Completion of Treatment

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Introduction to TB Nurse Case Management Online
Wednesdays, January 15 – February 5, 2025
Online from San Antonio, Texas

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 be able to describe the process for completion of therapy
- The learner will demonstrate an understanding of tools for accurate dose counting
- The learner will demonstrate the skills necessary to accurately count doses for treatment completion
- The learner will identify next steps and management issues in the diagnosis, care and treatment of a 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 observed 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 or 44 weeks

How do we know cure is achieved?

- Adherence to treatment

Appropriate number of doses of an appropriate regimen in a set amount of time?

- At least 6 months (26 weeks) of a working regimen

The more drugs your patient takes the better the outcomes.

What is treatment completion?

It is the appropriate number of doses ingested at a specified frequency within a specified time frame (duration).

Duration will depend on:

- Patient's response to treatment
- Smear results
- Culture Conversion
- X-ray results
- Weight
- Symptoms
- Site and Extent of Disease
- Patient Comorbidities
- Drugs used
- Drug susceptibility test results of the isolate

Phases of Treatment

Initial Phase

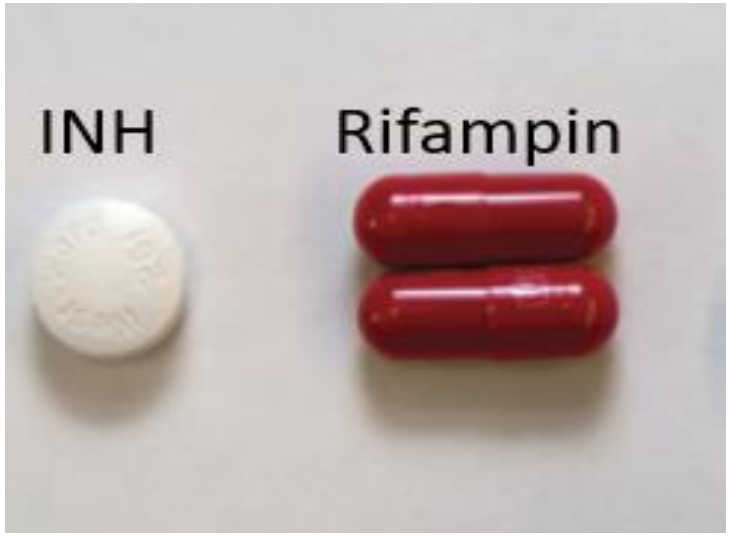
- Usually, 8 weeks for
  drug susceptible TB

Continuation Phase

18 weeks

31 weeks

44 weeks



All treatment should be completed in 365 days

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 the initial phase
- INH and RIF- allow for short-course regimens with high cure rates
- PZA- potent sterilizing activity allowing for further shortening of the regimen from 9 to 6 months
- EMB- Helps to prevent the emergence of RIF resistance when primary INH resistance is present

(**The Rifamycin's are your most important drug in a TB Regimen**)

If at the time that treatment is initiated susceptibilities are known, EMB need not be included if isolate is susceptible to INH and RIF

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

Continuation Phase

If adherence maintained, ensures cure

Two Drugs are usually included

INH and RIF- ensures high cure rates

The Rifamycin's are your most important drug in any regimen or in either phase of treatment

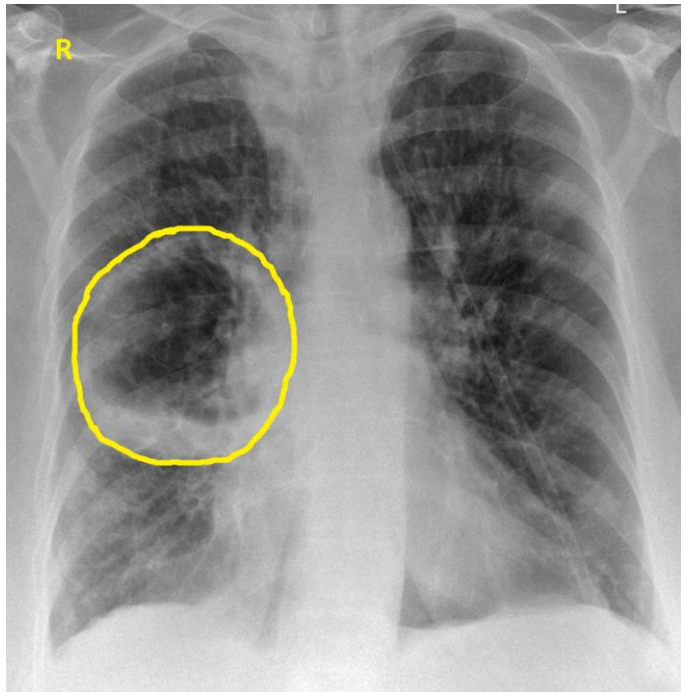
The duration will be 18 weeks, 31 weeks, or 44 weeks, based on the following:

- Patient's burden of disease
- Site of Disease
- Comorbidities

When should treatment be extended

A. Cavity on X-ray AND positive sputum cultures at 2 months of therapy

B. If only one of the above, consider if extending treatment if:
   - >10% below ideal body weight
   - Smoker
   - Diabetic
   - HIV infection
   - Other immunosuppressing condition
   - Extensive disease on X-ray



Weeks of Treatment: aka the finish line

6 month = 26 weeks

- Initial Phase (8 weeks) + Continuation phase (18 weeks) = Total treatment (26 weeks)

9 month = 39 weeks

- Initial Phase (8 weeks) + Continuation phase (31 weeks) = Total treatment (39 weeks)

12 month = 52 weeks

- Initial Phase (8 weeks) + Continuation phase (44 weeks) = Total treatment (52 weeks)

So....

If the initial phase of therapy is always 8 weeks and the individual must be treated for 52 weeks. How long is the continuation phase of treatment for the individual?

A. 52 weeks

B. 44 weeks

C. 40 weeks

How to calculate:

Number of doses needed to complete therapy

Let’s think about DOT this way

If I am an employee that is expected to work M- F and I work Sat and/or Sunday, do I get compensation for the work?

No, I may get an atta girl or I may get told you need to remember your work life balance.

If I am an hourly employee that is expected to work M-Sun and I cannot go to work for two days and the company does not offer PTO, will I get compensation?

Nope, I am out of luck, and I just don’t get compensated. Many of our patients get threatened by their bosses.

FIRST

How many times a week are you observing the patient taking TB meds?

WORK WEEK? = 5 days

CALENDAR WEEK? = 7 days

Work vs. Calendar Week

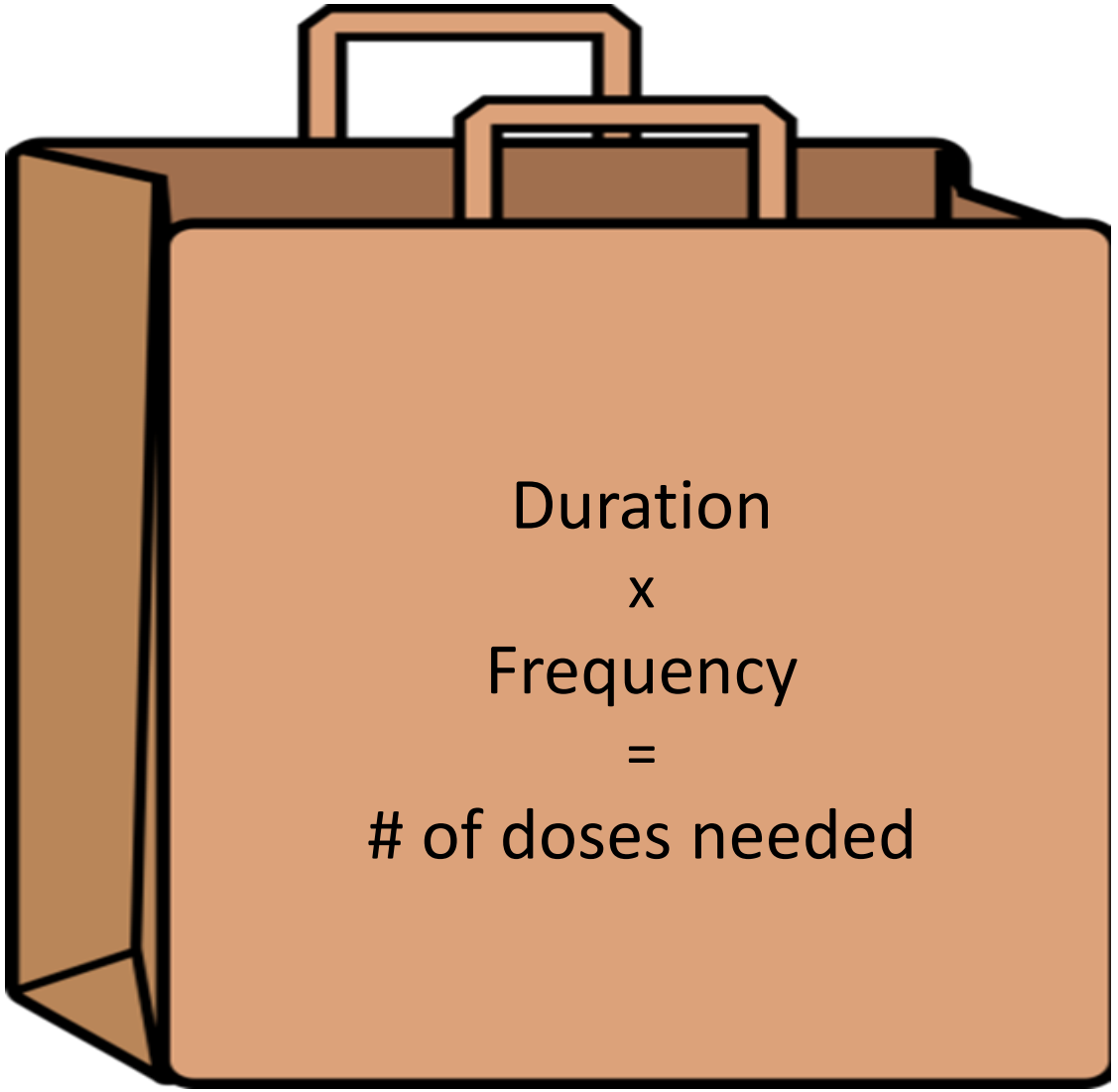
When might you use a work week (5 days a week) to provide DOT?

