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# TB Dose Counting

Barbarah Martinez, MSN, APRN, FNP-BC

***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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# Objectives

- The learner will have an understanding of the meaning of completion of therapy
- The learner will have an understanding and demonstrate the skills needed for dose counting
- Through case studies the learner will garner an understanding of nursing care and case management issues in the diagnosis, care and treatment of the TB patient

# Things to Remember

**Why do we treat?**

- Cure the patient
- Minimize risk and disability
- Reduce transmission of MTB to others

**How do we treat?**

- Directly observe therapy (in person or video) is the standard


**What do we treat with?**

- Usually 4- drug regimen x 8 weeks during the initial phase; followed by a continuation phase with at least two drugs based on how the patient is responding to treatment
  - Continuation phase can be 18-31 122

**How do we know if cure is achieved?**

- Adherence to treatment
- Appropriate number of a working regimen in a set amount of time
- The more drugs you get in the person the better the outcomes
- At least 6 months of a working regimen

# Completion of Treatment (COT)

- What is Completion of Treatment (COT)?
- How do we calculate COT?
- How do we apply it in the real world?

## What is treatment completion?

- Defines the number of doses ingested within a specified time frame (duration)
- Duration depends on
  - Drugs used
  - Drug susceptibility test results of the isolate
  - Patient's response to treatment
    - Smear results
    - Culture conversion
    - X-ray results
    - Weight
    - Symptoms
  - Site and extent of disease
  - Patient comorbidities

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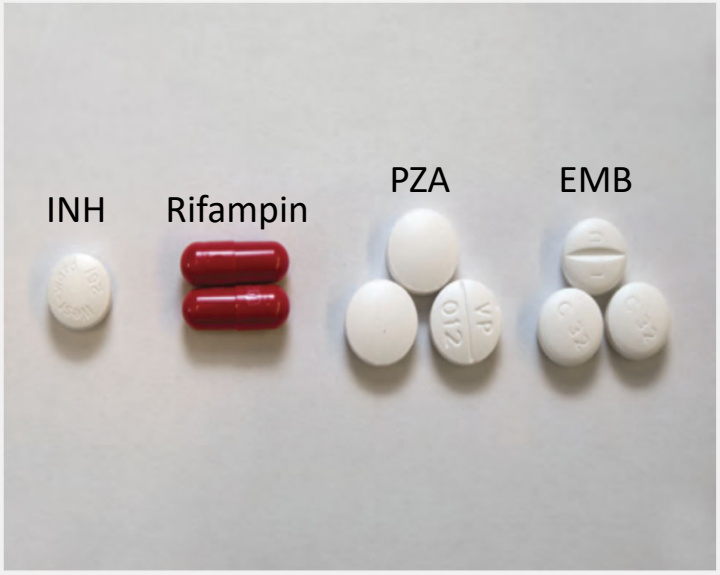
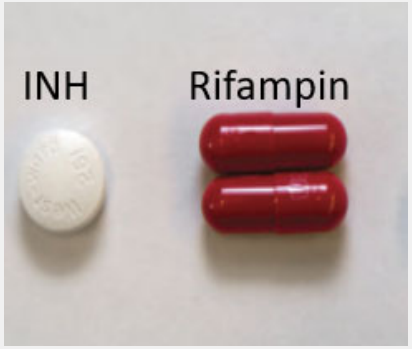
# Phases of Treatment

- **Initial Phase**
  - Usually 8 weeks for drug susceptible TB




- **Continuation Phase**
  - 18 weeks
  - 31 weeks
  - ? weeks




**All treatment should be completed in 365 Days**

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# So…

If the initial phase of therapy is always 8 weeks and the patient has to be treated for 52 weeks. How long is the continuation phase for the patient?

A. 52 weeks
B. 44 weeks
C. 40 weeks

**Answer:**
**B. 44 weeks**

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# Initial Phase

**Crucial for preventing the emergence of drug resistance and determining the ultimate outcome of the regimen!**

- All 4 drugs should be included in initial phase
- INH and RIF- allow for short-course regiments with high cure rates
- PZA- potent sterilizing activity allowing for further shortening of the regimen from 9 to 6 months
- EMB- helps to prevent emergence of RIF resistance when primary INH resistance is present
- 8 weeks in duration

(if drug-susceptibilities are known, EMB need not be included if EMB sensitive)

# Points to Remember

You often do not know how long the patient will need treatment until month 2 or 3

- Response to treatment
  - Culture conversion!
- Changes in treatment
- DST results

**Patient Education & Communication**

**don't make promises you can't keep**

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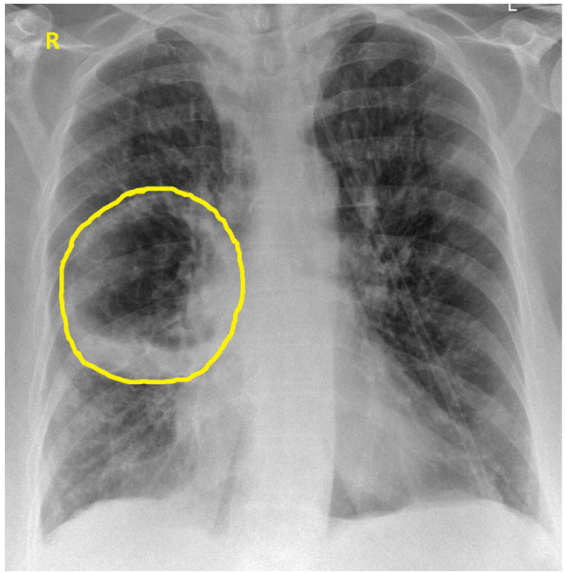
# When should treatment be extended?

- Cavity on X-ray **AND** positive sputum cultures at **2** months of therapy
- If only one of the above, **consider** if. . .
  - >10% below ideal body weight
  - Being a smoker
  - Diabetic
  - HIV infection
  - Other immunosuppressing condition
  - Or having extensive disease on Xray
- HIV infection not on ART (unusual situation)




**2016 Treatment of Drug Susceptible TB Guidelines**

# How to Calculate:

1. Expected Completion of Treatment (COT) date

# Weeks of treatment aka: the finish line

- 6 month = 26 weeks
- 9 month = 39 weeks
- 1 yr (12 month) = 52 weeks

| | |
|---|---|
| **Initial phase (8 weeks)** | ***8 weeks*** |
| ***+*** | ***+*** |
| **Continuation phase (18 weeks)** | ***31 weeks*** |
| **=** | **=** |
| **Total Treatment (26 weeks)** | ***39 weeks*** |

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# Data Duration Tool

- Project expected date of completion (or end of Initial phase), if no missed doses: http://www.timeanddate.com/date/dateadd.html
- Tip: At end of treatment/initial phase, double check that enough calendar time has passed: http://www.timeanddate.com/date/duration.html

# For Precision, Look at Calendar

**Calendar for Year 2017 (United States)**

**January**

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**February**

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**September**

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# How to Calculate:

- Number of doses needed for regimen

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| Intensive Phase | | Continuation Phase | | | | |
|---|---|---|---|---|---|---|
| Drug[a] | Interval and Dose[b] (Minimum Duration) | Drugs | Interval and Dose[b,c] (Minimum Duration) | Range of Total Doses | Comments[c,d] | Regimen Effectiveness |
| INH RIF PZA EMB | 7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk) | INH RIF | 7 d/wk for 126 doses (18 wk), or 5 d/wk for 90 doses (18 wk) | 182–130 | This is the preferred regimen for patients with newly diagnosed pulmonary tuberculosis. | Greater |
| INH RIF PZA EMB | 7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk) | INH RIF | 3 times weekly for 54 doses (18 wk) | 110–94 | Preferred alternative regimen in situations in which more frequent DOT during continuation phase is difficult to achieve. | |
| INH RIF PZA EMB | 3 times weekly for 24 doses (8 wk) | INH RIF | 3 times weekly for 54 doses (18 wk) | 78 | Use regimen with caution in patients with HIV and/or cavitary disease. Missed doses can lead to treatment failure, relapse, and acquired drug resistance. | |
| INH RIF PZA EMB | 7 d/wk for 14 doses then twice weekly for 12 doses[e] | INH RIF | Twice weekly for 36 doses (18 wk) | 62 | Do not use twice-weekly regimens in HIV-infected patients or patients with smear-positive and/or cavitary disease. If doses are missed, then therapy is equivalent to once weekly, which is inferior. | Lesser |

# Calculating number of doses: example from a standard regimen

## Initial Phase (8 weeks)

| Px frequency per week (dosage varies with frequency) | X | Week (duration) | = | Number doses |
|---|---|---|---|---|
| RIPE **5** days a week (daily dosage) | x | **8** weeks | = | **40** doses |

## Continuation Phase (18 weeks)

| | | | | |
|---|---|---|---|---|
| INH/RIF **5** times a week (daily dosage) | x | **18** weeks | = | **90** doses |

## Total Treatment (26 weeks)

| | | | | |
|---|---|---|---|---|
| | | **26 weeks** | | **130 doses** |

## Calculating number of doses: example from a standard regimen

Different regimens will have different total number of doses

# Initial Phase (8 weeks)

| | X | Week (duration) | = | Number doses |
|---|---|---|---|---|
| RIPE **7** days a week (daily dosage) | x | **2** weeks | = | **14** doses |
| RIPE **5** times a week (daily dosage) | x | **6** weeks | = | **30** doses |

+

# Continuation Phase (18 weeks)

| | | | | |
|---|---|---|---|---|
| INH/RIF **5** times a week (daily dosage) | x | **18** weeks | = | **90** doses |

=

# Total Treatment (26 weeks)

| | | | | |
|---|---|---|---|---|
| | | **26 weeks** | | **130 doses** |

# LTBI Case Study: Exercise

20 y/o, 185 lb., Hispanic male. He is a contact to a patient with smear positive, culture confirmed M.TB. He was screened and evaluated. Results are as follows:

- IGRA positive
- No signs and symptoms of TB disease
- CXR reported as normal

# Completion of Treatment

How many doses of LTBI therapy does the patient need to complete LTBI treatment with INH BIW?

A. 60-62 doses
B. 76-78 doses
C. 54 doses
D. 36 doses

**Answer:**
**B.) Twice-weekly INH regimens should consist of at least 76 doses administered within 12 months for the 9-month regimen.**

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# Case Study

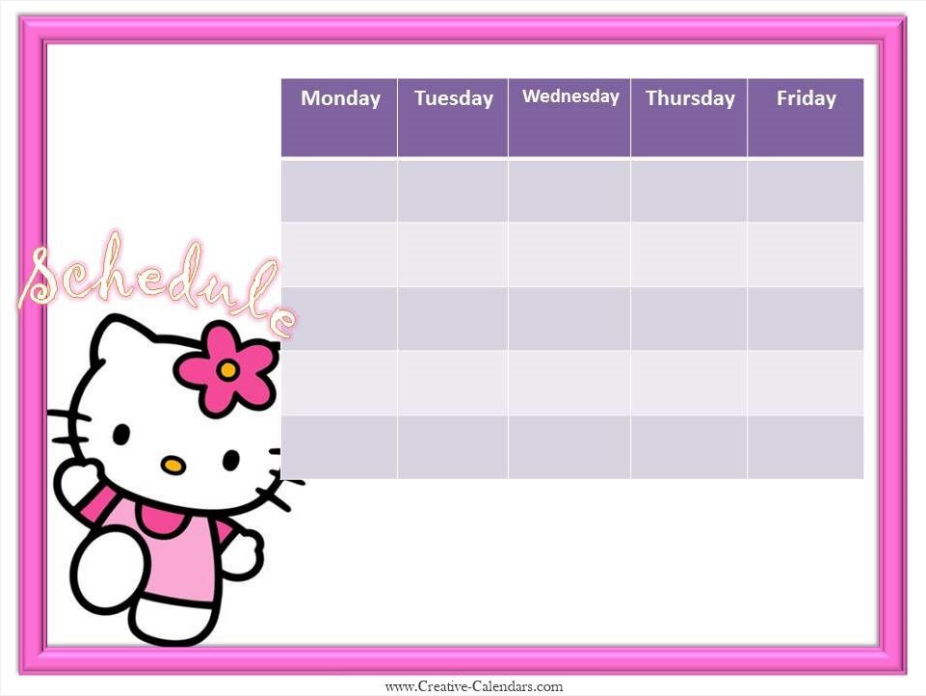
- 40 y.o. LatinX male who presents to clinic after a positive culture for mTB.  Significant PMHX for Type 2 DM with the last A1C  of 10.1. Patient's CXR is found to have bilateral cavities and the patient's smear are found to be 4 +.
- The provider decides to treat for 9 months 7 days a week via synchronous VDOT

# Case Study Questions

1. How many weeks of treatment total
   - 39 weeks
2. How many weeks is the initial phase
   - 8 weeks
3. How many weeks is the continuation phase
   - 31
4. How many total doses in the initial phase
   - 7 daily doses x 8 weeks = 56 doses
5. How many total doses in the continuation phase
   - 7 daily doses x 31 weeks = 217 doses

# How to Calculate:

## 3. Weeks of treatment received (dose counting)



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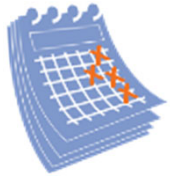
# Tools to Track Treatment



Each month calculate weeks of treatment received based on doses given. Helps to keep running summary of treatment.

- Can use physical calendar
- Can use monthly DOT log
  - Ex: Texas TB-206
- Can use excel

Tip for LTBI (self administered) count pills left in bottle at each office visit.

