Managing and Monitoring Side Effects and Toxicities of Anti-TB Therapy

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The HIV/STD/TB/Hepatitis Program and the Dakotas AIDS Education and Training Center (DAETC) conduct monthly Lunch and Learn Webinars for health care professionals in North and South Dakota.

Each month a new topic will be held from 12:00 p.m. to 1:00 p.m. CST on the **fourth Wednesday of the month**.
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You may take the post-test up to two weeks after the presentation. Post-test, along with the slides and the recording of this presentation can be found at:

https://www.ndhealth.gov/hiv/Provider/

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Managing and Monitoring Side Effects and Toxicities of Anti-TB Therapy

Presenter: Iris Barrera, RN
Nurse Consultant/Educator
Heartland National TB Center
Enjoy your lunch & learn 😊

- Thomas

A CDC TB Patient Testimonial
Objectives

- List medications used to treat TB.
  Content:
  - LTBI medications
  - First line anti-TB medications
  - Second line anti-TB medications

- Discuss tools used for monitoring the patient on anti-TB therapy
  Content:
  - HNTC Products
  - Regional Forms

- Discuss methods to identify toxicities to anti-TB therapy
  Content:
  - Labs
  - Vision Screening
  - Hearing/vestibular screening
  - DOT toxicity screening
LTBI Treatment Regimen Recap

Isoniazid
9 months
1 pill everyday
High incidence of hepatotoxic events

Rifampin
4 months
2 pills everyday
More interactions with other medications
LTBI Regimen Recap Cont.

3HP:
- B6

Isoniazid

Rifapentine
3HP Regimen Details

- Isoniazid (INH) and Rifapentine (RPT) (supplement with B6)
- Once weekly
- The body has a week to rest between doses
- 12 doses (minimum of 11 doses acceptable) administered in no fewer than 12 weeks (but no more than 16 weeks)
- Doses must be separated by ≥72 hours to be counted
- Clinicians can now prescribe self administered therapy
TB Disease Regimen

• Initial Phase:
  – Isoniazid (INH) Rifampin (RIF) Pyrazinamide (PZA) Ethambutol (EMB)
  – Five days per week for 40 doses
  – given in 8 weeks
  – Additional monitoring required

• Continuation Phase:
  – INH/RIF
  – Five days per week for 90 doses given in 18 weeks
  – Total of 6 months on treatment
  – Remember we count doses not months so it could take longer
Other Medications

• Second line drugs have increased risk of toxicity

• Assessment and intervention are crucial to patient safety and adherence

• Recommended: All drug resistance cases initiate an “expert consult” with Heartland TB Center Doctors: Armitage, Seaworth, or Griffith.
  
