Dose Counting

Barbarah Martinez, MSN, APRN, FNP-BC

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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 activity

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Texas Children's Hospital®

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Instructor - Baylor College of Medicine

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Directly Observed Therapy

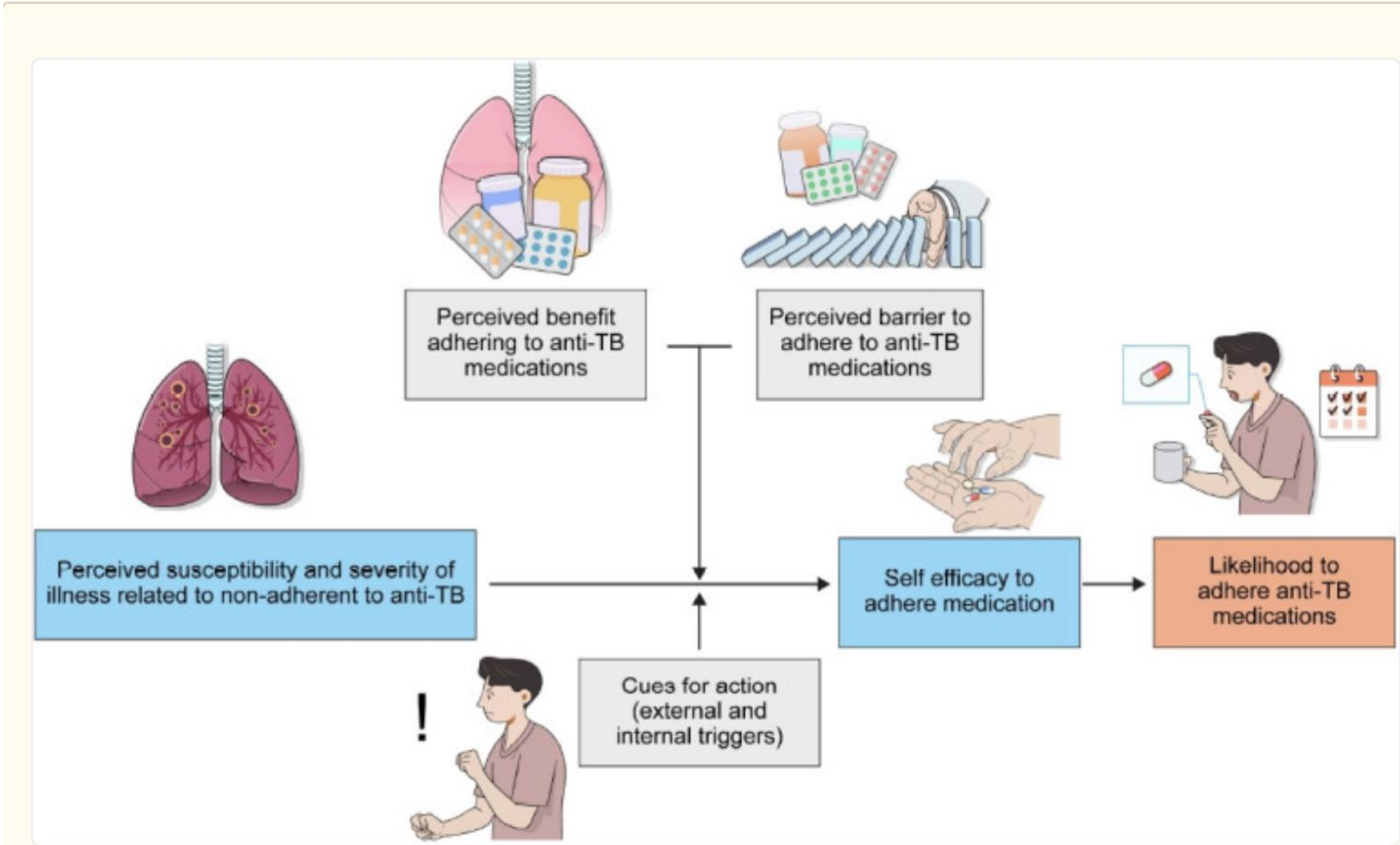
The main strategy to

Ensure TB patient adherence

Tolerability of prescribed regimen

DOT can be in person or eDOT (VDOT)

ALL patients with TB disease should participate in DOT


Perceived benefit adhering to anti-TB medications
Perceived barrier to adhere to anti-TB medications
Perceived susceptibility and severity of illness related to non-adherent to anti-TB
Self efficacy to adhere medication
Likelihood to adhere anti-TB medications
Cues for action (external and internal triggers)

Improving Tuberculosis Medication Adherence: The potential for Integrating Technology and the Health Belief Model

Literature Review using Pub Med and Google Scholar

Findings:

There is no standard definition of TB medication adherence

The World Health Organization (WHO) defines adherence as:

"The extent to which the patient follow medical instructions. Non-adherence to medication is a significant barrier to treatment of chronic diseases, including TB

Globally non-adherence to medication

- 50 % in developed countries
- Higher in developing countries

Factors Influencing Medication Adherence

Factors:

- Patient Related
- Condition Related
- Therapy Related
- Health System Related
- Socioeconomic

Could nurse case managers or other healthcare providers influence these factors?