| Date | DOT Adm | Self Adm | Dose Missed | DOT Provider's Initials | Client's Initials | Comments/Notes |
|---|---|---|---|---|---|---|
| /01/ | | | | | | |
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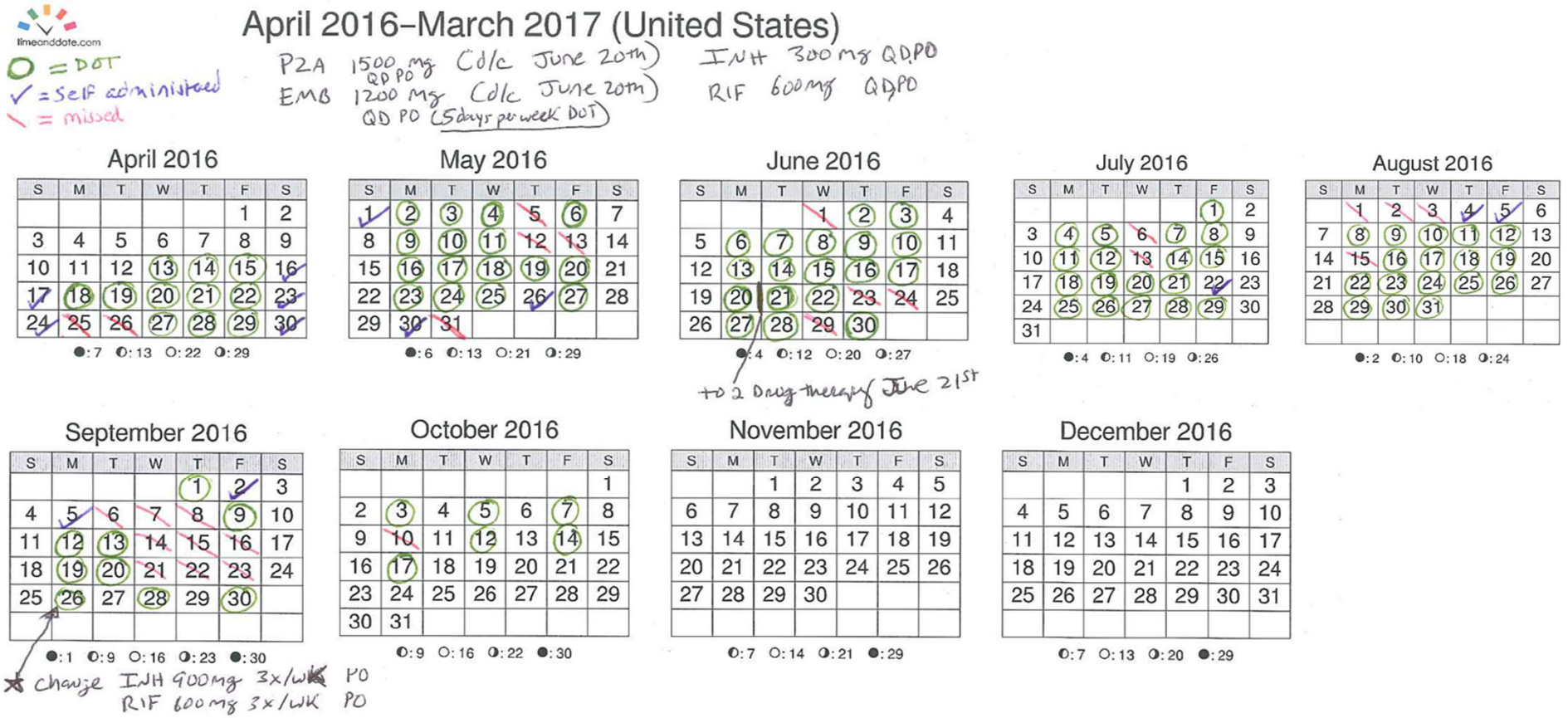
# 1. Use a Calendar



# Counting Apples and Oranges

To know where someone is in treatment
(weeks of treatment received)

- Organize treatment summary by same prescribed dose and frequency. (Divide at change in Px).
- For each separate section:
  - Count number of therapeutic doses given
  - Divide by prescribed frequency per week
  - Equals number of weeks of treatment received
  - Should be equal to or less than the number of weeks between the two dates
- Add the number of weeks for each section for Total weeks completed

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# Example 1

| Dates | Weeks (duration) | Doses administered | ÷ | Px (doses per week) | = | Weeks of Treatment *(total)* |
|---|---|---|---|---|---|---|
| 1/6/16 to 1/25/16 | 2.9 wks | 20 | ÷ | RIPE 7 days/wk | = | 2.9 *(2.9)* |
| 1/29/16 to 3/11/16 | 6.1 wks | 26 | ÷ | RIPE 5 days/wk | = | 5.2 *(8.1)* |
| 3/14/16 To 4/15/16 | 4.6 wks | 13 | ÷ | Rif/INH(900mg) 3 days/wk | = | 4.3 *(12.4)* |

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# Things to Look Out For

- Did they receive full 8 weeks PZA tx (# doses)?
- Periods of monotherapy/under dosing?
- Breaks in treatment

Figure 6.5
Algorithm for Management of
Initial Phase Treatment Interruptions

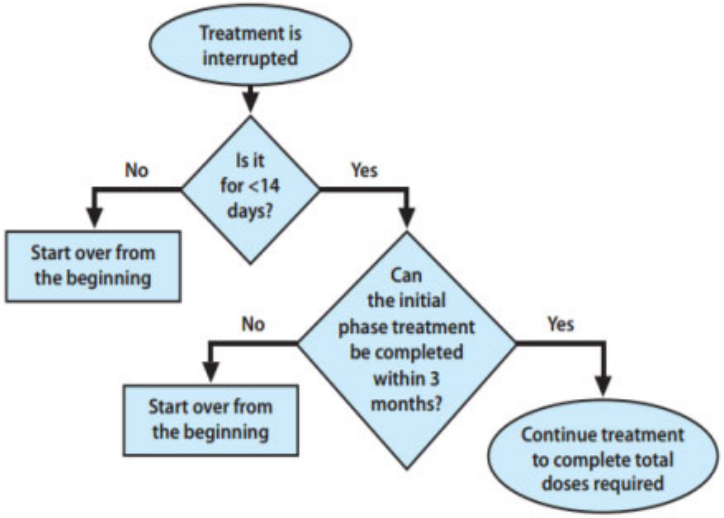
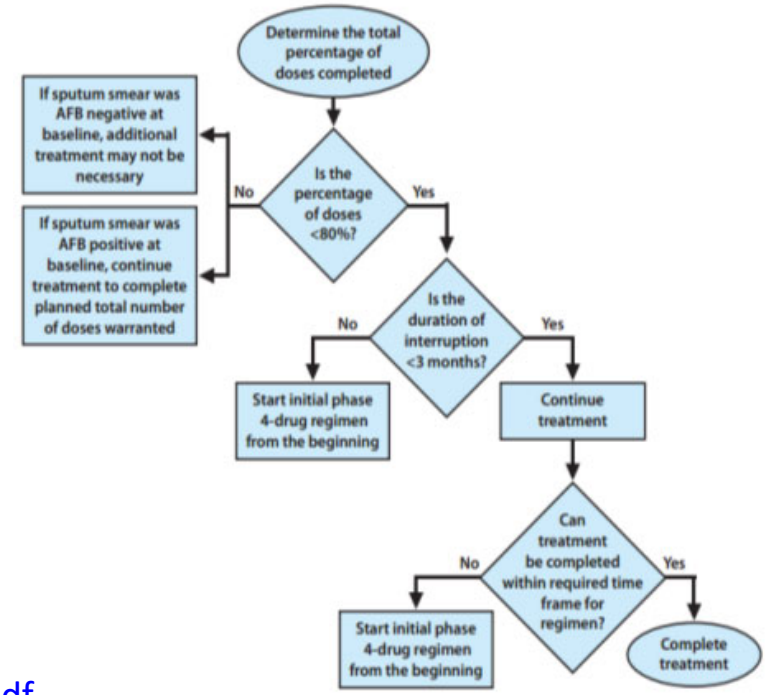



Figure 6.6
Algorithm for Management of
Continuation Phase Treatment Interruptions




http://www.cdc.gov/tb/education/corecurr/pdf/chapter6.pdf

**Table 6. Management of Treatment Interruptions[a]**

| Time Point of Interruption | Details of Interruption | Approach |
|---|---|---|
| During intensive phase | Lapse is <14 d in duration | Continue treatment to complete planned total number of doses (as long as all doses are completed within 3 mo) |
| | Lapse is ≥14 d in duration | Restart treatment from the beginning |
| During continuation phase | Received ≥80% of doses and sputum was AFB smear negative on initial testing | Further therapy may not be necessary |
| | Received ≥80% of doses and sputum was AFB smear positive on initial testing | Continue therapy until all doses are completed |
| | Received <80% of doses and accumulative lapse is <3 mo in duration | Continue therapy until all doses are completed (full course), unless consecutive lapse is >2 mo<br>If treatment cannot be completed within recommended time frame for regimen, restart therapy from the beginning (ie, restart intensive phase, to be followed by continuation phase)[b] |
| | Received <80% of doses and lapse is ≥3 mo in duration | Restart therapy from the beginning, new intensive and continuation phases (ie, restart intensive phase, to be followed by continuation phase) |

Abbreviation: AFB, acid-fast bacilli.

