

A circular logo with a white border and a grey inner circle. Inside the inner circle is a stylized star with five points, colored blue, green, and orange. The star is surrounded by small dots.

Managing the Patients Response to TB Treatment

Jacqueline I. Maldonado, DNP, RN
June 6, 2024

Comprehensive TB Nurse Case Management
June 5 – June 6, 2024
San Antonio, Texas

Jacqueline I. Maldonado, DNP, RN, has the following disclosures to make:

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



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Essentials of TB Nurse Case Management Online



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“Welcome to the I.V. league.”

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 (4 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

**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.

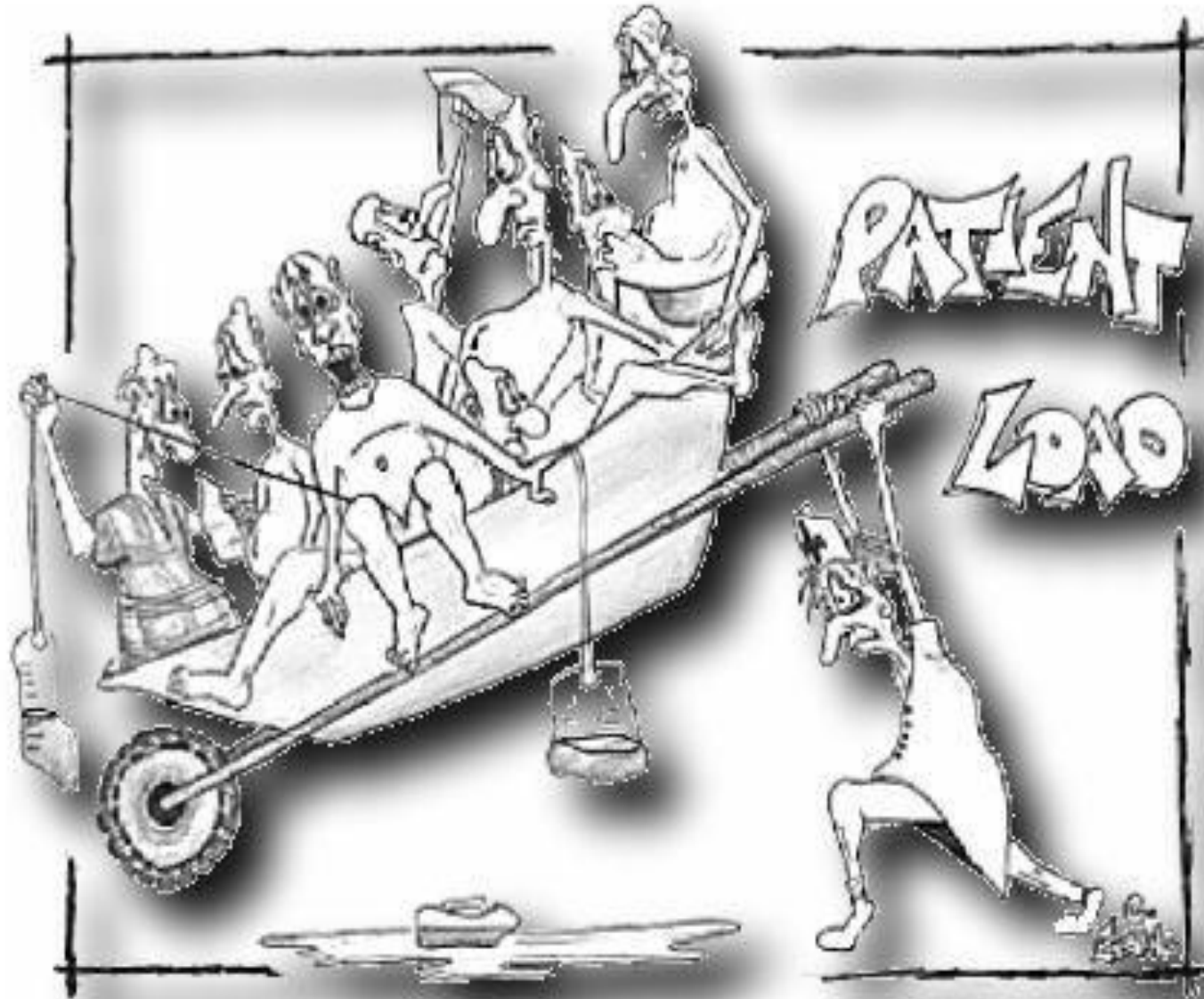
| Action Interval: | | 0 | 2 | 4 | 8 | 12 | 16 | 20 | 24 | 26 |
|--|---|-------|-----|-----|-----|-----|-----|-----|-----|-----|
| Date: | | Begin | Wks | Wks | Wks | Wks | Wks | Wks | Wks | Wks |
| Responsibility | Assign nurse case manager; establish team; document in client's record | | | | | | | | | |
| 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: _____ |
| PRINTED NAME: _____ | SIGNATURE: _____ | INITIALS: _____ |