Patient Related Factors

Not Modifiable

- Male
- Lower age: <35
- Divorced
- Widowed

Modifiable

- Forgetfulness
- Lack of Knowledge/Understanding
- Psychological distress/Fear
- Stigma
- Social Acceptance of Traditional Medicine
- Lack of Family Support

Disease Factors

Condition

- Pill Burden
- Depression
- Co-morbidities

Therapy

- Side effects/Adverse effects
- Feeling better
  - Non-adherence **increases** during the continuation phase

Systemic Factors

Health Care System

- Poor provider/patient relationship
- Inflexible schedule for DOT
- Health care workforce attitude
- Training of health care workers
- Overburdened Health System

Socioeconomic

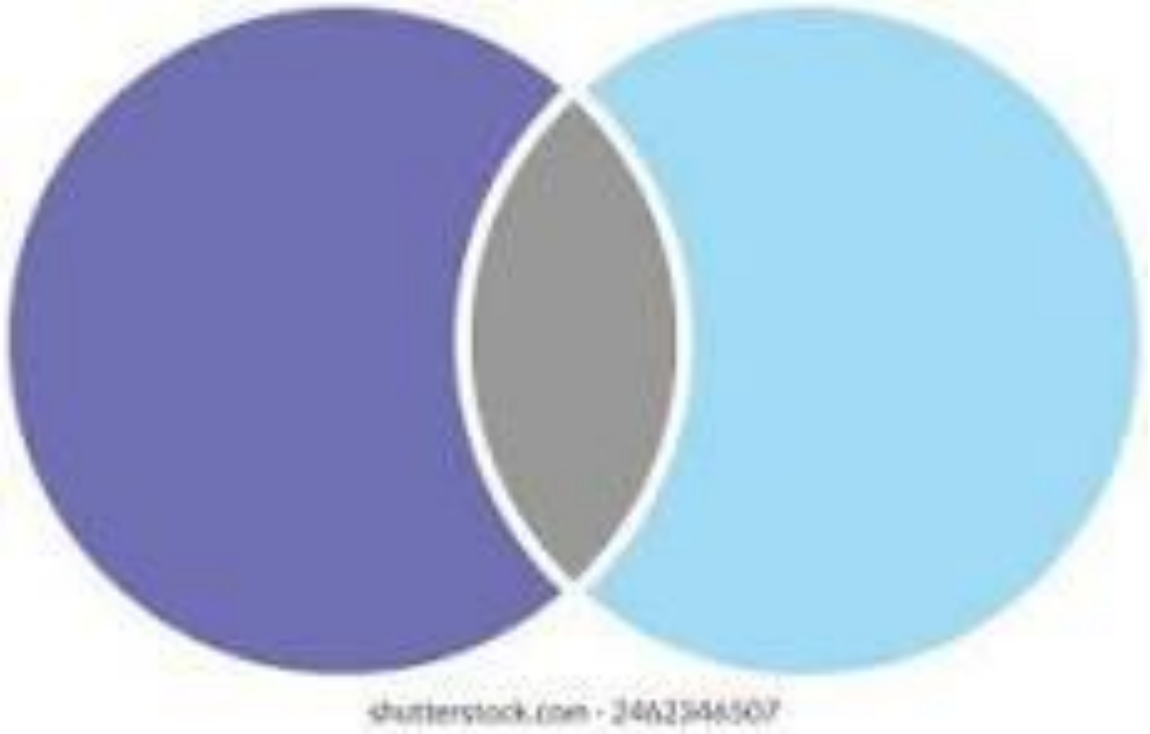
- Lack of access to care
- Situational increased risk of exposure
- Lack of financial support
- Poor or No transportation

Human Behavior Model

- Appropriate Perception of Self Vulnerability
- Perceived Seriousness of Non-adherence
- Self-Confidence to Adhere
- Self-Belief in the Benefits of Medication
- Self-Confidence to Adhere

Can nurse case managers/healthcare workers help patients with the behaviors for successful completion of therapy?

Adherence and Completion of Therapy



Adherence and completion of therapy intersect

Let's Review- For a Standard RIPE Regimen

To figure out the number of doses a patient needs to complete therapy:

- Number of days of the week the patient is expected to take **observed** doses X the total number of weeks the patient is prescribed treatment.
  - In person DOT by Health Department
    - Expected observed doses = 5 days a week
  - VDOT or In person DOT by a facility (hospital/correctional facilities)
    - Expected observed doses = 7 days a week

Some More Review

How many weeks is a person expected to complete if they are to receive 6 months of therapy?

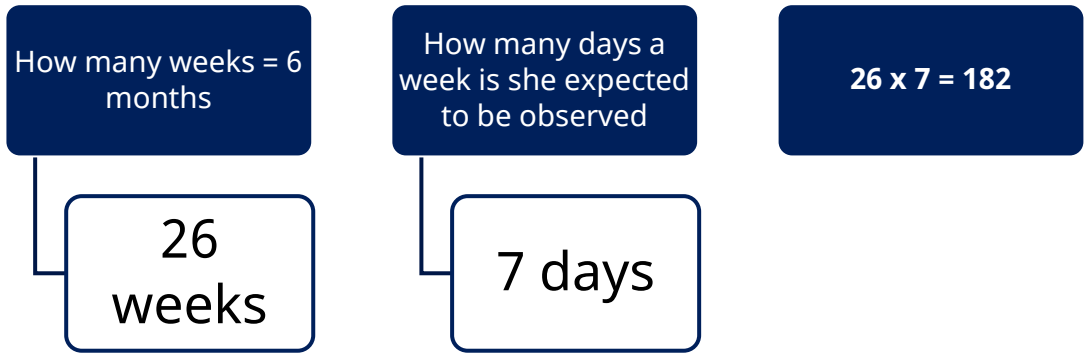
26 weeks

How many weeks is a person expected to complete if they are to receive 9 months of therapy?

39 weeks

Let's Compare

Mary is expected to complete 6 months of therapy on VDOT



Mary is expected to complete 6 months of therapy via in-person DOT

- Duration in weeks for 6 months:
  - 26 weeks
- Number of days per week she is anticipated to be observed:
  - 5 days

Calculating gives 26 x 5 = 130.

WAIT… Why are we making those on DOT Finish more Doses?

•Patients receiving in-person Directly Observed Therapy (DOT) are expected to take their own medications on weekends. While these doses cannot be counted in completion totals since they are not observed, they do aid in the overall cure.

Therefore, it is essential to

•Regularly remind patients that completing all doses is vital for curing the disease. Do not tell them they only need to complete 130 doses or that their weekend doses “do not count”. All doses ingested whether observed or self-administered **count towards CURE** .

•The expectation is that **all** patients complete a total of 182 doses, including the self-administered weekend doses.