[a] According to expert opinion, patients who are lost to follow-up (on treatment) and brought back to therapy, with interim treatment interruption, should have sputum resent for AFB smear, culture, and drug susceptibility testing.

[b] The recommended time frame for regimen, in tuberculosis control programs in the United States and in several European countries, is to administer all of the specified number of doses for the intensive phase within 3 months and those for the 4-month continuation phase within 6 months, so that the 6-month regimen is completed within 9 months.

2016 Treatment of Drug Susceptible Tuberculosis

82 y/o woman with history of stage IV ovarian cancer and diabetes. She began therapy with the standard 4 drug anti-TB therapy (RIPE) daily regimen on 6/01/2013. Shortly after initiation of therapy she started complaining of right upper quadrant pain and appeared to be jaundiced. Liver function tests were elevated more than 5 times the upper limits of normal. All medications were held 6/10/2013,  and were not re-started until 6/28/2013.

How long of an interruption was there?

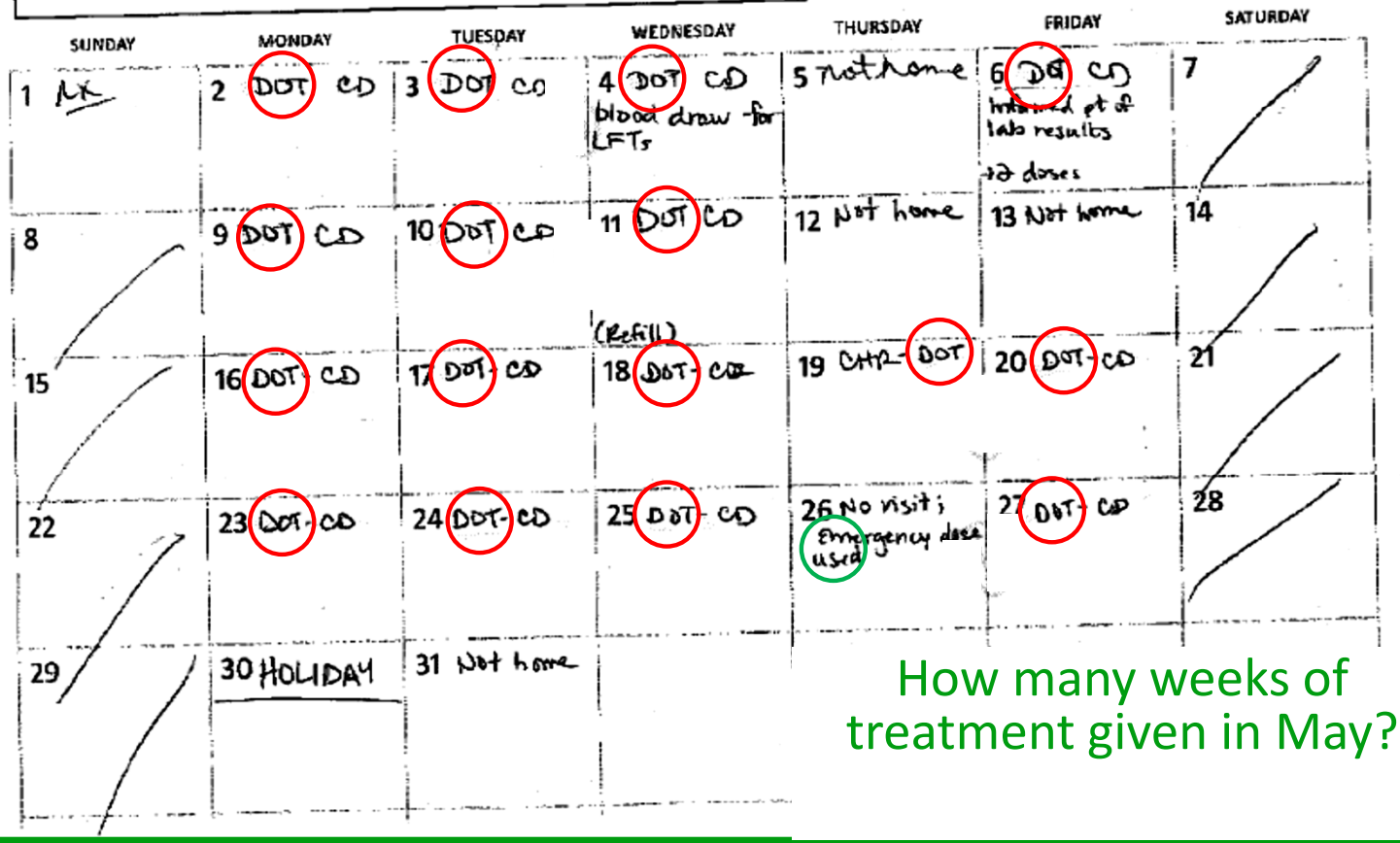
Answer: 18 days; meds were held 6/10/2013 - 6/28/2013

Does the patient have to re-start anti-TB therapy?

Answer: yes. If interruption occurs during the initial phase of treatment and the lapse is 14 days or more in duration, treatment should be restarted from the beginning. However, if the lapse is less than 14 days, the treatment regimen should be continued.

TB 4-drug therapy, carried out with direct observational therapy (DOT)
1) Pyrazinamide (PZA) – 1500 mg oral daily (500 mg tablets x 3)
2) Ethambutol (EMB) – 1200 mg oral daily (400 mg tablets x 3)
3) Isoniazid (INH) – 300 mg oral daily (300 mg tablet x 1)
4) Rifampin (RIF) – 600 mg oral daily (300 mg capsules x 2)
*Adjunctive medication: Pyridoxine 50 mg oral daily (50 mg tablet x 1)

# May 2016




How many weeks of treatment given in May?