  – Submit a patient summary

  – Labs, cultures, radiology, and assessments.
Let your drugs be your guide

<table>
<thead>
<tr>
<th>Drug</th>
<th>Efficacy</th>
<th>Bactericidal</th>
<th>Min-Max Level</th>
<th>Dosing</th>
<th>Dosage</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifabutin</td>
<td>Yes</td>
<td>Yes</td>
<td>0.25-0.5</td>
<td>3-9 mg daily</td>
<td>300-750 mg daily</td>
<td>Decreased white blood cell count, anemia, fatigue, nausea, vomiting, rash,</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>Yes</td>
<td>Yes</td>
<td>0.3-1.0</td>
<td>10-30 mg daily</td>
<td>500-1,000 mg daily (range 500-1,500 mg)</td>
<td>Renal impairment, increased bilirubin, cholestatic jaundice, nausea, vomiting,</td>
</tr>
<tr>
<td>Minocycline</td>
<td>Yes</td>
<td>No</td>
<td>0.25-80</td>
<td>100 mg daily</td>
<td>600 mg daily</td>
<td>None</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>Yes</td>
<td>Yes</td>
<td>0.5-1.5</td>
<td>1,200 mg daily</td>
<td>1 g daily</td>
<td>None</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>No</td>
<td>No</td>
<td>NA</td>
<td>250 mg b.i.d</td>
<td>1,500 mg b.i.d</td>
<td>None</td>
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<tr>
<td>Cipramycin</td>
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<td>Yes</td>
<td>NA</td>
<td>1,200 mg daily</td>
<td>1,500 mg daily</td>
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<td>Streptomycin</td>
<td>Yes</td>
<td>Yes</td>
<td>0.25-2.0</td>
<td>2-5 mg daily</td>
<td>25-50 mg daily</td>
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</tr>
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<td>Ciprofloxacin</td>
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<td>No</td>
<td>0.5-1.0</td>
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<td>None</td>
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<td>Chloramphenicol</td>
<td>Yes</td>
<td>Yes</td>
<td>0.5-1.0</td>
<td>300 mg daily</td>
<td>600 mg daily</td>
<td>None</td>
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<tr>
<td>Linezolid</td>
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<td>Yes</td>
<td>10-75</td>
<td>50-300 mg daily</td>
<td>400 mg daily</td>
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<td>Chloramphenicol</td>
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<td>Yes</td>
<td>0.5-1.0</td>
<td>300 mg daily</td>
<td>600 mg daily</td>
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<tr>
<td>Bedaquiline</td>
<td>Yes</td>
<td>No</td>
<td>NA</td>
<td>1,000 mg daily</td>
<td>1 g daily</td>
<td>None</td>
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<tr>
<td>Delamanid</td>
<td>Yes</td>
<td>No</td>
<td>NA</td>
<td>1,000 mg daily</td>
<td>1 g daily</td>
<td>None</td>
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<tr>
<td>Moxifloxacin</td>
<td>Yes</td>
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<td>0.5-1.0</td>
<td>400 mg daily</td>
<td>800 mg daily</td>
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<tr>
<td>RE6</td>
<td>No</td>
<td>No</td>
<td>NA</td>
<td>1,000 mg daily</td>
<td>2,000 mg daily</td>
<td>None</td>
</tr>
<tr>
<td>BIL (high dose)</td>
<td>Yes</td>
<td>Yes</td>
<td>0.5-1.0</td>
<td>1 g daily</td>
<td>3 g daily</td>
<td>None</td>
</tr>
</tbody>
</table>

*Table adapted from CDC tuberculosis treatment guidelines, 2017.*
Baseline Assessment

• History and physical: Identify any comorbidities and complete a drug to drug interaction check.

• Diagnostics: CXR

• Baseline labs: CBC, CMP, HIV, Hep Panel and A1C

• Drug specific assessments: PZA-joint pain EMB-visual acuity

If we don’t do it in the beginning we won’t know when we’re in trouble.
**Texas Department of State Health Services**

**Clinical Assessment for Tuberculosis Medication Toxicity**

| Name: __________________________________ | D.O.B.: _____ / _____ / _____ | SS#: _____ / ____ / ____ |

**Adverse Drug Reaction Assessment:** Ask all the below questions to monitor for medication toxicity, noting that some symptoms may be more commonly associated with certain medications. Those with **are associated with second-line drugs; those with †are associated with Isoniazid/Rifapentine (3HP) but may also be present in other regimens. Document any [+], incl. potential pregnancy in women, in progress notes & notify physician. Results: [+] = Present; [-] = Denies; [NA] = Not Applicable.

<table>
<thead>
<tr>
<th>Weight</th>
<th>Temperature</th>
<th>Blood Pressure</th>
<th>Pulse</th>
</tr>
</thead>
</table>

**Do you have any of the following symptoms now or since your last clinic appointment?**

- Abdominal pain/diarrhea **
- Abnormal behavior **
- Allergic reaction (specify) **
- Bruises, red/purple spots on skin†
- Change in heart rate *
- Change in urine output
- Convulsions **
- Dark urine (coffee colored) or change in color†
- Ear ringing/fullness/hearing loss **
- Eye pain/irritation (redness, excessive tears)
- Fever or chills†
- Flu-like symptoms†
- Headaches (chronic)
- Increased gas/stomach cramps **
- Jaundice (yellow skin/eyes) †
- Joint pain/swelling (chronic) – PZA
- Light colored stools†
- Loss of appetite
- Malaise/fatigue
- Memory Loss **
- Mood changes/depression **
- Musculoskeletal Pain†
- Nausea/vomiting
- Numbness/tingling/pain, arms, legs†
- Nervousness/Giddiness/Restlessness
- Skin discoloration **
- Skin rashes/itching
- Sleep problems **
- Sore on lips or inside mouth†
- Shortness of breath
- Teeter/Fall to Left or Right when standing (eyes closed)
- Unusual bleeding (nose, gums, stool, urine, etc.) or easy bruising - RIF, RPT†
- Vertigo/dizziness/fainting†
- Visual problems/changes in vision **
- Weakness, tiredness
- Weave/Stagger when walking (normal gait)
- Use of over the counter drugs, ie. Tylenol products?