Let's Break It Down Further - Initial Phase of Therapy

TB treatment is divided into two phases: the initial phase and the continuation phase

Initial Phase:

- The initial phase of treatment consistently lasts for 8 weeks.
- The patient must complete the required number of doses within a 12-week timeframe.
- Therapy interruptions must not exceed 14 consecutive days or patients gets a "do over".
  - Any doses taken prior to the interruption cannot be counted towards completion.
- The patient **cannot** progress to the continuation phase until susceptibility results are received.
  - INH mono-resistance in US 9-11 %
  - Rifampin mono-resistance in US approximately 1%
    - If Rifampin resistance **GET A CONSULT**. **Patient considered to have at least MDR TB.**
- During initial phase, the patient receives INH, Rifampin, EMB, PZA, and B6.
- If PZA not included initially the patient MUST complete 9 months of therapy.

And -
Continuation Phase of Therapy

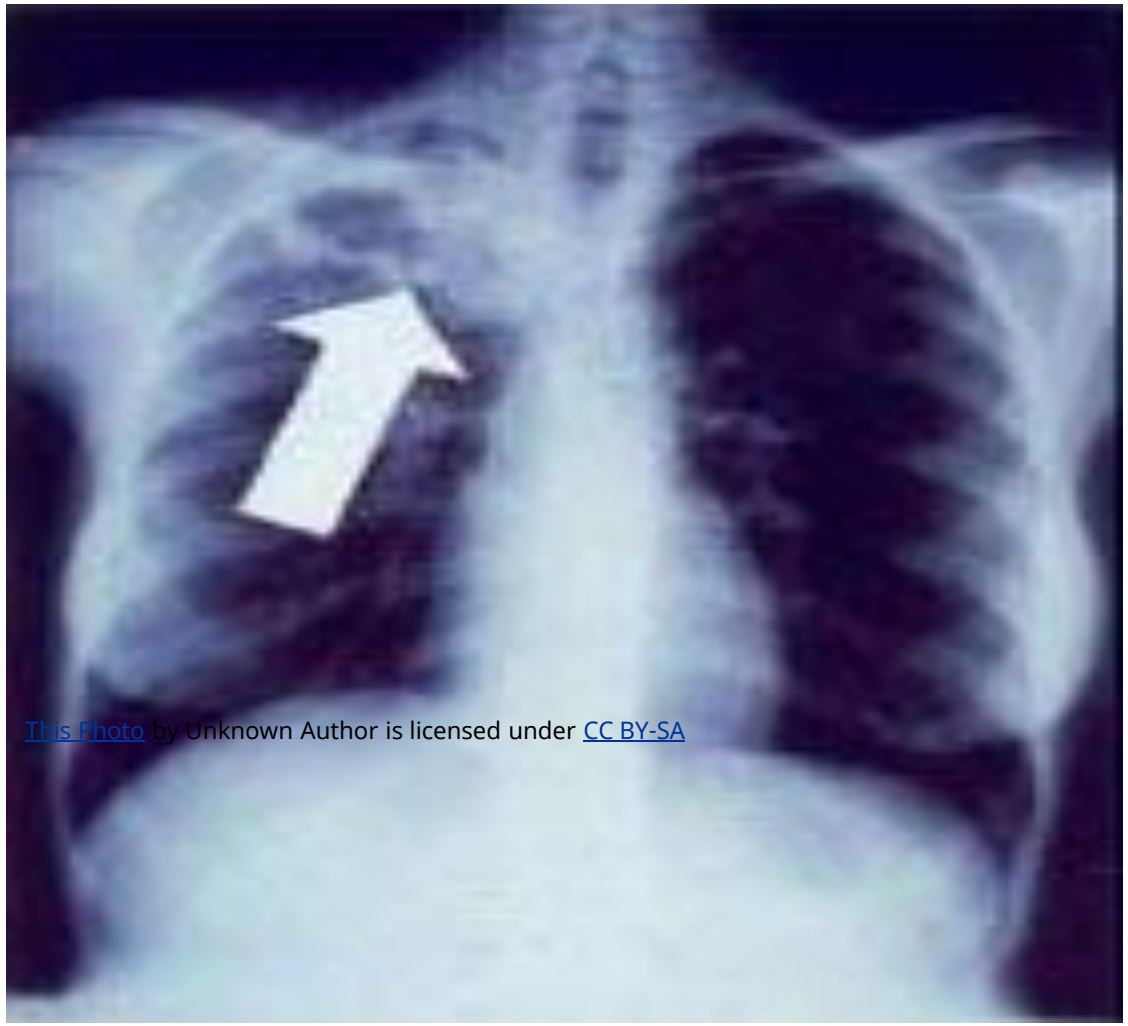
- The length of the continuation phase varies depending on the total length of therapy
  - For 6 months or 26 weeks – 18 weeks
  - For 9 months or 39 weeks – 31 weeks
- **DO NOT** advance to continuation phase if you do not have susceptibilities
  - PZA may be dropped after two months if:
    - Negative Smear/Negative Culture
    - Clinical case of TB.
  - INH mono-resistance in US 9-11% of cases
  - Rifampin mono-resistance in US 1% of cases
    - If Rifampin resistance patient is to be treated as if they have **MDR (OBTAIN A CONSULT)**
- Usually consists of INH, Rifampin and Vitamin B6
- There cannot be an **interruption longer than 3 months** or patient **must start all over again**
  - Sputum collection, medical evaluation and CXR

Case Study

- Maria is a 36-year-old female born in Mexico who was reported by the local correctional facility after she was evaluated at the local hospital for signs and symptoms of TB.
- Maria reported to the correctional facility staff that she coughed up blood the night before and that she was waking up drenched in sweat and that she had a cough that has lasted for several weeks. She also reported that she has lost her appetite and really does not feel like eating.
- Maria denies any contributing PMHX
- She denies any IV drug use or smoking
- She has been unhoused
- Currently lives with a friend and his children- no one at the house was sick.