# How to Calculate:

1. Expected Completion of Treatment (COT) date
2. Number of doses needed for regimen
3. Weeks of treatment received (dose counting)
4. Remaining number of doses & adjusted COT

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# Calculating Revised COT

## Option 1: Tag on missed doses to end

- If no missed doses, no need to adjust!
- Example: missed 2 doses during continuation phase of therapy due to a family emergency. Then adjust the calendar

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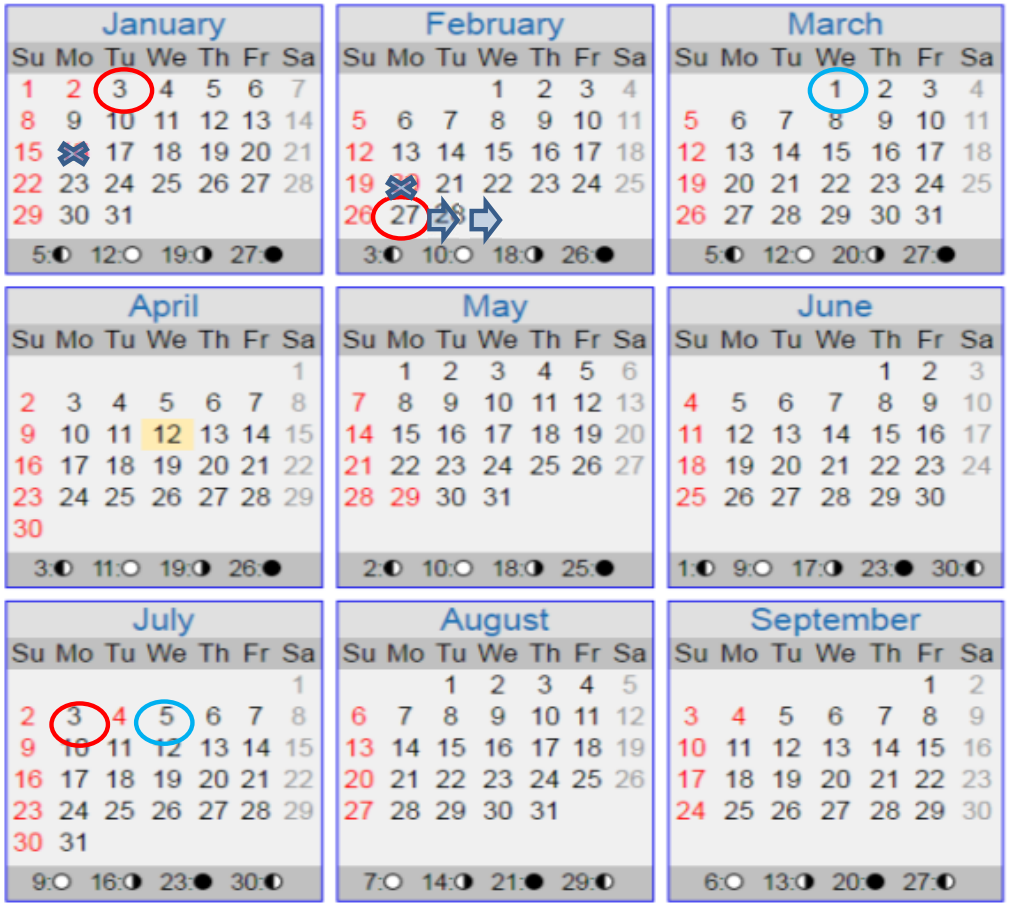
# Calendar based adjustments

## Calendar for Year 2017 (United States)



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**March**

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**May**

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**June**

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**July**

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**August**

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**September**

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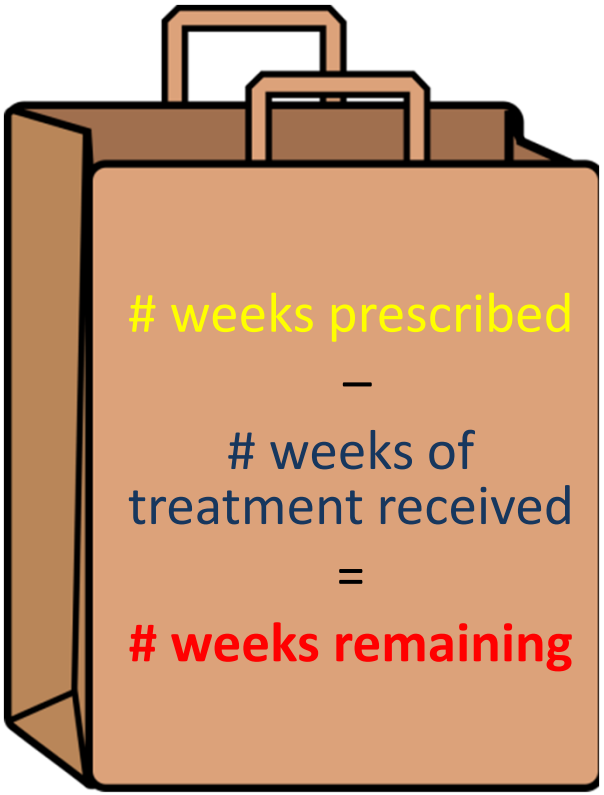
# Option 2: Add remaining weeks to date (good for lots of missing doses!)

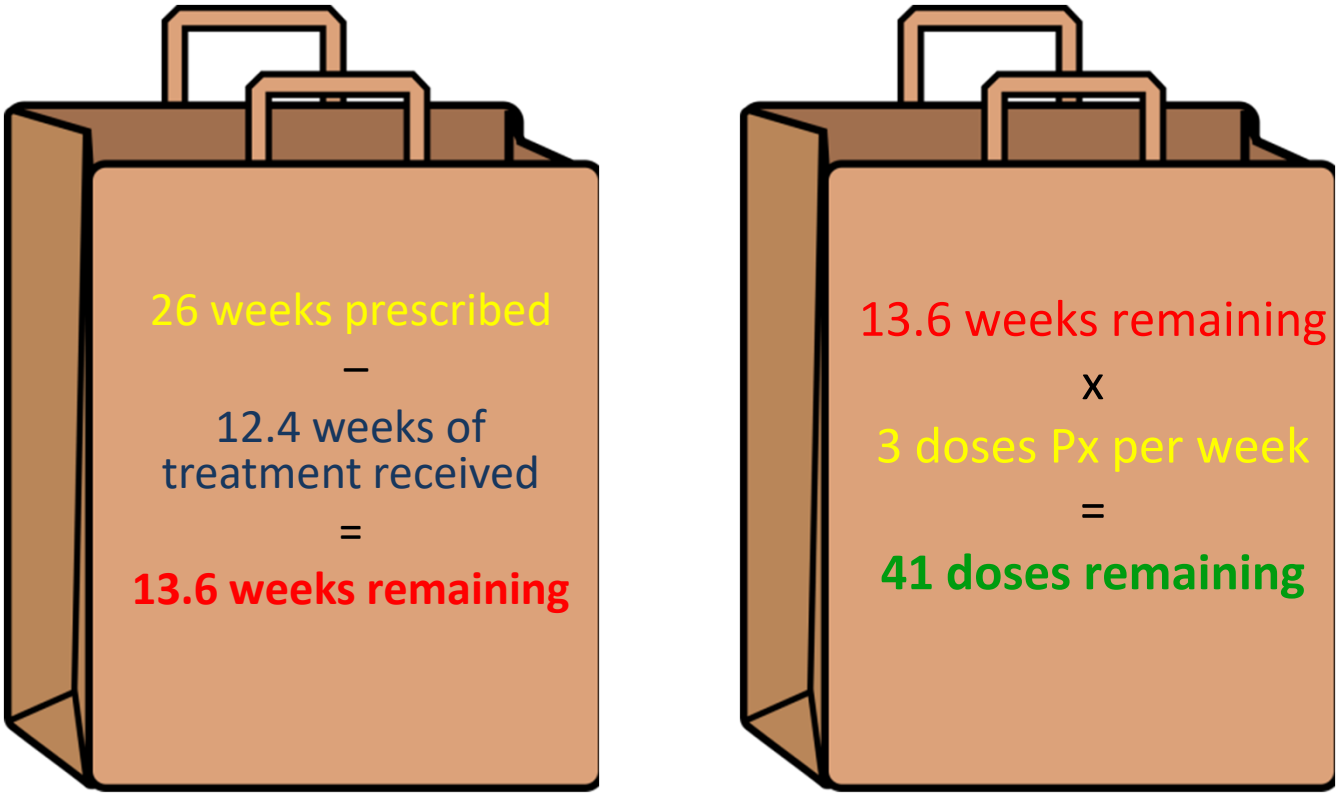
**Projecting out remaining doses and COT date**




