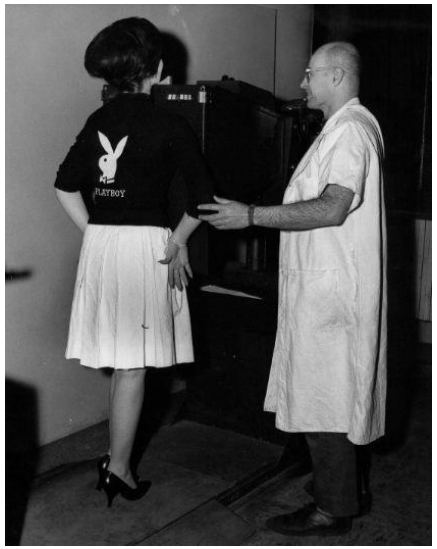
- Cultures have **not** become negative after 3 months of therapy
  - Reevaluate for
    - Potential drug-resistant TB
    - Potential failure to adhere (patient cheeking or vomiting medications after DOT)
    - Possible low serum drug levels

Bacteriologic Status-Cont.

- Cultures are still positive after 4 months of treatment
  - Consider treatment failure
  - TB therapy extension

Monitoring X-Rays

- Initial Chest radiograph at onset of treatment
  - Patients younger than 18 years old or patients with HIV infection should have Posterior-Anterior and Lateral Views (DSHS SDO attachment 5).
  - 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

- Sometimes chest x-rays get worse before they improve.
- This may worry the patient. Reassure them this is one measure of 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

- Please reference the Texas Department of State Health Services therapeutic drug monitoring process for further instructions for serum drug levels at

https://www.dshs.texas.gov/sites/default/files/LIDS-TB/forms/TherapeuticDrugMonitoringProcess.pdf

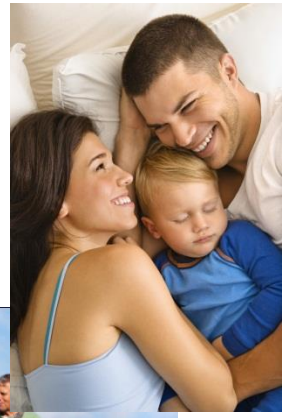
Support System




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







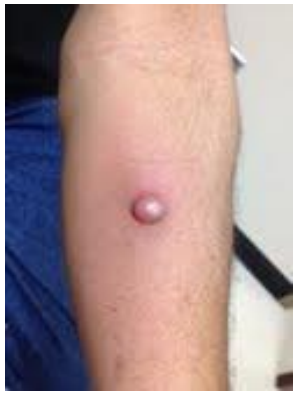
Summary

- Three methods to determine response
  - Clinical: gradual improvement → 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



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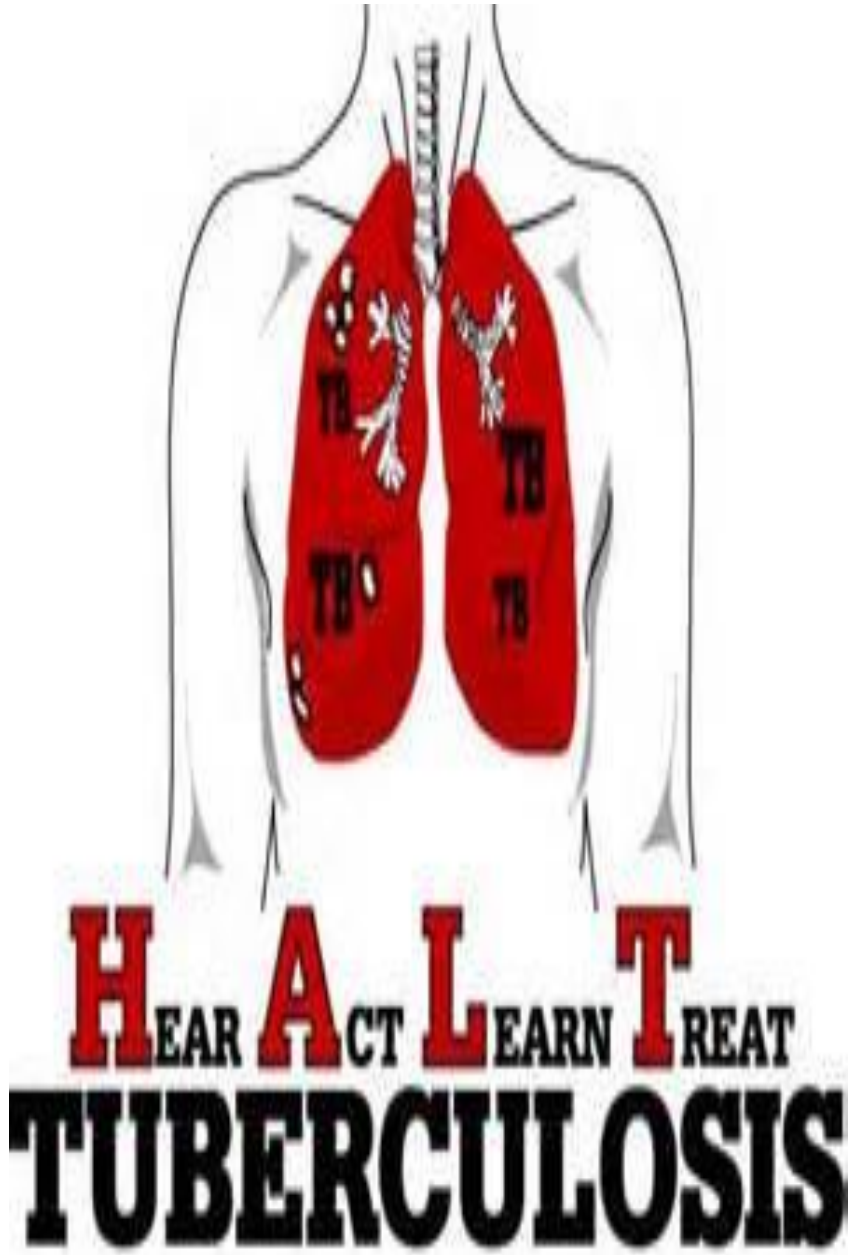
- Dawn Farrell, BSN, RN, Veronica Y. Dominguez, BSN,RN, Dora Marrufo, BSN, RN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HEAR ACT LEARN TREAT
TUBERCULOSIS


thank you
danke
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Баярлалаа
спасибо
gracias
tapadh leat
mersi
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kia ora
dank je
misaotra
matondo
paldies
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vinaka
спасибі
blagodaram
хвала
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