Maria's Hospital Stay and Bacteriology Results

- Maria was admitted for TB workup after the cavitary findings on the CXR.
- Sputum was collected on 2/14, 2/15 and 2/16 and a NAAT was sent on the sputum collected on 2/14: Findings below
  - >10 AFB seen on smear
  - NAAT
  - MTB detected
  - Rifampin resistance not detected (Copy de-identified bacteriology and NAAT here)
- Maria's weight on admission was 62 kg
- HIV was non-reactive
- A1C =8.9



CBC

Status: **Final result** Visible to patient: **Yes (not seen)**

0 Result Notes

Component Ref Range & Units	[redacted]
WBC 4.19 - 9.43 x 10*3/uL	5.48
RBC 3.93 - 4.90 x 10*6/uL	4.96 ^
HGB 10.8 - 13.3 g/dL	11.1
HCT 33.4 - 40.4 %	36.6
MCV 76.9 - 90.6 fL	73.8 v
MCH 24.8 - 30.2 pg	22.4 v
MCHC 31.5 - 34.2 g/dL	30.3 v
RDWCV 12.3 - 14.6 %	15.0 ^
RDWSD 37.1 - 44.2 fL	39.3
Platelet 194 - 345 x 10*3/uL	461 ^
MPV 9.6 - 11.7 fL	8.7 v

Liver Panel

Status: **Final result** Visible to patient: **Yes (not seen)**

0 Result Notes

Component Ref Range & Units	[redacted]
Alkaline Phosphatase 45 - 116 U/L	90
ALT 10 - 35 U/L	14
AST 5 - 30 U/L	29
Bilirubin Conjugated 0.0 - 0.3 MG/DL	0.0
Bilirubin Unconjugated 0.0 - 1.0 MG/DL	0.2
GGT 11 - 28 U/L	11
Albumin 3.5 - 5.2 G/DL	3.7

Maria's TB Regimen While in Hospital

- Maria was started on RIPE on February 15, 2025, with the following: Maria's weight is **62kg**
- INH 300 mg po daily
- Rifampin 600 mg po daily
- EMB 800 mg po daily
- PZA 1000 mg po daily
- Vitamin B6 50 mg po daily

Are these doses correct for Maria?

Dosing for Adults

TABLE 2. Doses of First-Line Anti-Tuberculosis Drugs for ADULTS

Daily Dosing				
Weight (kg) *Based on estimated lean body weight* ¥	**Isoniazid*** **(INH)** Dose, mg (mg/kg)	**Rifampin**** **(RIF)** Dose, mg (mg/kg)	**Pyrazinamide (PZA)** Dose, mg (mg/kg)	**Ethambutol (EMB)** Dose, mg (mg/kg)
40-55 kg	300† mg (5mg/kg)	600 mg (10-20mg/kg‡)	1,000 mg (18.2–25.0)	800 mg (14.5–20.0)
56-75 kg			1,500 mg (20.0–26.8)	1,200 mg (16.0–21.4)
76-90 kg			2,000† mg (22.2–26.3)	1,600† mg (17.8–21.1)
Thrice (3x) Weekly Dosing – *Consultation Required*				
Weight (kg) *Based on estimated lean body weight* ¥	**Isoniazid*** **(INH)** Dose, mg (mg/kg)	**Rifampin**** **(RIF)** Dose, mg (mg/kg)	**Pyrazinamide (PZA)** Dose, mg (mg/kg)	**Ethambutol (EMB)** Dose, mg (mg/kg)
40-55 kg	900† mg (15mg/kg)	600 mg (10-20mg/kg)	1,500 mg (27.3–37.5)	1,200 mg (21.8–30.0)
56-75 kg			2,500 mg (33.3–44.6)	2,000 mg (26.7–35.7)
76-90 kg			3,000† mg (33.3–39.5)	2,400† mg (26.7–31.6)
Forms available	**Scored tablets:** 100 mg, 300 mg and Syrup (50mg/5ml)	**Capsule:** 150 mg, 300 mg *Contact DSHS for compounding*	**Scored tablets:** 500 mg	**Tablets:** 100 mg, 400 mg

Let's Get Our Calendar's Out.

Maria was in the hospital from 2/15/25 to 2/18/25. She received dosing below the recommended amounts on 2/15/25