- Synchronous video DOT – an employee is watching the video while the patient is taking meds.
- Delivered DOT by staff

When might you use a calendar week (7 days a week) for DOT

- In hospital
- In correction facility
- Asynchronous video DOT : the patient uploads the video, and a staff watches the video at a later time.

Remember the frequency of DOT is as important as the duration of DOT when calculating the completion of treatment.


Duration
x
Frequency
=
# of doses needed

Let calculate # of doses needed for 2 patients

Duration
X
Frequency
=
# of doses

Patient 1 - needs 26 weeks of treatment, and they will get DOT via VDOT 7 days a week. How many doses will they need?

182 doses

Remember I am an hourly employee, if I do not work, I do not get paid. So, if the patient misses any doses (i.e. does not upload video) they do not get credit for the work.

Patient 2 - needs 26 weeks of treatment, and they will get DOT via in person DOT 5 day a week. How many doses will they need?

130 doses

Remember I am a salaried employee, I do not get "credit" for weekend meds because they are not observed. But we do encourage our patients to take the meds on the weekend to "get the job done"

Calculating the number of doses: Work week (5 days) vs. calendar week (7 days)

Total Treatment (26 weeks)

Work Week	5 days	x	26	=	130
Calendar Week	7 days	X	26	=	182

Initial phase of therapy (first 8 weeks)

DOT Work Week or Calendar week	Frequency # of times DOT is observed during the week	x	Duration # of weeks	=	Number doses
Work Week	5 days (M-F)	x	8	=	40
Calendar Week	7 days (M-Su)	x	8	=	56

Continuation Phase (last 18 weeks)

Work Week	5 days (M-F)	X	18	=	90
Calendar Week	7 days (M-Su	X	18	=	126

Calculating the number of doses: 9-month Regimen

Initial phase of therapy

DOT Work Week or Calendar week	Frequency # of times DOT is observed during the week	x	Duration # of weeks	=	Number doses
Work Week	5 days (M-F)	x	8	=	40
Calendar Week	7 days (M-Su)	x	8	=	56

Continuation Phase

Work Week	5 days (M-F)	X	31	=	155
Calendar Week	7 days (M-Su	X	31	=	217

Total Treatment (39 weeks)

Work Week	5 days	x	39	=	195
Calendar Week	7 days	X	39	=	273

Case Study

40 y.o. LatinX male presents to the clinic after a positive culture for mycobacterium tuberculosis.

TB findings:

- CXR- large bilateral cavities
- Smear 1+
- PMHX
- Smoker

T2DM:

- Last A1C 10.5 drawn while patient was hospitalized.

The provider starts RIPE and plans to treat for 9 months 7 days a week via video DOT

What are some questions we should ask

Is the patient getting DOT on a work week or calendar week?

A: Calendar Week

How many times per week is the patient receiving DOT?

A: 7 days

What contributed to the provider deciding to treat for 9 months?

A: Patient has extensive disease, patient has uncontrolled T2DM, and is a smoker

How many weeks of treatment in total will be needed?

A: 39 weeks

How many weeks is the initial phase of therapy?

A: 8 weeks

How many weeks is the continuation phase?

A: 31 weeks

How many total doses are needed in the initial phase of treatment?

A: 7 daily doses x 8 doses = 56 doses

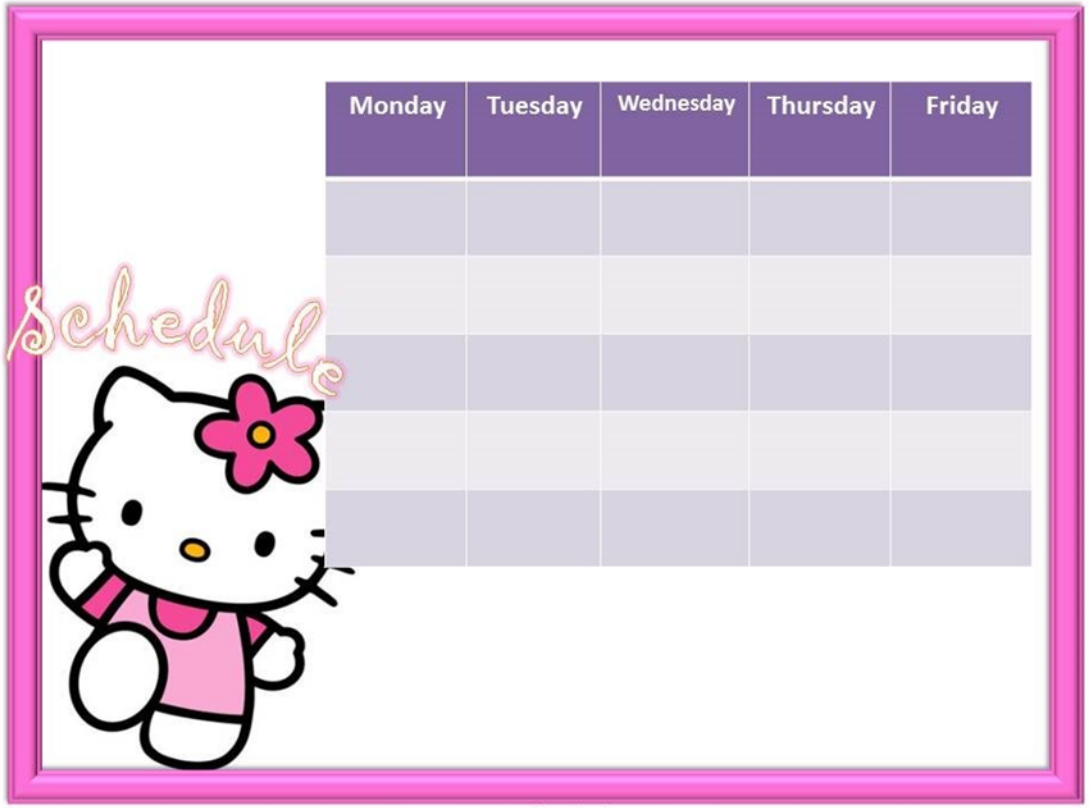
How many total doses in the continuation phase of treatment?

A: 7 daily dose x 31 weeks = 217 doses.

Table 2. Drug Regimens for Microbiologically Confirmed Pulmonary Tuberculosis Caused by Drug-Susceptible Organisms

	Intensive Phase		Continuation Phase				
Regimen	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
1	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
2	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.	
3	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.	
4	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

Weeks of Treatment



How to figure out weeks of treatment

Total doses / Frequency (work (5 days) or calendar week (7 days) = number of weeks

Example:

14 days/7 days (calendar week)= 2 weeks

14 days/5 days (work week)= 2.8

OK, So why does this matter..

Case Scenario

30 y.o. male recently released from your local corrections facility. He was started on RIPE on 6.10.24 and was released to the world on 7.19.24 daily. How many weeks of treatment has the individual received?

So, we look at:

How many days a week are the meds observed?

7 days a week

How many days of meds did the patient get between 6/10 to 7/19?

40 doses

So how many weeks of treatment has the individual completed?

40 doses/7 days = 5.7 weeks.. I always round down instead of up

Case Scenario

18 y.o. diagnosed with TB has received in person DOT from the health department from 3.11 to 3.31

How many days a week is the patient observed taking his medication?

5 days a week

So how many days of DOT did the patient take?