**Ask women about signs of pregnancy**

<table>
<thead>
<tr>
<th>Drug Issued</th>
<th>MG/Lot/#/Exp</th>
<th>Route/ Frequency</th>
<th>Amount</th>
<th>Amount</th>
<th>Amount</th>
<th>Amount</th>
<th>Amount</th>
<th>Amount</th>
<th>Amount</th>
</tr>
</thead>
</table>

**Name/Title**

**Interpreter**

**Next Appt.**

TB205 - Clinical Assessment for TB Medication Toxicity - Revised 8/2017 (Continued on Reverse)
**Texas Department of State Health Services**  
Vision/Hearing Screening Form

**NAME:** __________________________________

**D.O.B.: _____ /_____ /_____**

**SS#: _____ /____ /______**

**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.

**Results:** [N] = Normal  [A] = Abnormal

<table>
<thead>
<tr>
<th>Plate #</th>
<th>Red/Green Reading</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
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<tbody>
<tr>
<td>1</td>
<td>12</td>
<td></td>
<td></td>
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<tr>
<td>5</td>
<td>7</td>
<td>4</td>
<td>12</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>45</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>X</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>16</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Traceable</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Results**

<table>
<thead>
<tr>
<th>Ear</th>
<th>Strong</th>
<th>Mild</th>
<th>Strong</th>
<th>Mild</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>(5)</td>
</tr>
<tr>
<td>Left</td>
<td>6</td>
<td>9/6</td>
<td>9</td>
<td>(6)</td>
</tr>
<tr>
<td>Both</td>
<td>Can trace 2 lines</td>
<td>Purple</td>
<td>Purple</td>
<td>Red</td>
</tr>
</tbody>
</table>

**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:** [Y] = Yes  [N] = No

---

**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 and recorded. If a response is not heard at 40 dB, record as 40+ dB.

**Results:** [P] = Pass  [R] = Refer  [O] = Observe  
**Ear:** [R] = Right  [L] = Left

---

**Frequency**

<table>
<thead>
<tr>
<th>Ear</th>
<th>500 Hz</th>
<th>1000 Hz</th>
<th>2000 Hz</th>
<th>4000 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>L</td>
<td>R</td>
<td>L</td>
<td>R</td>
</tr>
<tr>
<td>L</td>
<td>R</td>
<td>L</td>
<td>R</td>
<td>L</td>
</tr>
</tbody>
</table>

**Initials**

---

**TB205- Clinical Assessment for TB Medication Toxicity - Revised 8/2017**

***From previous page: Changes in Vision may include blind spots in field of vision, blurred vision, changes in peripheral vision***
Ishihara
Color-blindness

- Red-green color blindness is split into two different types:
  - Protan color blindness are less sensitive to red light.
  - Deutan color blindness are less sensitive to green light

The take home:

Do your Ishihara and Snellen assessments every month and if there is a deviation from base-line **hold medication** and notify the physician.
Snellen
Ototoxicity

• Health care providers responsible for initiating, dispensing and managing DR-TB treatment should be aware of the risk of ototoxicity, its early symptoms and signs, diagnosis, and management.

• This must be a part of a training program for clinical staff in DR-TB management.

• TB programs must have a management protocol based on the resources of the health system, with clear roles and responsibilities to ensure early detection and proper management of hearing loss.
Ototoxicity

Mandatory

- Monthly and as needed while on treatment

Advised-

- 3 months and 6 months after completion of the SLI, if feasible.
Ototoxicity

- Tinnitus
- Dizziness
- Vertigo
- Hearing loss
Ototoxicity

**Amikacin**, **Capreomycin**, **Kanamycin**, or **Streptomycin**

Source: http://www.cluistrom.com/assets/images/kuduwave/kuduwave-prime-cluistrom-uk.jpg
Peripheral Neuropathy

• Tingling, prickling & burning balls of feet or tips of toes

• More likely: Diabetic, alcoholic, HIV infection, pregnancy, poor nutrition, hypothyroidism

• Sensory loss can occur; ankle reflexes lost; unsteady painful gait

• Can progress to the fingers and hands

Administer Vitamin B6 (pyridoxine) 50mg daily
Note: B6 in doses greater than 200mg can CAUSE neuropathy

* Linezolid, Isoniazid
Valoración de Neuropatía Periférica

Membres Inferiores

ENTREVISTA AL PACIENTE

Pregunta 1: ¿Tiene dolor en sus pies?