Maria received all doses of TB meds as per below on 2/16/25 and 2/17/25

INH 300 mg po q am

Rifampin 300 mg po am and pm

EMB 600 mg q and 600 mg q pm

PZA 1000 mg po am and 500 mg q pm

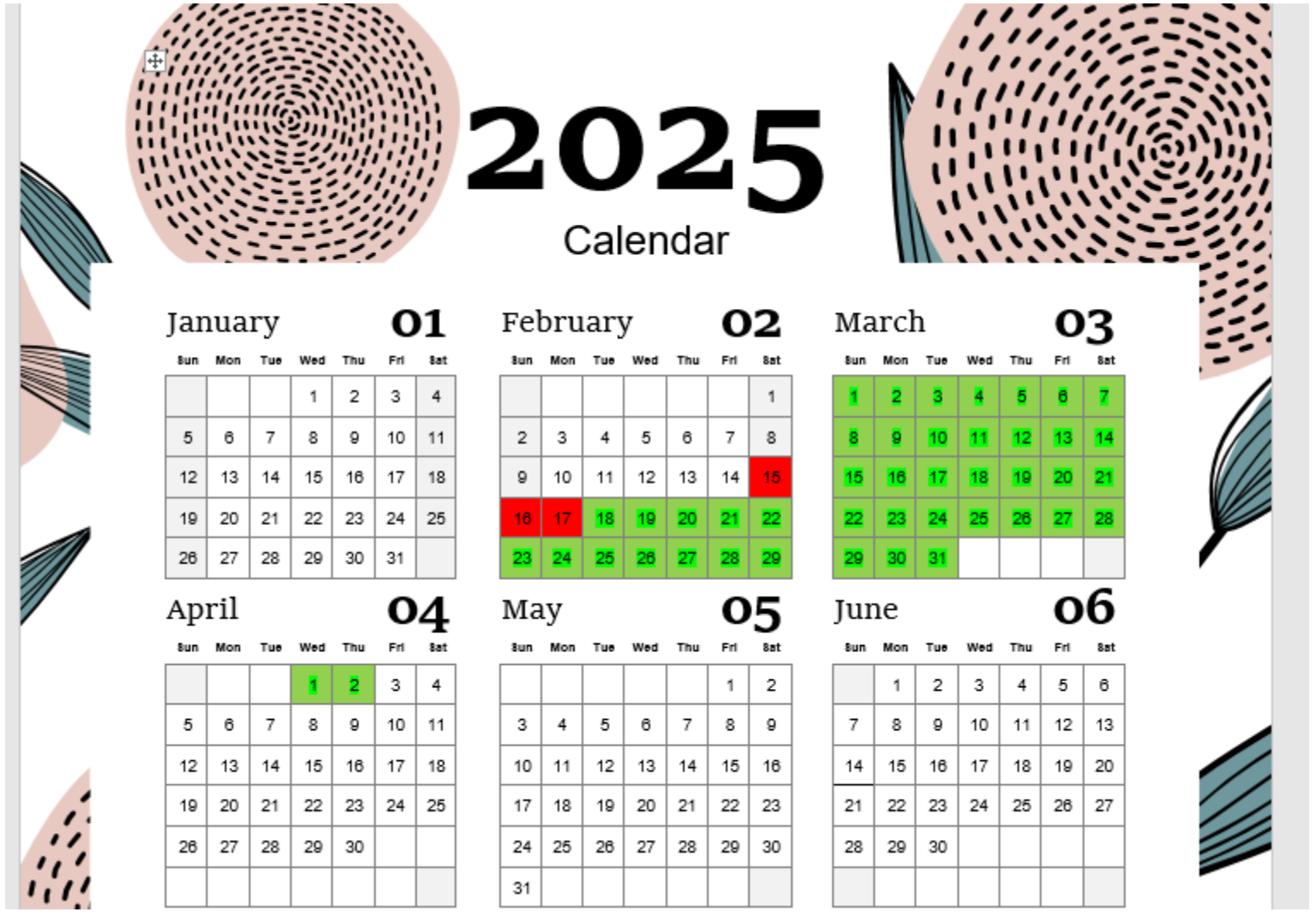
Would you count these doses? Why or Why not?

The preferred frequency is once daily for both the intensive and continuation phases

Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis

Let's Continue

- Maria stayed in the hospital from 2/15/25 to 2/22/25 but appropriate dosing was not started until 2/18/25
- So how many doses did Maria complete in the hospital?
- 4 doses
- Maria returned to the correctional facility and continued to receive her RIPE appropriately from 2/23/25 to 4/3/25
- The current plan is to treat Maria for 9 months she has a cavitary CXR. She is newly diagnosed with T2DM with an A1C of 8.9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So how much treatment has Maria received so far?

- How many doses?
  - 46 doses
- How many weeks?
  - 6.5 weeks
- Has she been adherent with her regimen?
  - Yes

LET THE GAME BEGIN, CAN WE BRING MARIA ACROSS HOME PLATE?

Maria Is Released

- Maria is released on April 3rd but you are **not** notified
- The address you have for Maria is **not** correct
- The phone is working but when you call, the man who answers the phone tells you Maria is not available.
- You and your team continue to search Maria and find her on April 28th when she finally answers the phone, and you can get an accurate address.