# Example 1:

| Dates | Weeks (duration) | Doses administered | ÷ | Px (doses per week) | = | Weeks of Treatment *(total)* |
|---|---|---|---|---|---|---|
| 1/6/16 to 1/25/16 | 2.9 wks | **20** | ÷ | RIPE **7** days/wk | = | **2.9** *(2.9)* |
| 1/29/16 to 3/11/16 | 6.1 wks | **26** | ÷ | RIPE **5** days/wk | = | **5.2** *(8.1)* |
| 3/14/16 To 4/15/16 | 4.6 wks | **13** | ÷ | Rif/INH(900mg) **3** days/wk | = | **4.3** *(12.4)* |

# Use date calculator to project end Monday, July 25, 2016




**Example 1 continued**

# Q: Is it adequate treatment?

- Full 8 weeks of PZA?
- Under dosed or periods of monotherapy?
  - Weight?
- Gaps in treatment?
- What were DST's?
- What was Xray?
- What were smear results?
- When did patient culture convert?
- Any significant comorbidities?
- Site of Disease?

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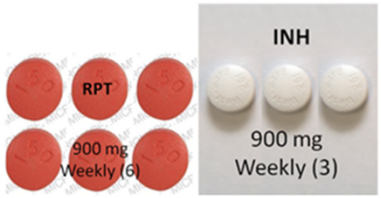
# What about Latent TB Infection?

| Regimens for Treating LTBI (dosage shown based on adults weighing ≥ 50 kg) | Length of Treatment<br>Number of Doses<br>Number of Pills | $* |
|---|---|---|
|  |  <br>Isoniazid and Rifapentine once a week for 12 weeks by DOT<br>(12 doses, 108 pills)<br>*Preliminary results for RPT/INH:* | $76 |
|  |  <br>Rifampin Every day for 4 months<br>(120 doses, 240 pills) | $110 |
|  |  <br>Isoniazid Every day for 9 months<br>(270 doses, 270 pills)<br>*Fewer than 60% complete full course* | $30 |

*Estimated cost based on possible 340B prices, excluding DOT and lab costs

**TABLE 3. Recommendations for regimens to treat latent tuberculosis infection**

| Priority rank* | Regimen | Recommendation (strong or conditional) | Evidence (high, moderate, low, or very low) |
|---|---|---|---|
| Preferred | 3 mos isoniazid plus rifapentine given once weekly | Strong | Moderate |
| Preferred | 4 mos rifampin given daily | Strong | Moderate (HIV negative)† |
| Preferred | 3 mos isoniazid plus rifampin given daily | Conditional | Very low (HIV negative) |
| | | Conditional | Low (HIV positive) |
| Alternative | 6 mos isoniazid given daily | Strong§ | Moderate (HIV negative) |
| | | Conditional | Moderate (HIV positive) |
| Alternative | 9 mos isoniazid given daily | Conditional | Moderate |

**Abbreviation:** HIV = human immunodeficiency virus.

* *Preferred:* excellent tolerability and efficacy, shorter treatment duration, higher completion rates than longer regimens and therefore higher effectiveness; *alternative:* excellent efficacy but concerns regarding longer treatment duration, lower completion rates, and therefore lower effectiveness.

† No evidence reported in HIV-positive persons.

§ Strong recommendation for those persons unable to take a preferred regimen (e.g., due to drug intolerability or drug-drug interactions).

Two months of rifampin plus pyrazinamide are not recommended for treatment of LTBI because of the hepatotoxicity risk. However, in persons treated empirically for TB disease with isoniazid, rifampin, and pyrazinamide for 2 months, this regimen will effectively treat LTBI in persons subsequently determined to have LTBI rather than TB disease.

https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6901a1-H.pdf

**TABLE 4. Dosages for recommended latent tuberculosis infection treatment regimens**

| Drug | Duration | Dose and age group | Frequency | Total doses |
|---|---|---|---|---|
| Isoniazid* and rifapentine† | 3 mos | **Adults and children aged ≥12 yrs**<br>Isoniazid: 15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg maximum<br>Rifapentine:<br>10–14.0 kg, 300 mg<br>14.1–25.0 kg, 450 mg<br>25.1–32.0 kg, 600 mg<br>32.1–49.9 kg, 750 mg<br>≥50.0 kg, 900 mg maximum<br>**Children aged 2–11 yrs**<br>Isoniazid*: 25 mg/kg; 900 mg maximum<br>Rifapentine†: see above | Once weekly | 12 |
| Rifampin¶ | 4 mos | **Adults:** 10 mg/kg<br>**Children:** 15–20 mg/kg**<br>**Maximum dose:** 600 mg | Daily | 120 |
| Isoniazid* and rifampin¶ | 3 mos | **Adults**<br>Isoniazid*: 5 mg/kg; 300 mg maximum<br>Rifampin¶: 10 mg/kg; 600 mg maximum<br>**Children**<br>Isoniazid*: 10–20 mg/kg††; 300 mg maximum<br>Rifampin¶: 15–20 mg/kg; 600 mg maximum | Daily | 90 |
| Isoniazid* | 6 mos | **Adults:** 5 mg/kg<br>**Children:** 10–20 mg/kg††<br>**Maximum dose:** 300 mg | Daily | 180 |
| | | **Adults:**15 mg/kg<br>**Children:** 20–40 mg/kg††<br>**Maximum dose:** 900 mg | Twice weekly§ | 52 |
| | 9 mos | **Adults:** 5 mg/kg<br>**Children:** 10–20 mg/kg††<br>**Maximum dose:** 300 mg | Daily | 270 |
| | | **Adults:** 15 mg/kg<br>**Children:** 20–40 mg/kg††<br>**Maximum dose:** 900 mg | Twice weekly§ | 76 |

12 weeks = 12 doses within 16 weeks

4 months= 120 doses within 6 months

6 months tx within 9 months

9 months tx within 12 months

* Isoniazid is formulated as 100-mg and 300-mg tablets.
† Rifapentine is formulated as 150-mg tablets in blister packs that should be kept sealed until use.
§ Intermittent regimens must be provided via directly observed therapy (i.e., a health care worker observes the ingestion of medication).
¶ Rifampin (rifampicin) is formulated as 150-mg and 300-mg capsules.
** The American Academy of Pediatrics acknowledges that some experts use rifampin at 20–30 mg/kg for the daily regimen when prescribing for infants and toddlers (**Source:** American Academy of Pediatrics. Tuberculosis. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. Red Book: 2018 Report of the Committee on Infectious Diseases. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:829–53).
†† The American Academy of Pediatrics recommends an isoniazid dosage of 10–15 mg/kg for the daily regimen and 20–30 mg/kg for the twice-weekly regimen.