15

So how many weeks of DOT has the patient completed?

Number of days/frequency = weeks

15 days/5= 3 weeks.

But Wait…

The patient took weekend self meds.. Why are we not counting them?

- Remember that for completion of treatment we only count observed doses.

Then why do we leave the meds with the patient?

- Remember the more doses the patient takes the more likely they are to reach cure faster.

Comparing Apples and Oranges

Case Scenario

A 28 y.o. female has presented to your clinic today 6.3.24 with the following information after admission to the hospital:

Patient was admitted to the local hospital from
- 5.1.24 to 5.16.24

You received a medication administration record from the hospital
- You can confirm patient received meds from 5.3 to 5.16

Patient was discharged from the hospital 5.16.24 and was provided:
- Medication RX for 5.16.24 to 5.19.24

Patient was unable to get the RX filled so did not take meds until health department started DOT

Health Department started In-Person Directly Observed Therapy on
- 5.21.24

How many weeks of treatment has the patient completed up to 5/21/24?

Let’s break this down to bite size bits

Start by asking:

1. Does the hospital provide DOT 5 days or 7 days a week?

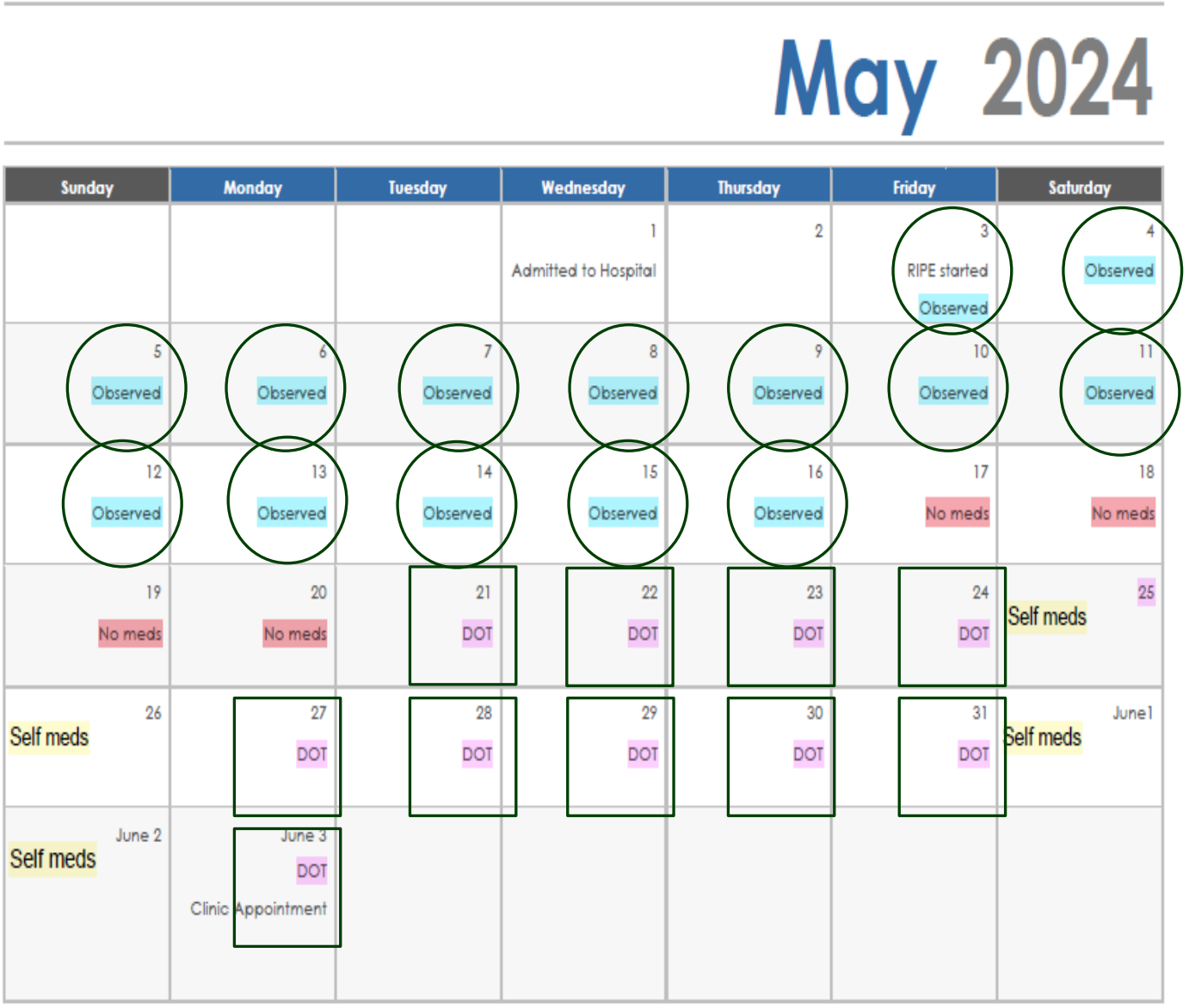
7 days a week

2. How about the health department? Do they provide observed therapy on the weekends or not?

No

3. So, how may times a week does the health department provide DOT?

5 days a week



Breaking this scenario more...

1. How many days a week are patients observed taking medication while in the hospital?

7 days a week

2. Based on the scenario, how many days did the patient receive meds while in the hospital?

14 days

3. How many days a week does a health department provide DOT?

5 days a week

4. How many days of meds did the patient receive meds via DOT:

10 days

Let’s figure out how many weeks

The formula:

# of observed doses/frequency (calendar - 5 days/work week-7 days) = number of weeks

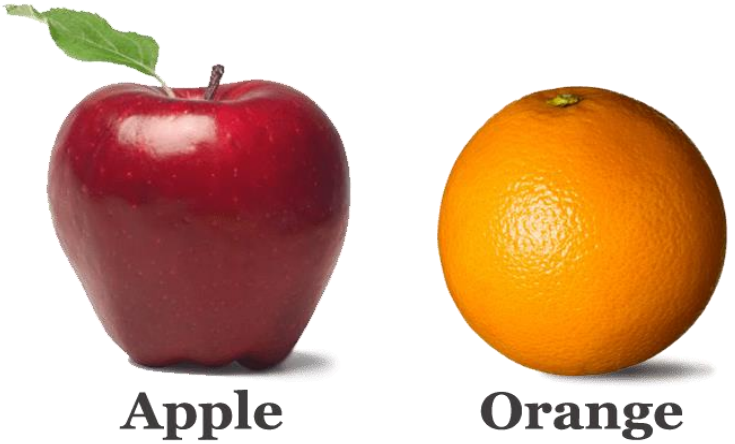
Hospital Stay : 5.3 to 5.16

14 doses/7 days = 2 weeks

DOT: 5.21 to 6.3

10 doses/ 5 days = 2 weeks

Total weeks = 2.0 + 2.0 = 4 weeks



The patient missed some days…

What happens since the patient did not have meds for 4 days after leaving the hospital?

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 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

Interruption in Therapy Case Scenario

82 y.o woman diagnosed with TB after a bronchoscopy to rule out metastasis to the lungs

PMHX
- Stage IV Ovarian Ca
- T2DM

Treatment for TB
- RIPE started on 6/1 via in person DOT by health department

Patient started to complain of
- RUQ pain
- DOT provider noted the patient appeared jaundiced

LABS
- AST 226
- ALT 168
- Total bili: 1.8

All TB meds placed on hold 6.10.23 to allow for “liver to cool”

Meds were restarted 6/28

How long of an interruption was there?

18 days; meds were held from 6/10 to 6/28

Does the patient need to restart TB therapy or are all doses counted towards completion of therapy?

The patient will need to restart treatment. If an interruption occurs during the initial phase of treatment and the lapse is 14 days or more in duration, treatment should be restarted.

What is the interruption was only 4 days like in the previous case scenario?

If the lapse is less than 14 days, the treatment regimen should be continued, and all doses counted towards completion of therapy.