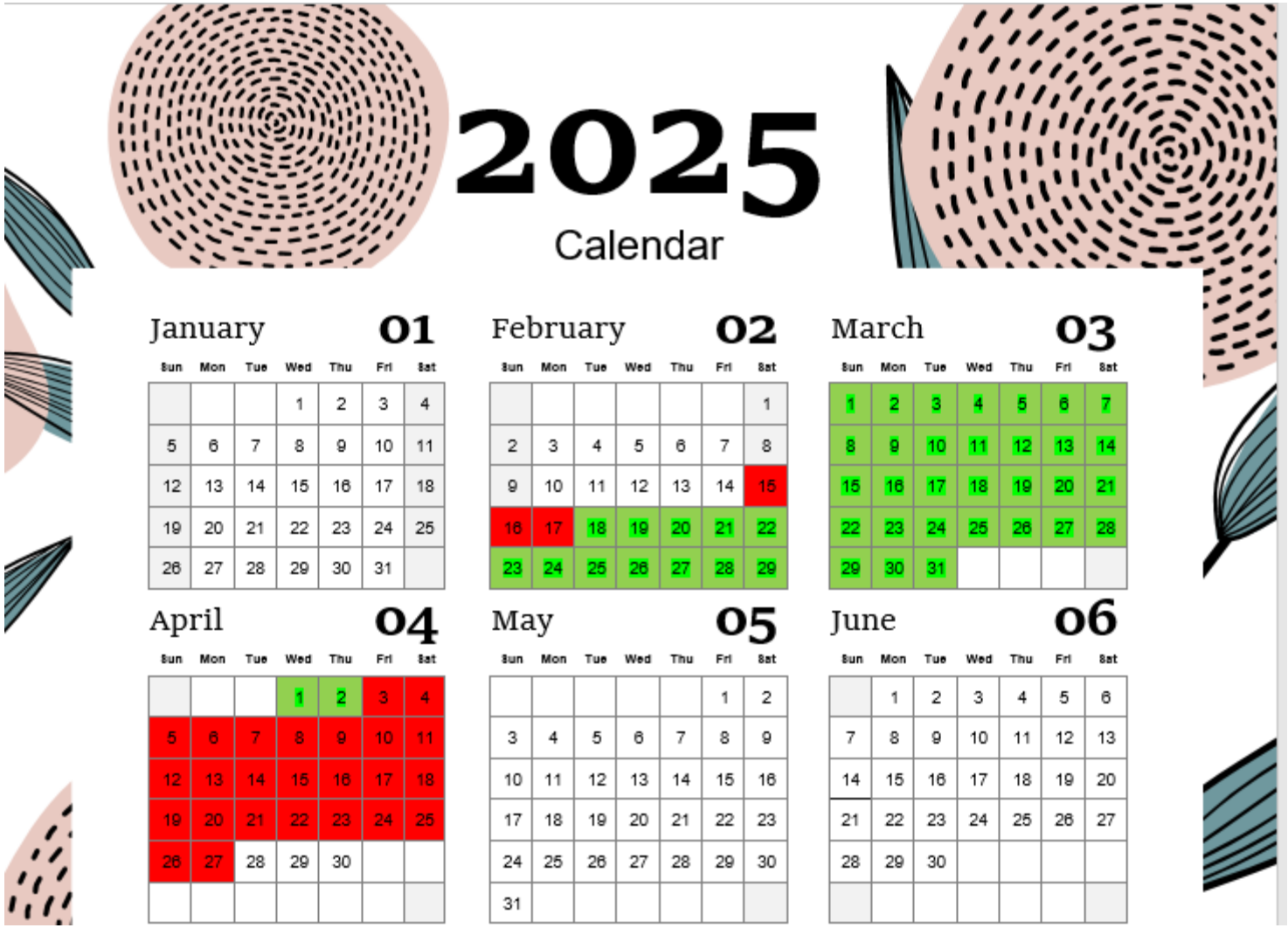
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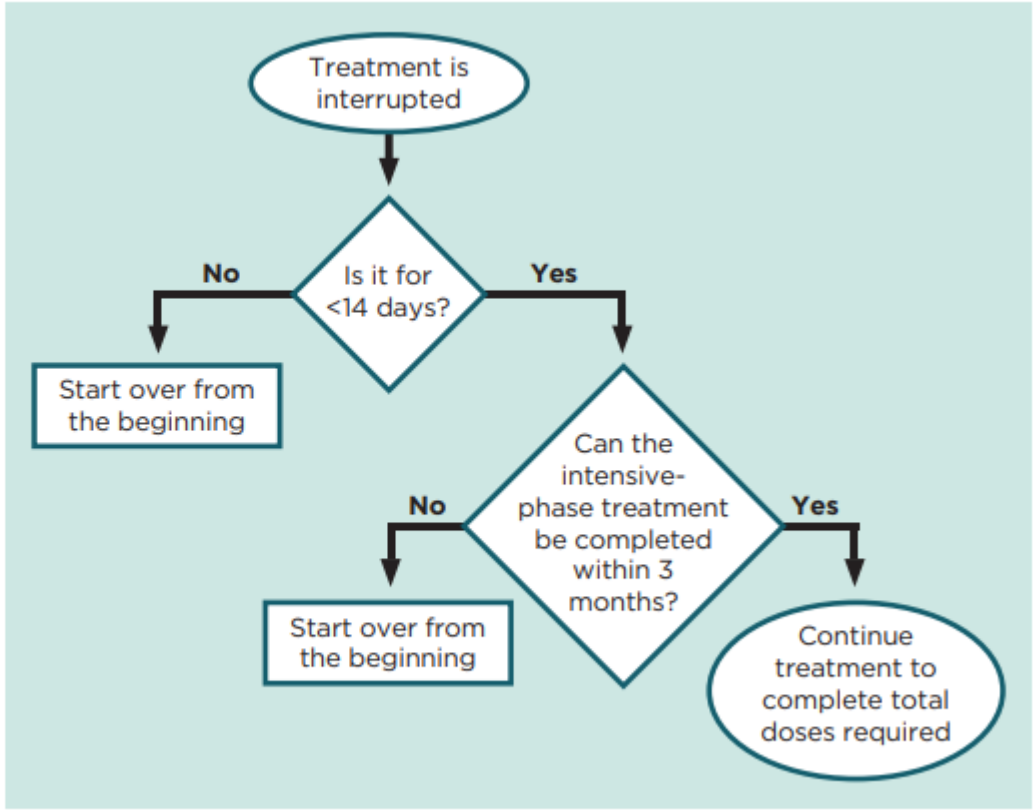
Figure 5.2
Algorithm for Management of Intensive-Phase Treatment Interruptions



CORE CURRICULUM ON TUBERCULOSIS:
WHAT THE CLINICIAN SHOULD KNOW
SEVENTH EDITION 2021

Break in Treatment

- How long was the break in treatment during the initial phase of therapy?
- 25
- More or less than 14 consecutive days?
- More
- Does any of the treatment before you were unable to find her count towards completion of therapy?
- **No**