Pregunta 2: ¿Tiene dolor en algunas de sus extremidades?

1. Oclusión
2. Sensibilidad de los dedos
3. Tetraparesis distal

Pregunta 3: ¿Cuál es la causa de la tasks alrededor de estas áreas?

1. Nefropatía
2. Diabetes mellitus
3. Extremidades distales

EXPLORACIÓN DEL PACIENTE

Pregunta 4: ¿Se evidencia que la exploración inferior de los miembros no es la zona dolorosa?

1. Alargamiento del tobillo
2. Hiperreflexia al pie

Pregunta 5: El dolor se presenta en una o ambas piernas?

1. El pie

Nombre del Paciente:
Fecha de Neuropatía:
Firma:

ENTREVISTA AL PACIENTE

Pregunta 1: ¿Tiene algo dolor en su mano?

Pregunta 2: ¿Tiene dolor en alguna de sus extremidades?

1. Quemadura
2. Sensibilidad de los dedos
3. Extremidades distales

Pregunta 3: ¿Cuál es la causa de la tasks alrededor de estas áreas?

1. Nefropatía
2. Diabetes mellitus
3. Extremidades distales

EXPLORACIÓN DEL PACIENTE

Pregunta 4: ¿Se evidencia que la exploración inferior de los miembros no es la zona dolorosa?

1. Alargamiento del tobillo
2. Hiperreflexia al pie

Pregunta 5: El dolor se presenta en una o ambas manos?

1. El pie
Monitor All The Danger Signs.

There... do you feel that?
Patient education

• Begins at the intake appointment

• Continues at least monthly during the required toxicity screenings

• Discuss medications:
  – Names, dose, side effects, when to call clinic.

• Distribute language and education level appropriate aids.
Tests show you have tuberculosis "TB." We have pills to help YOU cure your tuberculosis. TB can be cured with your help. The pills won't work unless taken correctly.

You will be taking:  

Comments:  

Unwanted side effects are rare with these pills. As with all medicines, side effects can happen. If you notice any of these symptoms, STOP TAKING YOUR PILLS AND CALL US RIGHT AWAY:

- Continued loss of appetite
- Always feeling tired for no reason
- Dark-colored urine (the color of coffee or tea)
- Yellow eyeballs or skin
- Rash, itching
- High fever
- Blurred vision, feeling dizzy or sleepy
- Unusual pain in hands, feet, joints
- Headache
- Nausea
- Vomiting

If you see another doctor, say you are taking medicine to treat TB—show this record. Be sure to tell us if you are taking other medicines. You'll need to take your medicine EVERY DAY for several months. We need to see you often to make sure your pills are working. It's up to YOU to whip TB! Take your pills each and every day! KEEP your appointments!

You have now had

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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</thead>
<tbody>
<tr>
<td>7</td>
<td>8</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

months of therapy.

Date Started ____________________

Nurse:

Telephone:

If you can't keep this appointment, please call us:

PREVENTIVE TREATMENT RECORD

NAME_______________________________________
DATE_______________________________________
LOCATION:

Texas Department of State Health Services

Revised 8/17          TB-621
# MEDICATION TRACKER
The 12-Dose Regimen for Latent Tuberculosis (TB) Infection

## Your Medication Schedule
(Providers: indicate the appropriate number of pills and day)

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Number of pills per week</th>
<th>Frequency</th>
<th>Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid: mg</td>
<td>(Isoniazid: mg)</td>
<td>TOTAL: mg</td>
<td>Once a week for 12 weeks (3 months)</td>
</tr>
<tr>
<td>Rifampin: mg</td>
<td>Rifampin: mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Your doctor may also add Vitamin B6 to your treatment plan.

## Keeping Track of Your Treatment

On the table below, check the box and write the date to show when you took your medicine.

<table>
<thead>
<tr>
<th>WEEK</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXAMPLE 6/7 - 6/13</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Week 3</td>
<td>☐</td>
<td>☐</td>
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<tr>
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<tr>
<td>Week 8</td>
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<td>Week 9</td>
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www.cdc.gov/tb

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[Heartland National TB Center Logo]

EXCELLENCE • EXPERTISE • INNOVATION
SYMPTOM CHECKLIST
The 12-Dose Regimen for Latent Tuberculosis (TB) Infection

Patient Name:

Normal Side Effects
Most people can take their TB medicines without any problems. The rifapentine medicine may cause your urine (pee), saliva, tears, or sweat to appear an orange-red color. This is normal and the color may fade over time.