Things to Remember

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

Figure 6.5
Algorithm for Management of
Initial Phase Treatment Interruptions

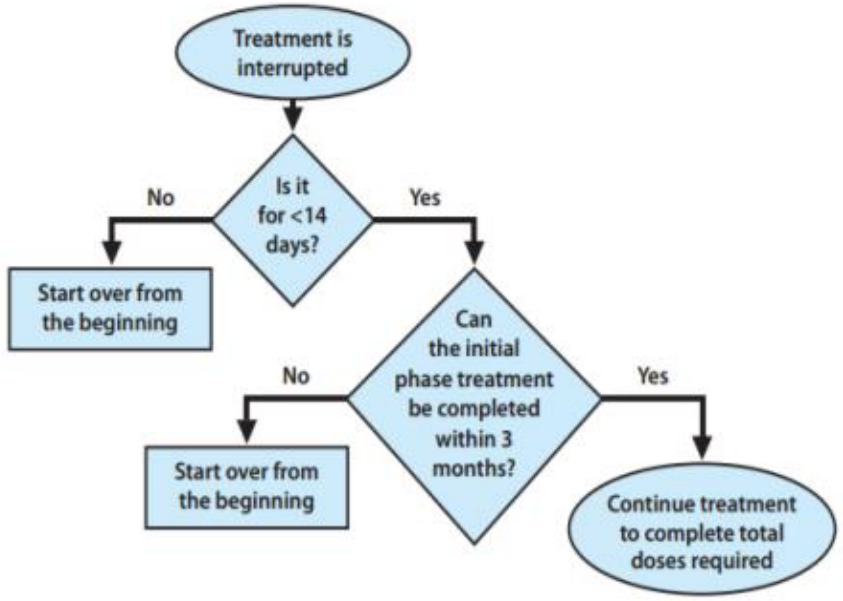
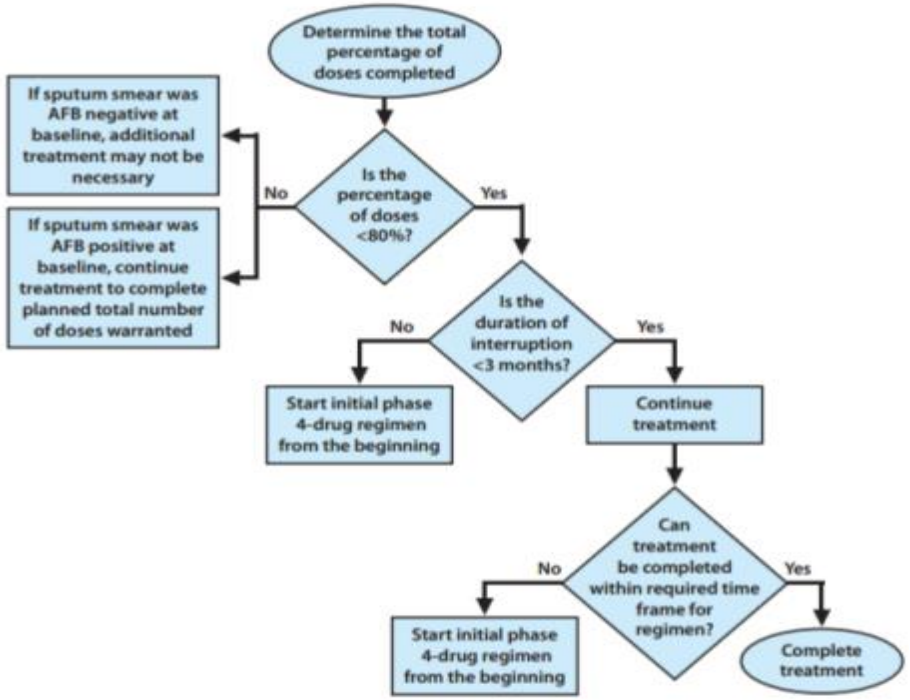


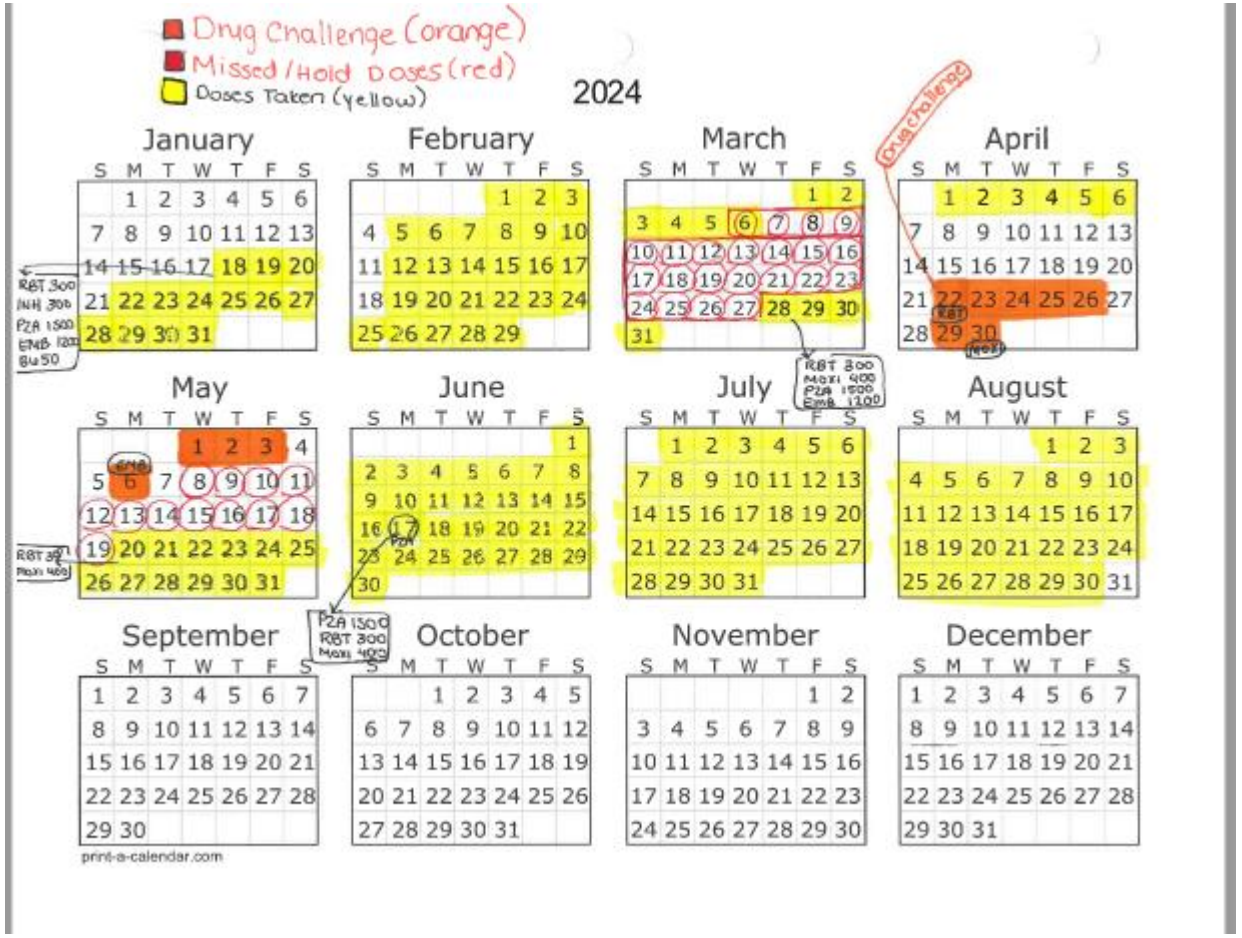
Figure 6.6
Algorithm for Management of
Continuation Phase Treatment Interruptions



How to calculate the number of weeks left

First, use a calendar to organize yourself

- Use a different color for doses taken, doses missed and self meds
- Indicate when the initial phase of treatment was completed.
- For each appropriate regimen or each phase of treatment:
  - Count the number of therapeutic doses given
  - Divide the number of doses by prescribed frequency per week
  - Add the number of weeks for each section for the Total number of weeks completed



Calculating Number of Weeks of Treatment Left

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	21	÷	RIPE 7 days/wk	=	3 weeks
1/29 to 3/11	25	÷	RIPE 5 days/wk	=	5 weeks
				Total Weeks of initial phase of therapy	8 weeks

Has the patient received an appropriate number of doses to advance to the continuation phase? Yes

8 weeks needed to complete the initial phase – 8 weeks completed per records = 0 weeks needed

What if the patient had received 46 doses receiving RIPE 5 days in person DOT, how many weeks would they have completed? 9.2 weeks

What if the patient received 46 doses receiving RIPE 7 days via V-DOT, how many weeks would they have completed? 6.5 weeks

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	18	÷	RIPE 7 days/wk	=	2.5 weeks
1/29 to 3/11	23	÷	RIPE 5 days/wk	=	4.6 weeks
				Total Weeks of Initial Phase of therapy	7.1 weeks

Has the patient received an appropriate number of doses to advance to the continuation phase? No

How many more weeks do they need of therapy?

8 weeks - 7.1 weeks completed = .9 weeks (At this point I round up to one more week)

What are some things we need to check before advancing the patient to the continuation phase of therapy?

Has the patient completed 8 weeks of PZA?

Has there been any significant breaks in treatment?

Are the DST's back?

Remember: DO NOT provide a final date to the patient because the date may change!

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

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	20	÷	RIPE 7 days/wk	=	2.9 weeks
1/29 to 3/11	26	÷	RIPE 5 days/wk	=	5.2 weeks
				Initial phase total weeks	8.1 weeks
3/14 to 5/15	40	÷	Rif/INH 5 days/wk	=	8 weeks
				Total Weeks	16.1 weeks

Did the patient complete 8 weeks of RIPE before advancing to continuation phase? Yes

If the patient must complete 26 weeks of therapy, how many more weeks do they have to complete?