## Part 2: Case Studies

# Applying COT to the Real World

*May you live in interesting times*

A patient on the 12 week regimen just took their 4th dose and told you they are moving in a month.
How many doses are left?
Which of the following would you do?

A) You have four weeks to complete 8 more doses. Just double them up to completed 12 doses
B) Give the patient the rest of their meds to self administer
C) Do an interjurisdictional transfer to the new health department
D) Educate the patient on the importance of completing treatment and tell them to find a new doctor after they arrive

IJN

http://www.tbcontrollers.org/resources/interjurisdictional-transfers/#.V-lxDYgrKM8

**A three year old household contact tests positive for TB infection. After being ruled out for TB disease, which regimen do you expect her to be on?**

a) Isoniazid and rifapentine once weekly (DOT)
b) Rifampin daily for 4 months
c) INH DOT twice a week (can give during DOT of the index case)

DST’s came back and the index case is INH resistant. The child has had 4 doses of weekly INH & Rifapentine. How much treatment does she have left?

-Even though she’s had 4 weeks of INH & Rifapentine, she has to restart with Rifampin (as long as it’s susceptible).

42 y/o presented to the ER with a history cough and hemoptysis for 3 weeks, 40 lb. weight loss; his current weight is 124 lb. CXR revealed cavitary lesions. Sputum specimens collected were grossly positive.

**The case manager from the hospital has faxed DOT orders to you as follows:**

**DOT x 10 days with:**
– INH 300 mg qd
– Rifampin 600 mg qd
– Ethambutol 800 mg qd
– PZA 1000 mg qd

**After 10 days give:**
— INH 900 mg qd
— Rifampin 600 mg qd
– Ethambutol 1200 mg qd
– PZA 1500 mg qd

## Are the doses accurate for the patient's weight?

Answer: No; The patients weight is 56kg which puts the dosage at INH 300, RIF 600, EMB 1200, and PZA 1500.

## Are the doses accurate?

Answer: No; the maximum dose for INH daily is 300 mg.

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# When should EMB and PZA be discontinued?

Answer: EMB can be discontinued once susceptibilities are known and patient organism is  identified as being pan susceptible. PZA can be discontinued after 2 months

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# What is the role of the HD during hospitalization?

- Reporting
- Coordinating with hospital for discharge and continuity of care
- Interview patient for discharge planning and contact investigation

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# Interesting Case Study

- 6/15: 65 year old US born female with type 2 DM, HTN, asthma, hx of LTBI with 9 months INH treatment in 1977. Presented with 1 -2 months of cough, with fatigue and muscle aches. Medical record shows blood tinged sputum, which patient denies. CT in ER showed “RUL cavitary mass contiguous to the R hilum & multiple bilateral pulmonary nodules.”
- 6/17 BAL done. Doctor doubts that it is TB, but gives orders to “remain on airborne isolation until results are back.”

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# Labs sent to outside facility

- 6/18: sputums collected 6/15 reported as 3+ and 4+. NAA ordered on bronch specimen. RIPE started.
- 6/19: NAA (equivalent test) detected MTB

| Date collected | Time | Specimen | Smear | Culture | NAA |
|---|---|---|---|---|---|
| 6/15 | 16:00 | sputum | 3+ | MTB | |
| 6/15 | 18:25 | sputum | 4+ | MTB | |
| 6/16 | 7:05 | sputum | 4+ | MTB | |
| 6/17 | 11:05 | bronch | 3+ | MTB | MTB |
| 6/20 | 17:15 | sputum | 4+ | MTB | |
| 6/24 | 5:03 | sputum | 4+ | MTB | |
| 6/25 | 10:45 | sputum | 4+ | MTB | |
| 6/27 | 9:40 | sputum | 4+ | MTB | MTB |
| 6/28 | 10:00 | sputum | 4+ | MTB | |
| 7/2 | 11:15 | sputum | 4+ | MTB | |
| 7/2 | 9:15 | sputum | 4+ | MTB | |
| 7/5 | 8:30 | sputum | 3+ | MTB | |

# Discharge Planning

## Discharged home on 7/6.

- Smears from 7/5 are 3+.
- On daily RIPE since 6/18.
- Improved symptoms, but still ill.  Epidemiology for pansensitive TB.  She lives with husband and adult son.

# Q: Does she need to continue on airborne isolation?

- A: Continue until 3 consecutive smear negative sputums are collected at least 8 hours apart, at least one early morning specimen.

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| Date collected | Smear | Culture |
|---|---|---|
| 6/15 | 4+ | MTB |
| 7/5 | 3+ | |
| 7/9 | neg | |
| 7/10 | 2+ | |
| 7/10 | 2+ | |
| 7/12 | neg | |
| 7/15 | 1+ | |
| 7/16 | rare | |
| 7/17 | rare | |

6/18: RIPE started

7/17: results come back: PANSEN (INH/RIF/EMB/PZA/Strep)

2 month: Still smear positive. Clinically and radiology doing well.

## Q: When was culture conversion?

3 month: Still smear positive. Repeat susceptibilities automatically done.

4 month: finally smear neg. Close to culture conversion? Repeat susceptibilities PANSEN.

## Guidance on Release from Hospital Tuberculosis Isolation[a]

| Diagnostics: | Clinical Impression: | Under Airborne Isolation (AII) and discharging to: | Patient must meet all criteria: |
|---|---|---|---|
| Sputum **AFB Smear Positive** ***AND*** **NAAT Positive** | Active TB Disease | **Home**—**No** high risk individuals or individuals without prior exposure | • Follow-up plan has been made with local TB program and DOT has been arranged[b]<br>• Started on standard TB treatment<br>• All household members, who are not immunocompromised, have been previously exposed to the person with TB<br>• Patient is willing to not travel outside the home until negative sputum smear results are received<br>• No infants or children younger than 5 years of age or persons with immunocompromising conditions are present in the household who have not been evaluated and started on appropriate treatment |
| | | **Home**—**WITH** high risk individuals OR **High-Risk/Congregate Setting** | Patients with infectious TB should NOT be allowed to return to a setting with high risk individuals. The patient can be *discharged* and is considered non-infectious if:<br>• Three consecutive negative sputum smears from sputum collected in 8 - 24 hour intervals (at least one early morning specimen) ***AND***<br>• Started on drug regimen and tolerating for AT LEAST 2 weeks or longer ***AND***<br>• Symptoms have improved |
| Sputum **AFB Smear Negative** (or No Sputum AFB Smear Done) ***AND*** **NAAT Positive** | High likelihood of TB | **Home**—with/without high risk individuals OR **High-Risk/Congregate Setting** | • Three consecutive negative sputum smears from sputum collected in 8 to 24 hour intervals (at least one early morning specimen)<br>• Started on standard TB treatment and tolerating for AT LEAST 5 days<br>• A plan has been made to follow-up on culture results<br>• No infants or children younger than 5 years of age or persons with immunocompromising conditions are present in the household who have not been evaluated and started on appropriate treatment |
| Sputum **AFB Smear Negative** ***AND*** **NAAT Negative** | High likelihood of TB | **Home**—with/without high risk individuals OR **High-Risk/Congregate Setting** | |

***AFB*** *- Acid-fast bacilli* ***AII*** *- airborne infection isolation* ***DOT*** *- Directly Observed Therapy* ***DST*** *- Drug Susceptibility Testing* ***MDDR*** *- Molecular Detection of Drug Resistance* ***MDR*** *- Multi-drug resistant* ***NAAT*** *- Nucleic Acid Amplification Test* ***TB*** *- Tuberculosis* ***XDR*** *- Extensively-drug resistant*

[a]Pulmonary Tuberculosis

[b]The hospital and/or treating clinician should contact the local health department prior to release of a patient with confirmed active TB disease.