STOP taking your medicine and CALL your TB doctor or nurse right away if you have any of the problems below:

- Dizzy or lightheaded when sitting or standing
- Less appetite, or no appetite for food
- Stomach upset, nausea, or vomiting
- Stomach pain or stomach cramps
- Pain in your lower chest or heartburn
- Flu-like symptoms with or without fever
- Severe tiredness or weakness
- Fevers or chills
- Severe diarrhea or light colored stools (poop)
- Brown, tea-colored, or cola-colored urine
- Skin or whites of your eyes appear yellow
- Skin rash or itching
- Bruises, or red or purple spots on your skin that you cannot explain
- Nosebleeds, or bleeding from your gums or around your teeth
- Shortness of breath
- Pain or tingling in your hands, arms, or legs
- Feelings of sadness or depression

Please talk to your doctor or nurse if you have any questions or concerns about treatment for latent TB infection.

Doctor/Clinic Contact Information
Name of the staff caring for you: __________________________
Phone number: __________________________
Address: __________________________
Hours: __________________________

Centers for Disease Control and Prevention
National Center for HIV/AIDS,
Viral Hepatitis, STD, and TB Prevention

www.cdc.gov/tb
Let the treatment begin
Desired Outcomes

- Early identification of adverse effects
- Promote adherence and completion of treatment
- Collect data
- Make changes to the plan of care
Side Effects

• What if they said yes?
  – Side Effect v Adverse Effect

• Determine if the patient is experiencing symptoms that requires intervention.

• There are many side effects associated with TB medication.

• These are unpleasant but do not have lasting health effects.

• May treat symptom and continue medication.
Side Effects

- Gas/Bloating
- Indigestion
- Mild Nausea
- Orange bodily fluids
Side Effects

• Gas/ Bloating - Simethicone

• Indigestion- Omeprazole

• Mild Nausea- Zofran

• Orange bodily fluids- increased hydration
Adverse Effects

- These can be serious or even life threatening.
- Will require immediate intervention.
- The patient may need to be hospitalized
- Stop medication.
- Anticipate medication changes.
Adverse Effects

- Hepatitis
- Renal toxicity
- Ototoxicity
- Ophthalmic toxicity
- Severe G.I. and Dermatologic Disturbances
- Psychosis
Adverse Effects

- Hepatotoxicity
- Renal toxicity
- Ototoxicity
- Ophthalmic toxicity
- Severe G.I. and Dermatologic Disturbances
- Psychosis

The above will require ongoing assessment and even referrals to specialty doctors
Toxicity

Stop the medication immediately with any suspicion of vision, hearing loss, or hepatitis

• In most cases vision or hearing loss is irreversible
• Stopping the medication halts the extensiveness of the damage.
• It’s better for the patient to miss a few doses vs Disability
• Notify the physician
• Anticipate changes to medication regime
COMPREHENSIVE INFORMATION LOG: 12-Dose Isoniazid-Rifapentine Latent TB Infection Treatment Dose & Symptom Monitoring

Patient ID: ___________  Age:_________  Sex: M / F  Ethnicity: Hispanic / Non-Hispanic  Race: ______  Weight: ________lbs  Height: _____ft/_____inches

Treatment reason: ☐ Contact  ☐ Corrections  ☐ Homeless  ☐ Refugee  ☐ Foreign-born  ☐ Convertor  Dose: INH _____mg  RPT______mg

*Check ✓ symptoms or events reported on the listed date; otherwise, leave blank.

<table>
<thead>
<tr>
<th>Date:</th>
<th>/ / / 0 Baseline</th>
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<tbody>
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<td>Directly Observed Therapy (DOT) received</td>
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<td>Nausea or vomiting</td>
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<td>Yellow eyes or skin</td>
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<td>Rash/hives</td>
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<td>Fever or chills</td>
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<td>Sore muscles or joints</td>
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<td>Numbness or tingling</td>
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<td>Dizziness/fainting</td>
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<td>Abdominal pain</td>
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<td>Treatment stopped or held</td>
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</table>