26 weeks – 16.1 weeks completed= 9.9 weeks

What if the patient had to complete 52 weeks of treatment?

52 weeks-16.1 weeks completed = 35.9 weeks

Remember: DO NOT provide a final date to the patient because the date may change!

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	23	÷	RIPE 7 days/wk	=	3.2 weeks
1/29 to 3/11	24	÷	RIPE 5 days/wk	=	4.8 weeks
				Total weeks of initial phase	8 weeks
3/14 to 5/15	32	÷	Rif/INH 5 days/wk	=	6.4 weeks
				Total Weeks	14.4 weeks

If the patient must complete 39 weeks of therapy, how many more weeks do they have to complete?

39 weeks-14.4weeks completed = 26.4 weeks left of therapy.

If it was 26 weeks of treatment?

26 weeks -14.4 weeks completed = 11.6 weeks left of therapy

Remember: DO NOT provide a final date to the patient because the date may change!

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	23	÷	RIPE 7 days/wk	=	3.2 weeks
1/29 to 3/11	25	÷	RIPE 5 days/wk	=	5.0 weeks
			Weeks of initial phase		8.2
3/14 to 5/15	13	÷	Rif/INH 5 days/wk	=	2.6 weeks
				Total Weeks	10.8 weeks

Another example:

If the patient must complete 26 weeks of therapy, how many weeks of therapy does the patient still need to complete?

26-10.8 = 15.2 weeks

Remember: DO NOT provide a final date to the patient because the date may change!

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	7	÷	RIPE 7 days/wk	=	1 weeks
1/29 to 3/11	38	÷	RIPE 5 days/wk	=	7.6 weeks
			Total Weeks Initial Phase (RIPE)	=	8.6 week
3/14 to 5/15	46	÷	Rif/INH 5 days/wk	=	9.2 weeks
				Total Weeks	17.8 weeks

Did the patient complete the appropriate number of weeks of the initial phase of therapy with RIPE?

YES

How many total weeks of treatment has the patient received?

17.8

How many weeks does the patient have left to complete to complete a 39 week?

21.2

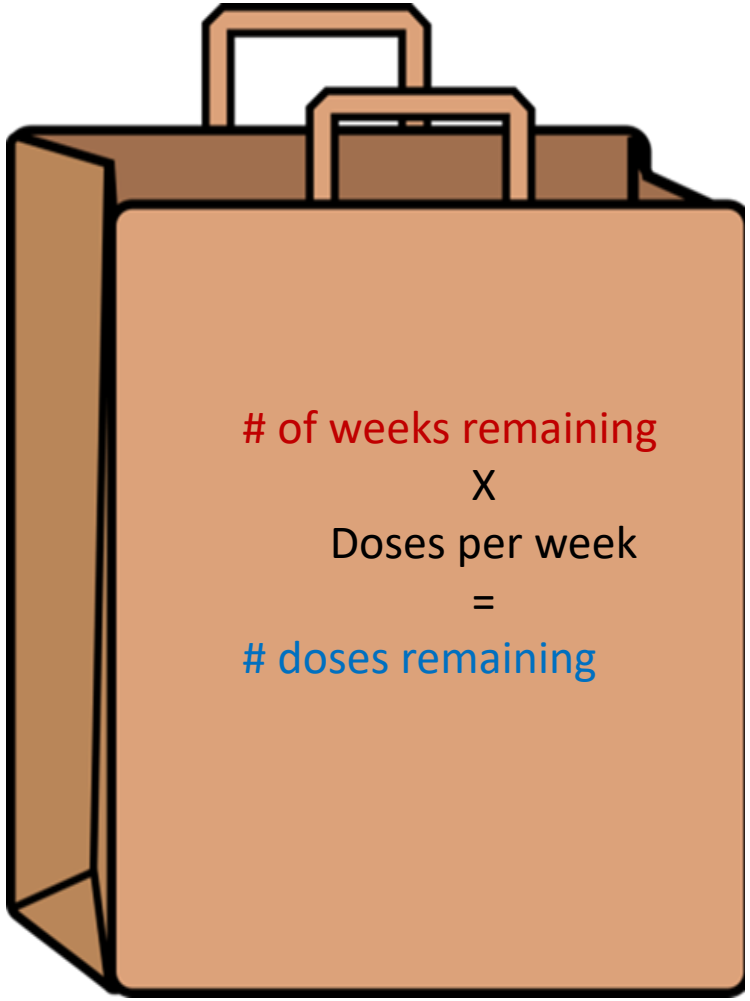
How many weeks of treatment would the patient have received if all 91 doses were given 5 days DOT?

18.2

What about 7 days DOT?

13

How do we figure out how many doses (days) the patient has left?


# of weeks remaining
X
Doses per week
=
doses remaining

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	14	÷	RIPE 7 days/wk	=	2 weeks
1/29 to 3/11	20	÷	RIPE 5 days/wk	=	4 weeks
				Total Weeks	6 weeks

So how many weeks does the patient need to complete the initial phase of therapy?

8 weeks -6 weeks = 2 weeks

So how many doses does the patient need if they are receiving RIPE via DOT 5 days a week?

2 x 5 days (frequency) = 10 doses

What if the patient is receiving VDOT 7 days a week?

2 x 7 days (frequency) = 14 doses

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	18	÷	RIPE 7 days/wk	=	2.5 weeks
1/29 to 3/11	28	÷	RIPE 5 days/wk	=	5.6 weeks
3/14 to 6/30	76	÷	INH/RIF 5 days/wk	=	15.2 weeks
				Total Weeks	23.3

<u>The patient needs to complete 26 weeks of therapy:</u>

How many doses do they still need to complete their regimen?

13.5 doses

How many doses would they have to complete if the frequency was 7 days a week?

18.9 doses

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	18	÷	RIPE 7 days/wk	=	2.5 weeks
1/29 to 3/11	28	÷	RIPE 5 days/wk	=	5.6 weeks
3/14 to 6/30	76	÷	INH/RIF 5 days/wk	=	15.2 weeks
				Total Weeks	23.3

<u>The patient needs to complete 39 weeks of therapy:</u>

How many doses do they still need to complete their regimen?

78.5 (round up to 79 doses)

How many doses would they have to complete if the frequency was 7 days a week?

109.9 (round up to 110 doses)

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/6 to 1/25	18	÷	RIPE 7 days/wk	=	2.5 weeks
1/26 to 1/29	0	÷	RIPE 5 days/wk	=	0
1/30 to 3/13	30	÷	RIPE 5 days/wk	=	6 weeks
3/13 to 5/28	54		INH/RIF 5 days/wk		10.8
			Total weeks of initial phase		8.5
			Total weeks of treatment		19.3

Patient was prescribed a 6-month regimen:

How many weeks of treatment do they have left ? 6.7

How many doses do they have left? 33.5 (roundup to 34 doses)

Do we need to worry about the interruption in therapy? No, because the interruption was only 4 days

What if the interruption was longer than 14 days? Yes, the patient would have to start treatment all over again

Is it adequate treatment?

Things to be considered before closing the record as adequate treatment.

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

Drug Challenges OH MY!!!

Remember most patients will have difficulty with their treatment during the first 8 weeks, the initial phase of therapy.

So how do you figure out when to start counting doses and when to complete treatment?

1. Make yourself a calendar so you can see the starts and stops of the regimens to help you determine the date from when you can start counting doses.
2. Was the medication regimen the patient was on a therapeutic regimen?
3. Did the patient have any of the following interruptions in treatment that would meet the criteria for starting the treatment over?
    - Was the interruption more than 14 days?
    - Will the initial phase be completed in three months?