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) <input type="checkbox"/> 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: <ul style="list-style-type: none"> • 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: <input type="checkbox"/> <ul style="list-style-type: none"> • Proper use of masks and tissues • Isolation/return to work after 3 negative smears, clinically improved, DOT for 2 weeks • Sputum collection | ✓ | ✓ | ✓ | | | | | | | |
| EVALUATION: <ul style="list-style-type: none"> • PPD testing/significance, CXR results, other tests | ✓ | | | | | | ✓ | | | ✓ |
| HIGH RISK GROUPS/FACTORS: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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, DOT/DOPE | ✓ | ✓ | ✓ | | | | | | | |

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 hepatotoxicity, 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 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 | 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 response is obtained.

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 | <ul style="list-style-type: none">● mild (shivering and diarrhea)● severe (muscle rigidity, fever and seizures)● Severe serotonin syndrome can cause death | Serious to minor |
| PZA | Stomach upset | <ul style="list-style-type: none">●Stomach Upset●Vomiting●Lack of Appetite | May be serious or minor |
| PZA | Gout | <ul style="list-style-type: none">●Abdominal uric acid level●Joint aches | Serious |

| | | | |
|------------|------------------------------|---|-------------------------|
| RIF | Bleeding problems | <ul style="list-style-type: none"> ●Easy bruising ●Slow blood clotting | Serious |
| RIF | Discoloration of body fluids | <ul style="list-style-type: none"> ●Orange urine ●Permanently stained soft contacts | Minor |
| RIF | Drug Interactions | <ul style="list-style-type: none"> ●Interferes with certain medications i.e. BCP, methadone | May be serious or minor |
| RIF PZA | Sensitivity to the sun | <ul style="list-style-type: none"> ●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 until culture negative x 2 months

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
 - Monthly sputums
 - 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
 - Anterior/Posterior and Lateral Views recommended for <18
 - Dr. Seaworth/Armitige request PA/Lat CXRs for all adult patients.
 - 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

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



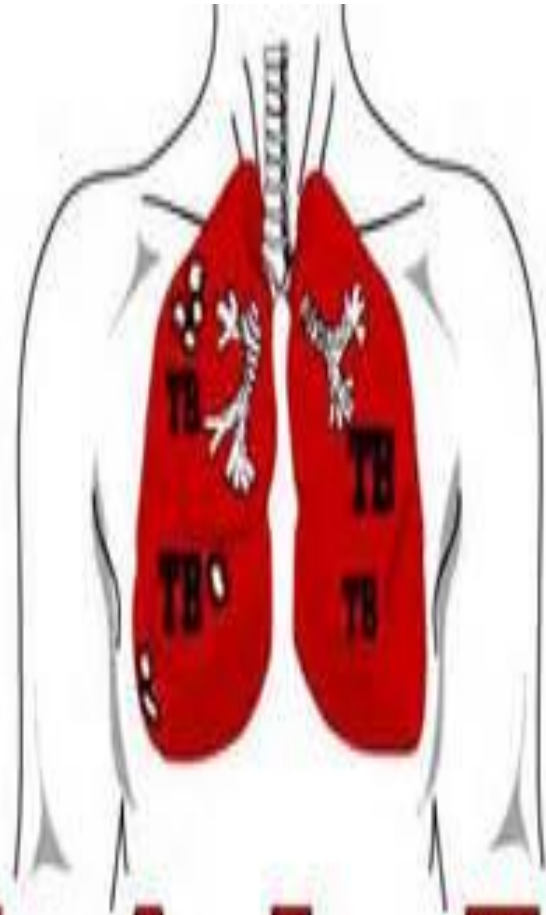
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S2405579415300097

- CDC
- TB Educate
- TBResources.com
- Dawn Farrell, BSN, RN
- Veronica Y. Dominguez, BSN, RN
- Dora Marrufo, BSN, RN



HEAR **A**CT **L**EARN **T**REAT
TUBERCULOSIS

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