Final Disposition: ☐ Completed 3HP treatment  ☐ Stopped 3HP treatment  Date __/__/__
☐ Lost to follow-up  ☐ Moved  ☐ Other  ☐ Adverse event (fill out last page if treatment stopped for AE)
☐ Pending Completion of Alternate Regimen
<table>
<thead>
<tr>
<th>Class of Drugs</th>
<th>Name and Dose of Medication</th>
<th>Start Date</th>
<th>Stop Date (if applicable)</th>
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</thead>
<tbody>
<tr>
<td>Phenytoins (anti-seizure)</td>
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<tr>
<td>Anti-depressants or anti-psychotics</td>
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<td>Methadone</td>
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<td>Diabetes medication</td>
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<td>Diabetes medication</td>
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<td>Blood pressure medication</td>
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<td>Blood pressure medication</td>
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<tr>
<td>Warfarin (blood thinner)</td>
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<tr>
<td>Statins (cholesterol-lowering drugs)</td>
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<tr>
<td>TNF-α inhibitors**</td>
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<td>Other</td>
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</table>

**verapamil, diltiazem, amlodipine, nifedipine**

**ertanecept, adalimumab, infliximab, golimumab, pegsnercept, certolizumab**
**FILL OUT ONLY FOR ADVERSE EVENTS:**

<table>
<thead>
<tr>
<th>Symptom Related DOSE</th>
<th>Re: Stopped or Held</th>
<th>Date Symptom Began</th>
<th>Symptom Onset after Dose</th>
<th>Symptom Duration</th>
<th>Hospital Admission</th>
<th>Medication Re-challenge</th>
<th>Outcome</th>
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</thead>
<tbody>
<tr>
<td>□ Yes</td>
<td>□ No</td>
<td>□ &lt; 2 hrs</td>
<td>□ 2 – 48 hrs</td>
<td>□ &gt; 48 hrs</td>
<td>□ Unknown</td>
<td>□ &lt; 1 day _____ hrs</td>
<td>□ Yes</td>
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<tr>
<td>□ Yes</td>
<td>□ No</td>
<td>□ &lt; 2 hrs</td>
<td>□ 2 – 48 hrs</td>
<td>□ &gt; 48 hrs</td>
<td>□ Unknown</td>
<td>□ &lt; 1 day _____ hrs</td>
<td>□ Yes</td>
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</table>

Comments: Please (briefly) describe the adverse event, including symptoms, time of onset in relation to last INH-RPT dose, duration and resolution and any other factors (other medical conditions, medications). Enter comments in text box below.
<table>
<thead>
<tr>
<th>Test name</th>
<th>Result</th>
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<td>Date (mm/dd/yyyy)</td>
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<td><strong>Liver function test</strong></td>
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<td>AST (0 – 35 U/L)</td>
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<td>ALT (0 – 35 U/L)</td>
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<td>Alk Phos (36 – 92 U/L)</td>
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<td>T. Bili (0.3 - 1.2 mg/dL)</td>
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<td><strong>Complete Blood Count</strong></td>
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<td>Hemoglobin (Male: 14 – 17 g/dL, Female: 12 – 16 g/dL)</td>
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<td>Hematocrit (Male: 41% - 51%, Female: 36% - 47%)</td>
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<td>White Blood Cell Count (4.0 – 10 x 10^9/L)</td>
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<td>Platelets (150 – 350 x 10^9/L)</td>
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<td><strong>Metabolic Panel</strong></td>
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<td>Na (Sodium) (136 – 150 meq/L)</td>
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<td>K (Potassium) (3.5 - 5.0 meq/L)</td>
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<td>BUN (urea nitrogen) (8 – 20 mg/dL)</td>
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<td>Ėr (Creatinine) (0.7 – 1.3 mg/dL)</td>
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## MDR TB CARE PLAN