1. **Did the patient have interruptions in treatment?**

   Yes

2. **Did the interruption last more than 14 days?**

   Yes

3. **Does the patient need to start treatment from the beginning?**

   Yes

4. **What date is the first date that we can count to begin the patient's treatment?**

   5/20

5. **Based on what we know, how many weeks of treatment has the patient finished?**

   103 doses divided by 7 = 14.7

The patient must complete 6 months of treatment:

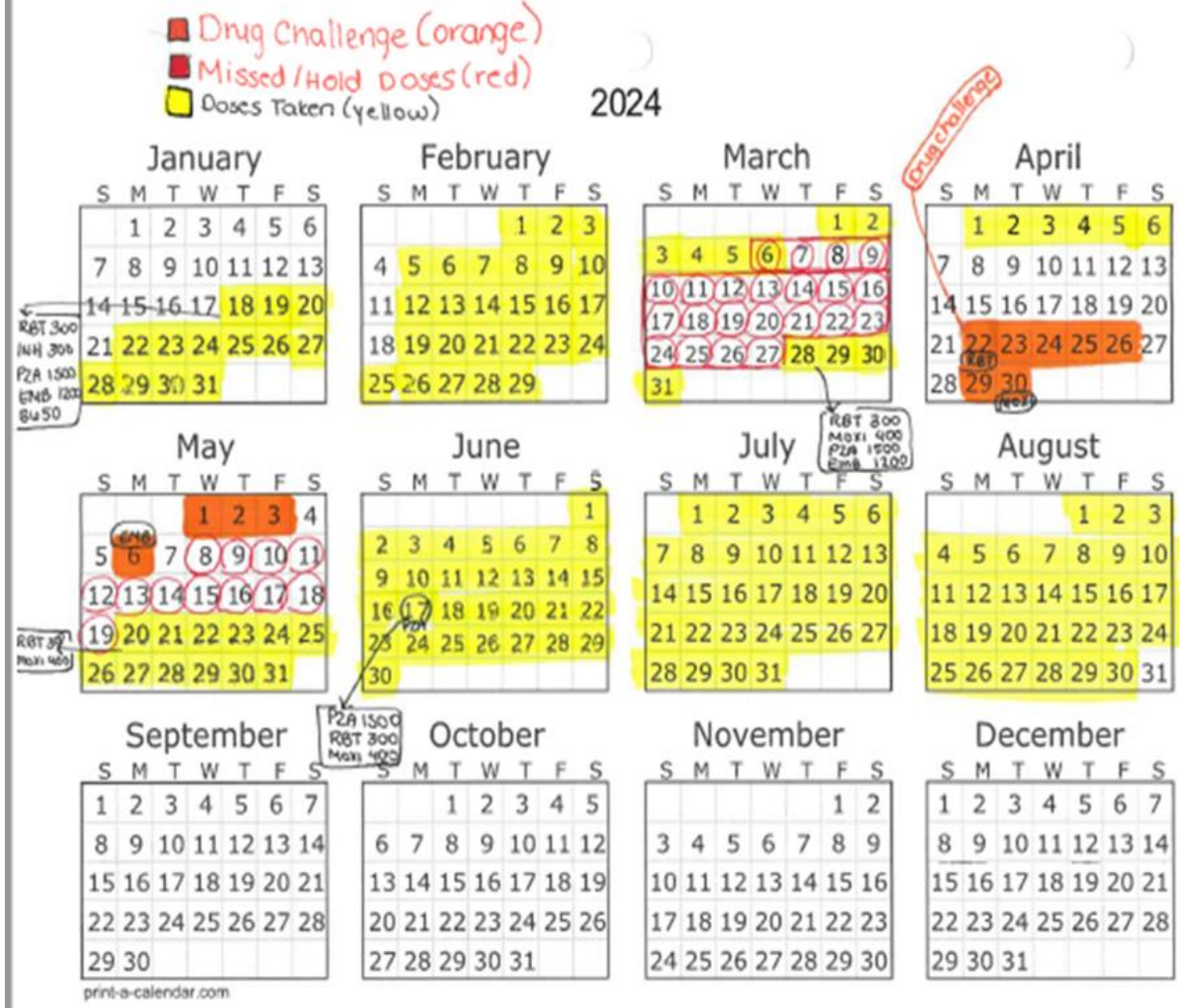
1. **How many more weeks does he have to complete treatment?**

   26-14.7 = 11.3 weeks

2. **How many doses does the patient need to complete?**

   11.3 x 7 = 79.1 doses

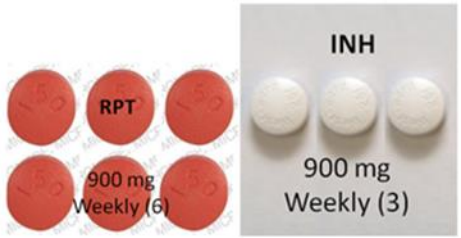
3. **What is the expected date of completion?**



November 18th. At that time, the patient would have received 80 doses of DOT if no days are missed.

Dates	Medication Regimen	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
1/18 to 3/5	Rifabutin 300 mg INH 300 mg PZA 1500 mg EMB 1200 mg	44	÷	7 days a week	=	6.2
3/6 to 3/27	Meds Held	0 doses for 22 days				0
3/28 to 4/6	Rifabutin 300mg Moxi 400mg PZA 1500 mg EMB 1200 mg	10	÷	7 days/wk	=	1.4
4/7 to 4/21	Meds held	0 doses for 15 days				0
4/22 to 4/26	Rifabutin 300mg	5	÷	5 days per week		1
4/29 to 5/3	Rifabutin 300 mg Moxi 400 mg	5	÷	5 days per week		1
5/6	Rifabutin 300mg Moxi 400 mg PZA 1500 mg	1	÷	5 days per week		0.2
5/7 to 5/19	Meds held	0 doses for 12 days	÷	5		0
5/20 to 8/30	PZA 1500 mg Rifabutin 300 mg Moxi 400 mg	103	÷	7 days per week		14.7

What about Latent TB Infection?

Regimens for Treating LTBI (dosage shown based on adults weighing ≥ 50 kg)	Length of Treatment Number of Doses Number of Pills	$*
	 Isoniazid and Rifapentine once a week for 12 weeks by DOT (12 doses, 108 pills) *Preliminary results for RPT/INH:*	$76
	 Rifampin Every day for 4 months (120 doses, 240 pills)	$110
	 Isoniazid Every day for 9 months (270 doses, 270 pills) *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** Isoniazid: 15 mg/kg rounded up to the nearest 50 or 100 mg; 900 mg maximum Rifapentine: 10–14.0 kg, 300 mg 14.1–25.0 kg, 450 mg 25.1–32.0 kg, 600 mg 32.1–49.9 kg, 750 mg ≥50.0 kg, 900 mg maximum **Children aged 2–11 yrs** Isoniazid*: 25 mg/kg; 900 mg maximum Rifapentine†: see above	Once weekly	12
Rifampin¶	4 mos	**Adults:** 10 mg/kg **Children:** 15–20 mg/kg** **Maximum dose:** 600 mg	Daily	120
Isoniazid* and rifampin¶	3 mos	**Adults** Isoniazid*: 5 mg/kg; 300 mg maximum Rifampin¶: 10 mg/kg; 600 mg maximum **Children** Isoniazid*: 10–20 mg/kg††; 300 mg maximum Rifampin¶: 15–20 mg/kg; 600 mg maximum	Daily	90
Isoniazid*	6 mos	**Adults:** 5 mg/kg **Children:** 10–20 mg/kg†† **Maximum dose:** 300 mg	Daily	180
		Adults:15 mg/kg **Children:** 20–40 mg/kg†† **Maximum dose:** 900 mg	Twice weekly§	52
	9 mos	**Adults:** 5 mg/kg **Children:** 10–20 mg/kg†† **Maximum dose:** 300 mg	Daily	270
		Adults: 15 mg/kg **Children:** 20–40 mg/kg†† **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.

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

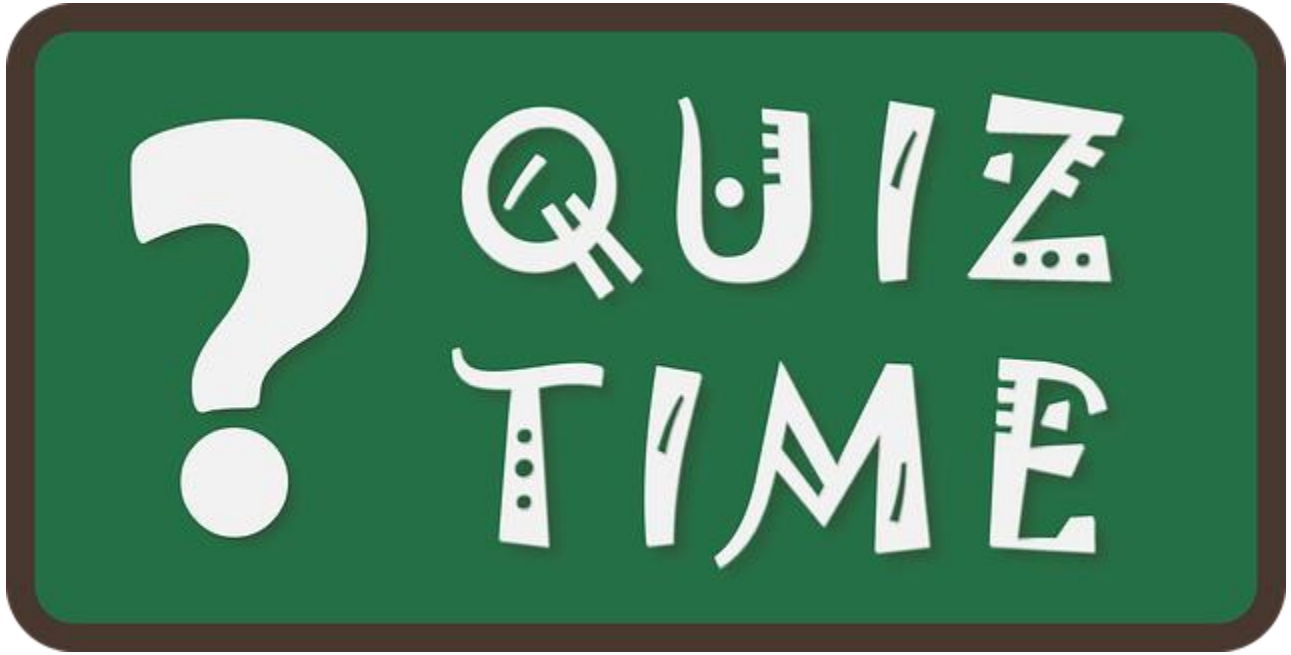
Completion of LTBI Therapy

How many doses of LTBI therapy does the patient need to complete if patient is prescribed 6 months of INH via asynchronous VDOT?