# Guidance on Release from Hospital Tuberculosis Isolation[a]

| Diagnostics: | Clinical Impression: | Under Airborne Isolation (AII) and discharging to: | Patient must meet all criteria: |
|---|---|---|---|
| Sputum **AFB Smear Negative** ***AND*** **NAAT Negative** | TB is unlikely | **Home**—with/without high risk individuals OR **High-Risk/Congregate Setting** | • Three consecutive negative sputum smears from sputum collected in 8 to 24 hour intervals (at least one early morning specimen)<br>• A plan has been made to follow-up on culture results<br>• A diagnosis other than TB is identified or is likely |
| Sputum **AFB Smear Positive** ***AND*** **NAAT Negative**<br><br>**A second NAAT should be considered to confirm** | High likelihood of TB | **Home**—with/without high risk individuals OR **High-Risk/Congregate Setting** | • Three consecutive negative sputum smears from sputum collected in 8 to 24 hour intervals (at least one early morning specimen)<br>• Started on standard TB treatment and tolerating for AT LEAST 5 days<br>• A plan has been made to follow-up on culture results<br>• No infants or children younger than 5 years of age or persons with immunocompromising conditions are present in the household who have not been evaluated and started on appropriate treatment |
| | TB is unlikely | | • Three consecutive negative sputum smears from sputum collected in 8 to 24 hour intervals (at least one early morning specimen)<br>• A plan has been made to follow-up on culture results<br>• A diagnosis other than TB is identified or is likely |
| **Confirmed** or **Strongly Suspected** MDR or XDR Diagnosed via: DST, MDDR, GeneXpert, or MTB/RIF Assay | N/A | **Home**—with/without high risk individuals OR **High-Risk/Congregate Setting** | • Three consecutive negative sputum smears from sputum collected in 8 to 24 hour intervals (at least one early morning specimen) ***AND***<br>• Started on adequate DR-TB drug regimen and tolerating for AT LEAST 2 weeks (14 daily doses) or longer ***AND***<br>• At least 2 consecutive negative sputum cultures without a subsequent positive culture |


*References:*

1. Centers for Disease Control and Prevention. *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings.* MMWR: December 30, 2005; Volume 54 (RR17).
2. Centers for Disease Control and Prevention. *Controlling Tuberculosis in the United States.* MMWR: November 4, 2005; Volume 54 (RR12s).



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HEARTLAND NATIONAL TB CENTER
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
2303 Southeast Military Drive
San Antonio, Texas
1-800-TEX-LUNG www.HeartlandNTBC.org

# Final Presentation

A Little Bit of Everything

Patient is a 21 y/o male from Guatemala. Patient arrived to the USA in 2009. Patient presented to the ER on 5/5/13 with a 3 month history of 12 lb. unintentional weight loss, cough, chills, and roughly 500 cc's hemoptysis at home the morning prior to admission. CXR showed a LLL opacity with possible cavitations. CT thorax was obtained which showed scattered consolidation, tree in bud opacities with cavitations throughout both lungs. On admission the patient hemoglobin was found to be 8 . The patient received 4 units of packed red cells. Patient's weight is 126 lbs. HIV test negative. Sputum was collected on 5/7/13 negative smear, 5/8/13 smear 1+, 5/9/14 smear 1+. The patient was noted to have a major episode of hemoptysis and underwent an embolization during his hospital stay. The patient also underwent a bronchoscopy. The smear on the bronchoscopy was positive and a NAAT was obtained. The NAAT was found to be positive for *M.TB* the patient was started on RIPE on 5/7/13 with INH 300 mg, Rifampin 600mg, PZA 1500mg, EMB 1200mg daily.

# Therapy

- Based on his weight of 126 lbs. is the dosage of INH 300 mg, Rifampin 600mg, PZA 1500mg, EMB 1200mg daily appropriate?
  - Answer; yes, this is the appropriate dosage
- Would daily or intermittent dosing during the initial phase of therapy be more effective for this patient?
  - Answer; Daily would be most effective

# Conversion

What might be some reasons why this patient might not convert his culture in 60 days?

A. Resistance
B. Extensive Disease
C. Both resistance and extensive disease
D. Cultures should convert in 60 days; patient is young and has no comorbidities.

The lab calls and reports low level INH resistance.

# The patient is interviewed and you find the following…

- He lives with his wife, 9 month old daughter, and his brother.
- He is employed at a restaurant as a cook.
  - 5 contacts identified

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# Wife

19 y/o female, born in Guatemala. TST(+) 20mm. On evaluation she had no signs and symptoms of active TB disease. CXR was abnormal and noted questionable left suprahilar opacity. Questionable pulmonary vessel vs. consolidation. Lordotic view noted no evidence of active TB disease. Sputum specimens collected were AFB smear negative, NAAT negative, and AFB cultures are pending. The doctor has decided to hold off on treating until cultures are back.

Since she is a contact to an INH resistant case do we need to obtain a consult?

Yes, contact your local state consultant or Heartland NTBC

# 9 Month old Daughter

9 month old baby is positive TST 20mm. CXR was normal and was asymptomatic for TB disease. Baby was started on LTBI therapy with INH, then was switched to Rifampin once the source cases susceptibilities indicated low level INH resistance.

Should therapy be delivered by directly observed therapy?

Answer: Yes!

# Brother

Co-worker is an 18 y/o Hispanic male. Born in Guatemala. Entered U.S. in ?? QFT (+). Had no signs or symptoms of active TB disease. CXR indicated left lower lobe infiltrate. Sputum specimens were AFB smear negative, PCR negative. AFB cultures are pending. Patient was started on RIPE.

## What is the definition of a clinical case of TB?

Answer; Culture negative pulmonary TB case with abnormal CXR and clinical evaluation consistent with TB

# Co-Worker

Brother of source case is a 23 y/o Hispanic male, born in Guatemala. Entered U.S. in 2006. TST (+) 22 mm. No signs or symptoms of active TB disease. CXR was abnormal with questionable right upper lobe opacity. Lordotic view noted right upper lobe consolidation. Sputum specimens collected were AFB (+) rare, NAAT was (+). AFB cultures are pending. He was started on RIPE.

**Is he a case based on the NAAT results?**

Answer: Yes

**What guidelines can be used to return to work?**

Answer; On treatment for 2 weeks, *and* symptom clinical improvement, *and* improved labs.

# Discharge

You receive a call from the case manager at the hospital telling you that they want to discharge the patient today. The patient is still smear positive and the plan is to be discharged to home.

**Is it appropriate to discharge?**

- No

**What are the criteria for release from isolation?**

- 3 consecutive negative smears and 10 days of meds and clinical improvement

# The patient expires.

What social support services will the family need?

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**Contact:**

**Barbarah Martinez, MSN, APRN, FNP-BC**

**Clinical Health Services Division Manager**

**email: Barbarah.Martinez@fortbendcountytx.gov**