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Initiation of Treatment</th>
<th>Month 1</th>
<th>Month 2</th>
<th>Month 3</th>
<th>Month 4</th>
<th>Month 5</th>
<th>Month 6</th>
<th>Month 9</th>
<th>Month 12</th>
<th>Month 18</th>
<th>Month 24</th>
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<tbody>
<tr>
<td>CXR/PA/Lat, Compare to old films</td>
<td>Consider CT &amp; alternate views</td>
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<td>TST/Report case</td>
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<tr>
<td>Request/review old records</td>
<td>Physician assessment</td>
<td>Physician assessment q 1-2 wks</td>
<td>Physician assessment q 1-2 wks</td>
<td>Physician assessment q month</td>
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<td>Create drug-o-gram</td>
<td>Update drug-o-gram</td>
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<td>Review prior lab: CBC, BUN, Cr, LFT's, 24 hr Cr G1+, Ca, Mg, Bl, Hb, Hbc, glucose</td>
<td>CBC, BUN, Creat, LFT's, K, Ca, Mg at least q month</td>
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<td>HIV screen with pre/post counseling</td>
<td>If positive CDA, viral load</td>
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<tr>
<td>Review prior sputum results. Repeat sputum</td>
<td>Sputum q a.m. x3 days smear &amp; culture</td>
<td>Sputum q a.m. x3 days smear &amp; culture</td>
<td>Sputum q month culture</td>
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<td>Review susceptibility, request extended susceptibility test</td>
<td>Repeat susceptibility if sputum positive</td>
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<td>Infection control isolation</td>
<td>Continue until culture negative x3</td>
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<td>Aminoglycoside and/or Capreomycin IV (IM) 5 day/wk</td>
<td>Peak/trough drug level</td>
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<td>Peak to trough drug level Δ to 3x/wk after 4-6 months if culture negative</td>
<td>D/C after culture neg x6-12 month</td>
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<td>4-6 oral drugs</td>
<td>Peak drug levels 2 hrs post dose (PAS 6 hr)</td>
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<td>DOT initiated/patient educated</td>
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<td>Pyridoxine 100mg</td>
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<td>Nutritional assessment</td>
<td>Nutritional supplement as needed (no milk products, aluminum, CA, Mg containing antacids, iron or MVI's within 2 hours of flucloxacillin)</td>
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<td>Audiogram/vestibular screen. Continue monthly as long as aminoglycoside/capreomycin given</td>
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<td>Vision screen. Continue as long as ethambutol, rifabutin, linezolid, clofazamine given</td>
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*Repeat clearance if decreased & adjust medications (aminoglycosides, capreomycin, ethambutol, PZA, levofloxacin, cyclosyne*)

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This publication was supported by the Cooperative Agreement Number U52PS004687-01 from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

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HEARTLAND NATIONAL TB CENTER

EXCELLENCE  •  EXPERTISE  •  INNOVATION
## MDR - TB Toxicity Monitoring Checklist

**Start Date**

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<td>AFB Culture</td>
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- Isoniazid
- Rifampin
- Rifabutin
- Pyrazinamide
- Ethambutol
- Streptomycin
- Kanamycin
- Amikacin
- Capreomycin
- Ethionamide
- Cycloserine
- P-Aminosalicylic Acid
- Clofazamine
- Moxifloxacin
- Linezolid
- Levofoxacin
- Other
- Weight (Kg)
- AST (SGOT)
- ALT (SGPT)
- Bilirubin, Total
- Alk. Phosphatase
- BUN
- Serum Creatinine
- Hemoglobin/Hematocrit
- WBC
- Platelets
- TSH
- HgbA1C
- CD4
- Viral Load
- Visual Screen
- Vestibular Screen
- Audiogram
- Other

* S/R = Sensitive/Resistant
LTBI Case Study

A 58 year old male from Israel who immigrated to the US 20+ years ago was referred to TB Clinic by dermatology for a positive QFT and normal CXR. Patient was diagnosed with pyogenic dermatitis and immunosuppressive therapy is planned.
Health History and Assessment

The patient assessment was WNL with the exception of CDI pinpoint necrotic papules, sparsely distributed on his arms and legs bilaterally. The patient denied pain and stated, “They only itch occasionally.”

He has no co-morbidities and is on no other medications. He does admit to smoking a pack a week and drinking one beer at night.

He also denies previous history or exposure to TB. He states he has never been tested for TB before.

Of note baseline CBC, CMP, and HIV are within WNL.

3HP is prescribed by the clinic physician.
What in this patient’s assessment would be of concern to the public health nurse?

- Nothing. The patient is on no medications and has no co-morbidities.

- The patient drinks only one beer a night and has normal LFT’s so this should not be a problem.

- The patient has planned immunosuppressive therapy, smokes a pack a week, and admits to daily ETOH consumption.
What in this patient’s assessment would be of concern to the public health nurse?

- Nothing. The patient is on no medications and has no co-morbidities.
- The patient drinks only one beer a night and has normal LFT’s this should not be a problem.
- The patient has planned immunosuppressive therapy, smokes a pack a week, and admits to daily ETOH consumption.
Patient Education

The nurse realizes concurrent immunosuppressive therapy can put the patient at risk for activation TB disease.

The clinic physician is prompted for parameters and a letter is created notifying the referring entity that immunosuppressive therapy should be held until LTBI treatment completion or a minimum of 8/12 3HP doses are completed.