7	x	26	=	182 doses
How many days a week will the patient receive VDOT?		How many weeks will be needed to complete treatment?		

VDOT is given 7 days a week

6 months = 26 weeks


QUIZ
TIME

A patient on the 12-week regimen just took their 4th dose and told you they are moving in a month.

1. How many doses are left? 8

2. Which of the following would you do?

A. You have four weeks to complete 8 more dose. Just double them up to complete 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

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

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] • Started on standard TB treatment • All household members, who are not immunocompromised, have been previously exposed to the person with TB • Patient is willing to not travel outside the home until negative sputum smear results are received • 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: • Three consectutive negative sputum smears from sputum collected in 8 - 24 hour intervals (at least one early morning specimen) ***AND*** • Started on drug regimen and tolerating for AT LEAST 2 weeks or longer ***AND*** • 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) • Started on standard TB treatment and tolerating for AT LEAST 5 days • A plan has been made to follow-up on culture results • 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) • A plan has been made to follow-up on culture results • A diagnosis other than TB is identified or is likely
Sputum **AFB Smear Positive** ***AND*** **NAAT Negative** **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) • Started on standard TB treatment and tolerating for AT LEAST 5 days • A plan has been made to follow-up on culture results • 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) • A plan has been made to follow-up on culture results • 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*** • Started on adequate DR-TB drug regimen and tolerating for AT LEAST 2 weeks (14 daily doses) or longer ***AND*** • 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

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.”

FORT BEND
HEALTH & HUMAN SERVICES
Prevent. Promote. Protect.

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	

Date collected	Smear	Culture
6/15	4+	MTB
7/5	3+	MTB
7/9	neg	9 colonies
7/10	2+	3+
7/10	2+	3+
7/12	neg	5 colonies
7/15	1+	1+
7/16	rare	17 colonies
7/17	rare	2+
7/23	rare	1+
7/29	rare	1 colony
8/5	1+	5 colonies
8/6	rare	8 colonies
8/7	neg	1 colony
8/11	1+	1 colony
8/12	1+	3 colonies
8/18	1+	3 colonies
8/19	neg	neg
8/20	rare	2 colonies
8/26	1+	neg
8/27	1+	neg
8/28	3+	MGIT only
9/10	1+	neg
9/11	2+	neg
9/16	1+	MGIT only
9/17	1+	4 colonies
9/18	rare	MGIT only
9/21	2+	MGIT only
9/22	1+	neg
9/23	rare	neg
9/30	rare	neg
10/1	neg	neg
10/2	neg	neg
10/22	neg	neg

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. Consider requesting a consult based on medical hx

4 month: finally smear neg. Close to culture conversion? Repeat susceptibilities PANSEN. At this point considered treatment failure we **must** get a consult.

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.
- What the hospital staff did not share is that the adult son has an 18-month-old baby that lives in the house as well

Does she need to continue on airborne isolation?

- Continue until 3 consecutive smear negative sputums are collected at least 8 hours apart, at least one early morning specimen.
- At least two weeks of meds and
- Clinical Improvement

Dates	Doses Administered	÷	Frequency (doses per week	=	Weeks of Treatment
6/18 to 7/6	19	÷	RIPE 7 days/wk	=	2.7
7/12 to 8/18	28	÷	RIPE 5 days/wk	=	5.6
				Total weeks (initial phase)	2.7 + 5.6 = 8.3
8/22 to 10/31	49	÷	INH/RIF 5 days/wk	=	9.8
11/1 to 11/30	18	÷		=	3.6
			Total weeks of treatment		8.3 + 9.8 + 3.6 = 21.7

Do we do anything for the 18-month-old?

Child needs a complete evaluation including:

- Complete physical exam
- CXR
- IGRA

Does the child need treatment? *Yes, window prophylaxis*

Follow up:

- Repeat IGRA in 8 weeks if first IGRA was negative
- If second IGRA is negative stop meds
- If second IGRA is positive continue treatment to finish a complete course of treatment for TB infection

Let’s Practice and try to put it all together

O RIPE
O RI
O weekend self meds

2023

JANUARY

s	m	t	w	t	f	s
1	2	3	4	5	6	7
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15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

FEBRUARY

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26	27	28				

MARCH

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26	27	28	29	30	31	

APRIL

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30						

MAY

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JUNE

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JULY

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30	31					

AUGUST

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SEPTEMBER

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OCTOBER

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29	30	31				

NOVEMBER

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DECEMBER

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17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

If you ever see a calendar like this, go by a lotto ticket!

0 DOT taken
0 missed doses

2023

JANUARY

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22	23	24	25	26	27	28
29	30	31				

FEBRUARY

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MARCH

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APRIL

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30						

MAY

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14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

JUNE

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(3) 18	19	20	21	22	23	24
(4) 25	26	27	28	29	30	

JULY

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(8) 23	24	25	26	27	28	29
(9) 30	31					

AUGUST

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(12) 20	21	22	23	24	25	26
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SEPTEMBER

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(16) 17	18	19	20	21	22	23
(17) 24	25	26	27	28	29	30

OCTOBER

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(19) 8	9	10	11	12	13	14
(20) 15	16	17	18	19	20	21
(21) 22	23	24	25	26	27	28
(22) 29	30	31				

NOVEMBER

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(26) 26	27	28	29	30		

DECEMBER

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3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						


RIPE
RI
X missed
self-meds
2023
JANUARY
FEBRUARY
MARCH
APRIL
MAY
JUNE
JULY
AUGUST
SEPTEMBER
OCTOBER
NOVEMBER
DECEMBER

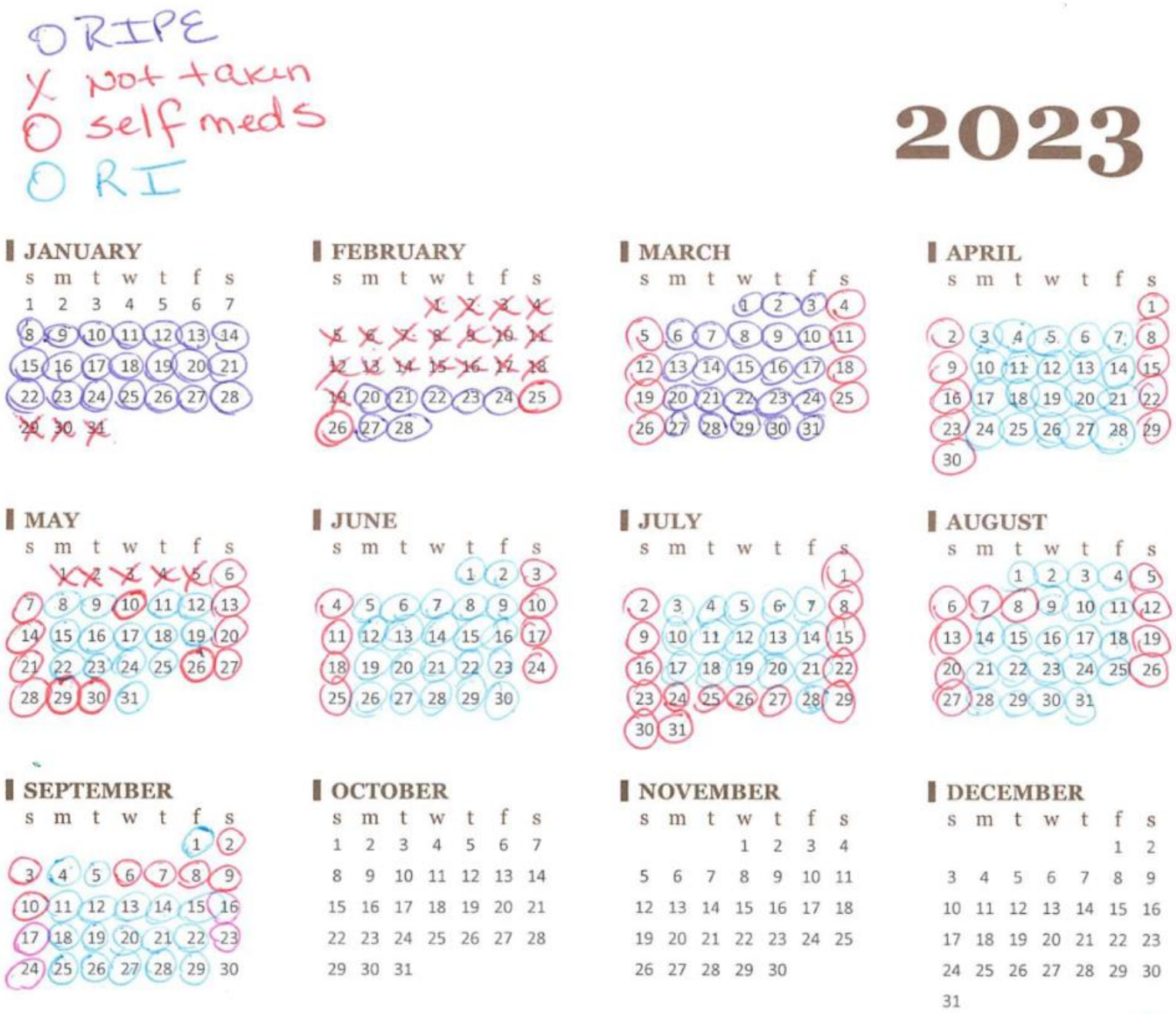
More Practice

Let's look at the previous calendar in a table

Dates	Doses Administered	Doses Missed	Meds		Frequency Doses per week		Weeks of Treatment
1/2 - 1/8	7	0	RIPE	÷	7 days a week	=	1
1/9 - 1/15	0	7	NONE	÷	0	=	0
1/16 – 3/3	35	0	RIPE	÷	5 days a week	=	7
3/6 – 7/10	90	1	RI	÷	5 days a week	=	18
					Total Weeks	=	26

How many week of therapy did the patient receive? 26 weeks

Did the one week of treatment mean that the patient starts over? No



Why can we not count the doses from 1/8 to 1/28?

- Because there was an interruption in the treatment that lasted more than 14 days during the initial phase of therapy.

What date can I start counting the doses toward completion?

- February 20th

Looking at the example the patient received 30 doses (6 weeks) of RIPE before they were switched to RI, the patient received 111 doses 22 weeks. Has this patient completed therapy?

- No

Wait.. What.. Why???

- The patient must have 8 full weeks of PZA to complete a six-month regimen.
- The patient only had 6 weeks of RIPE...
- We cannot count “extra RI” doses to complete the weeks...

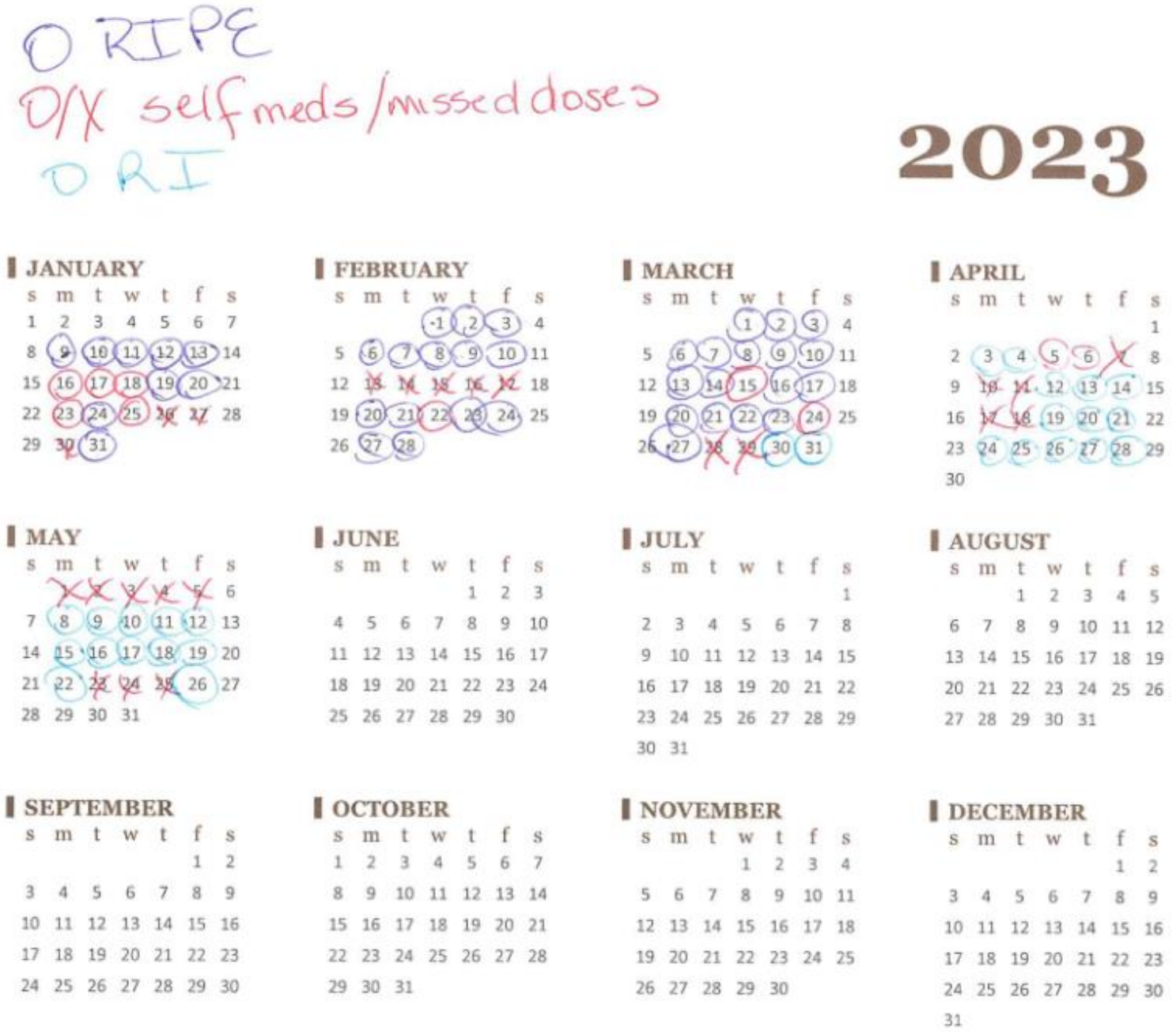
So now what??

We now get to call the provider and the patient and tell them..

- The patient needs to be extended to 9 months because they did not have PZA in the regimen for the full 8 weeks.

This is what it usually looks like

Dates	Doses Administered	Doses Missed	Meds		Frequency Doses per week		Weeks of Treatment
1/8 – 1/28	21	0	RIPE	÷	7 days a week	=	3
1/29 – 2/19	0	22	NONE	÷	7days a week	=	0
2/20 – 3/31	30	0	RIPE	÷	5 days a week	=	6
4/3 – 4/28	20	0	RI	÷	5 days a week	=	5
5/1 - 5/6	0	5	RI	÷	5 days a week	=	0
5/8 – 9/29	91	13	RI		5 days a week	=	18.2
					Total Weeks of Treatment	=	32.2



Adherent?

We can tell from the X's on the calendar the patient is not very adherent.

As a case manager what would you say?

- *Remember the more meds you take, the better your chances of cure.*
- *The more doses you miss, the longer you are going to keep seeing us and the longer the disruption.*
- *Remember the paper you signed that said you would comply... Well... If you don't...*

Is there anything you can do?

- Switch to video DOT?
- Provide treatment at work?

Drug Challenge: To count or not to count

Doses given to the patient during a drug challenge cannot be counted if it is a single dose given at a time.

INH 100mg daily x 1 week
INH 200mg daily x 1 week
INH 300mg daily x 1 week

Doses can be counted once the patient is on INH and a Rifamycin and is tolerated:

Rifampin 600 mg and EMB 800 mg x 1 week
Rifampin 600 mg, EMB 800 mg, INH 300 mg x 1 week
Rifampin 600mg, EMB 800mg, INH 300 mg, and PZA x 1 week

Note from the field: I do not customarily count challenge doses.

Take Aways:

Remember to look at the adherence for each phase.

Remember it is important to look at frequency and duration

Remember to only count observed doses

Remember to only count therapeutic regimens, especially with drug challenges.

Formulas:

Weeks of Treatment:
- Observed doses x frequency

Weeks of Treatment remaining:
- Weeks of Treatment Received – Total prescribed weeks of treatment = Weeks of Treatment remaining

Number of doses remaining :
- Number of weeks of Treatment remaining x frequency per week of dosing

A story from the field.
Why the TB team is so important.

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