The patient is given a copy of the letter and educated in regard to it’s content.
The patient admitted to drinking one beer every night and while this is not a significant amount; most persons who admit to daily alcohol consumption tend to minimize intake.

The patient is educated on the effects of ETOH intake and asked to abstain for the duration of treatment.

The patient states he’s, “Not an alcoholic and it will be no problem to quit.”
The patient is given information on smoking cessation and started on 3HP.

Upon weekly DOT the patient denies signs and symptoms of toxicity and appears in good general health to the clinic staff.

The patient continues his treatment without issue and on dose #5 a monthly toxicity screening is done.

A CMP is drawn, VS are stable, and the patient continues to deny s/s of toxicity; so the medication is again administered.
The labs return the following day and the results are as follows:

- AST 1109
- ALT 1950
- T Billi 1.0
- Alk Phos 86
Upon reviewing the labs what should the first action by the public health nurse be?

- Stop the medication.
- Call the physician.
- Contact the patient and schedule a clinic appointment for labs and assessment
- All of the above
Upon reviewing the labs what should the first action by the public health nurse be?

- Stop the medication.
- Call the physician.
- Contact the patient and schedule a clinic appointment for labs and assessment.
- All of the above
Managing Hepatotoxicity

Guidelines state that medication can be continued if:

- LFT’s > 3 times upper limit of normal and *symptomatic*
- LFT’s > 5 times upper limit of normal and *asymptomatic*

Our Patient:

- AST 1109/42 = 26.4 x the normal limit
- ALT 1950/40 = 48.7 x the normal limit

- (normal values: AST 10 - 42 u/L, ALT 10 - 40 u/L)
Managing Hepatotoxicity

• Restarting therapy
  – LFT’s must be < 2 times upper limit of normal

  – Re-challenge Medications
    • Introduce one drug at a time
    • Monitor enzymes carefully
    • Stop therapy if symptomatic or increased enzymes and eliminate last drug added from regimen
The physician was notified and gave orders to:

- Hold medication

- CMP qweek until there’s a return to baseline

- Instruct patient to notify the clinic if symptoms develop

- Assess for any changes in lifestyle or medications
Patient returns to the clinic and denies ETOH intake stating, “I haven’t drank since I started the medication. I’m not an alcoholic.” Additionally he denies any other medications, illness, or other changes.

- Labs are drawn every week and the results are as follows:

  Week 1   AST 956 ALT 1327
  Week 2   AST 353 ALT 987
  Week 3   AST 174 ALT 398
At this point the clinic physician requests a Heartland Center consult to help evaluate the patient’s clinical history, response to 3HP, and make treatment recommendations.

Consultation recommendations:

• Give the patient credit for the 5 doses of 3HP completed.

• Discontinue 3 HP

• Start Rifabutin 300mg qday x 2 months to complete adequate treatment for LTBI.

• Rifabutin is considered a liver friendly medication
What additional toxicity assessments should the nurse include in the plan of care?

- Nothing. The medication is the same as Rifapentine.
- Visual acuity screening by Ishihara and Snellen charts.
- Auditory screening
- Neutropenia
What additional toxicity assessments should the nurse include in the plan of care?

- Nothing. The medication is the same as Rifapentine.
- Visual acuity screening by Ishihara and Snellen charts.
- Auditory screening
- Neutropenia
Toxicity Assessment
Rifabutin

Monthly CBC screening is recommended with the administration of Rifabutin.

Caution: Avoid drinking alcohol. Same birth control precautions as with Rifapentine.
The patients LFT’s returned to baseline the following week.

Rifabutin was started as were assessments for additional toxicities.

The patient was educated through out the process and although he was concerned that his numbers were slow to normalize he remained cooperative with his POC and came to all scheduled follow-up appointments.

He stated he felt cared for and trusted his nurse/doctor.

He completed his alternate regime without issue.
Keys to Success

• Establish open communication with the patient by actively listening and even engaging in social conversation.

• Let them share their life with you and they WILL share their concerns.

• The patient’s level of understanding is the foundation of toxicity monitoring.

• Have a process in place for monthly toxicity screening.

• Let your drugs be your guide.

• Your assessment should change with your regime.
Thank You 😊
Questions

- CEU: https://www.ndhealth.gov/hiv/Provider/
- Next Lunch and Learn: PEP and nPEP on October 24th at 12pm CT.
- Presenters:
  
  Iris Barrera, RN
  Nurse Consultant/Educator
  Heartland National TB Center