Home Visit

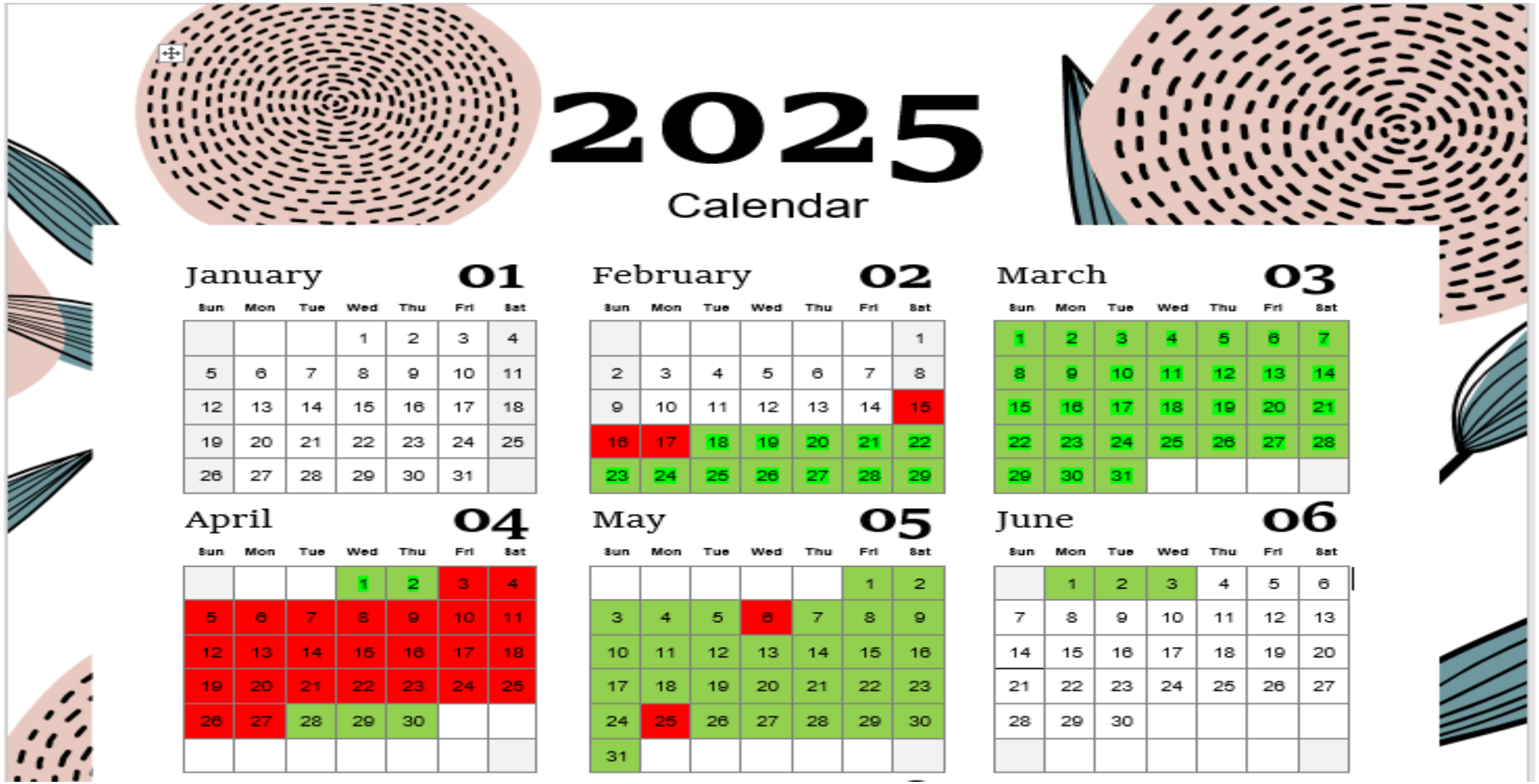
- You make a home visit to Maria, and she tells you that she had not wanted to take her medicines because she went to her "curandera" who gave her some herbal medication that she said would cure her TB.
- **What would you do???**

- You also notice that there are three children in the home ages 3 months, 2 years and 7 years of age…. (**Keep these ages in the back of your mind for now**)

Home Visit

- You have a long discussion with Maria, and you ask to see what the herbal medicines are. It is a mixture of basil, chamomile and rosemary. You encourage to keep taking the tea the curandera has provided her but also are able to educate her on the need for her to take her TB meds.
- The patient verbalizes understanding and agrees to take the DOT

What question could you ask to ensure patients tell you about all the pills/supplements they take? Why is it important to know?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Reviewing Adherence

Based on the calendar, what is Maria's start date of treatment?

4/28/25

How many weeks of therapy has she completed?

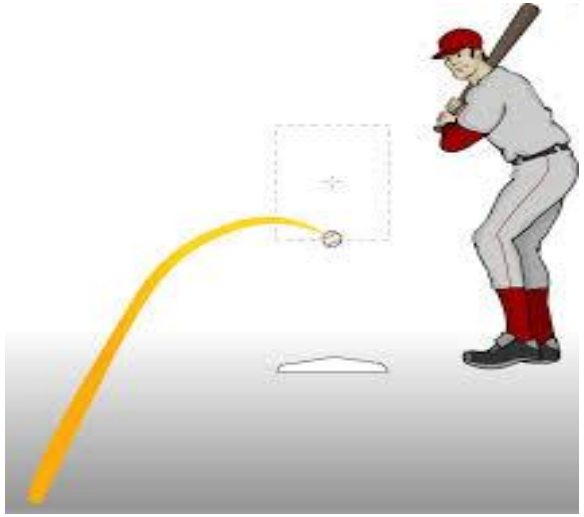
35 doses 35/7 = 5 weeks

As you start looking ahead since she is almost done with the initial phase of therapy what are some things that you should be reviewing before you advance?

- Susceptibilities
- Repeat CXR?
- Symptom Improvement?
- Adverse Drug effects?

There is Always a Curve Ball....
Are you ready for it?

- Maria has completed 5 weeks of DOT with RIPE without any complaints.
- On June 4th Maria contacts you complaining of the following:
- Nausea
- Vomiting
- Rash all over body
- Fever of 101
- Headache
- N/V



NOW WHAT???

Medical Evaluation – What Do You Do?

You make an emergent appointment for Maria Your clinic provider asks to hold meds, draws a CBC and Liver enzymes with the following results:

WBC 11.28

RBC 4.70

Hgb 13.0

HCT 38.2

Platelets 150

ALT 191

AST 93

Consult with Heartland

Consult from Heartland:

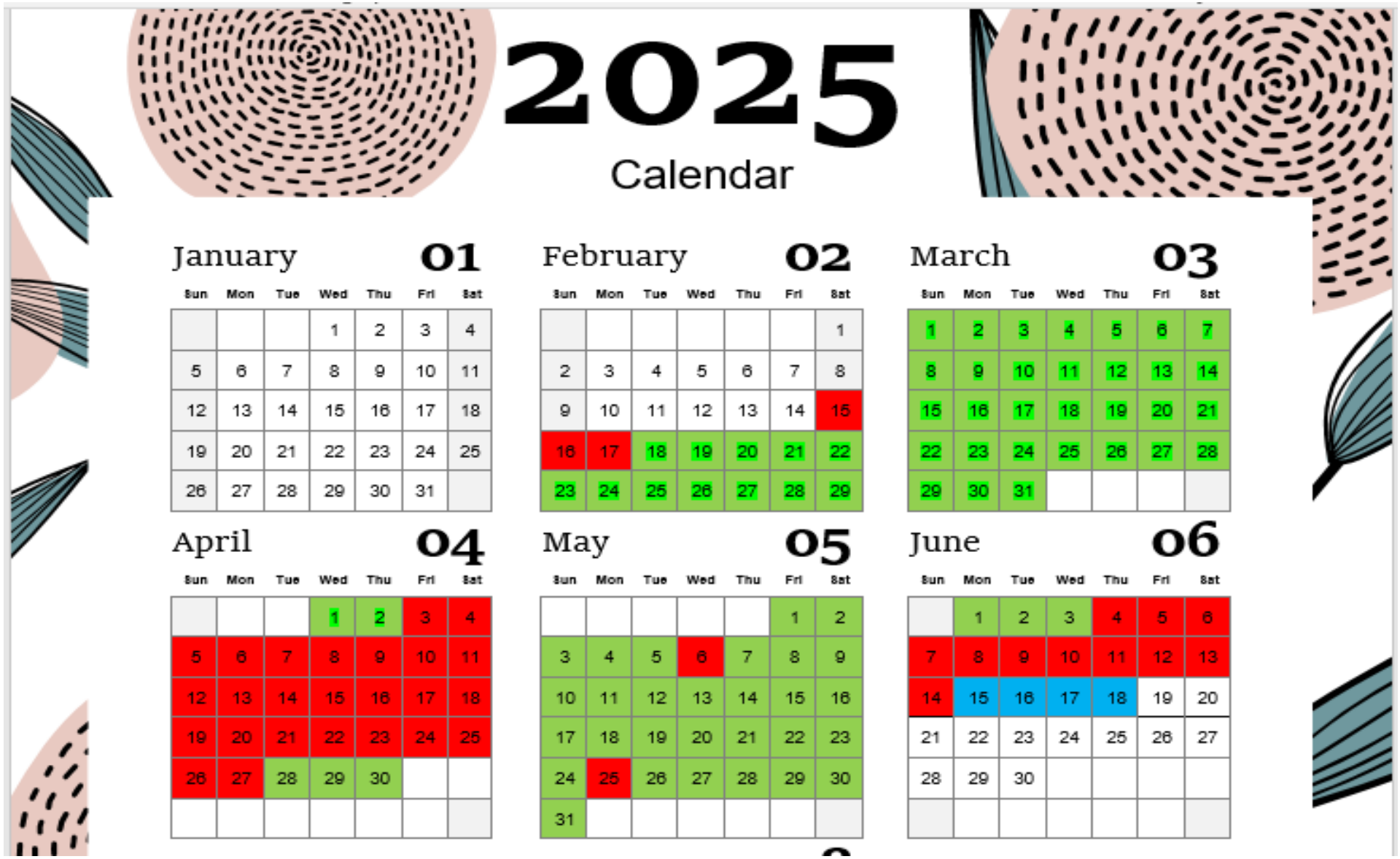
" Let the liver cool down" Levels back down to less than 2x ULN

Start a drug challenge as follows:

- Rifampin 600 mg and EMB 1200 mg daily x 7 days if no problems,
- Add INH 300 mg daily x 7 days if no problems
- Add PZA 1500 x 7 days, if no problem continue regimen to complete the initial phase of therapy.

What would you communicate with Maria?

How would you encourage her to continue treatment?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Do any of the Doses Count Prior to the Drug Challenge Count Towards Completion?

- Her treatment start date is 4/28/25
- How long is the latest break in treatment?
- 11 days so far
- Do the doses during the challenge count when you are introducing one drug at a time?
  - Only regimens that **are considered therapeutic** are counted towards completion

Here Comes the FASTBALL

The meds are on hold until the LFT's are below 2 x ULN and the platelets have recovered to 195

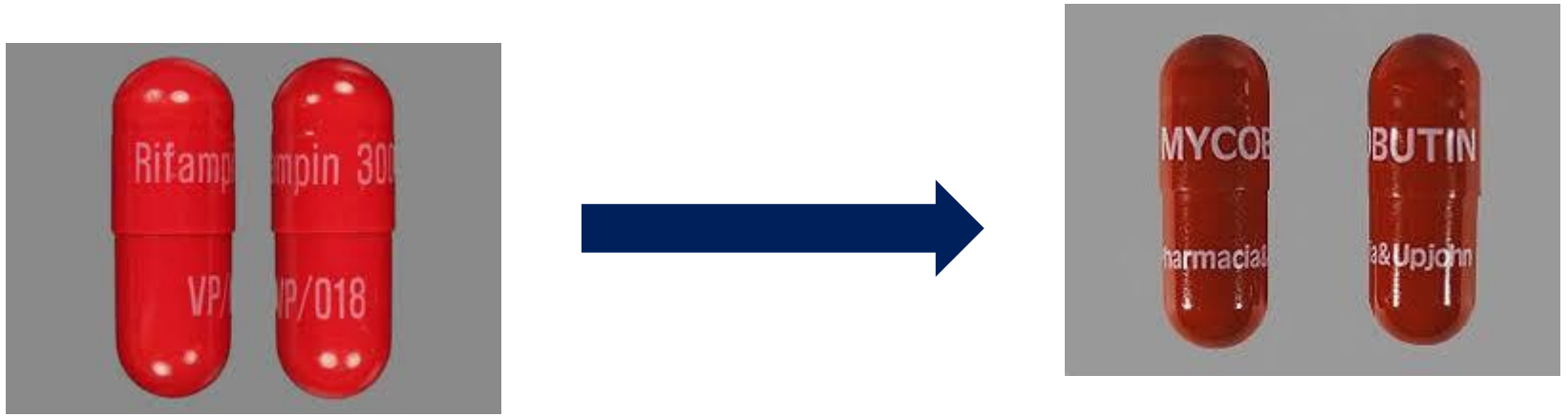
You start the drug challenge with Rifampin and EMB on 6/15/25.

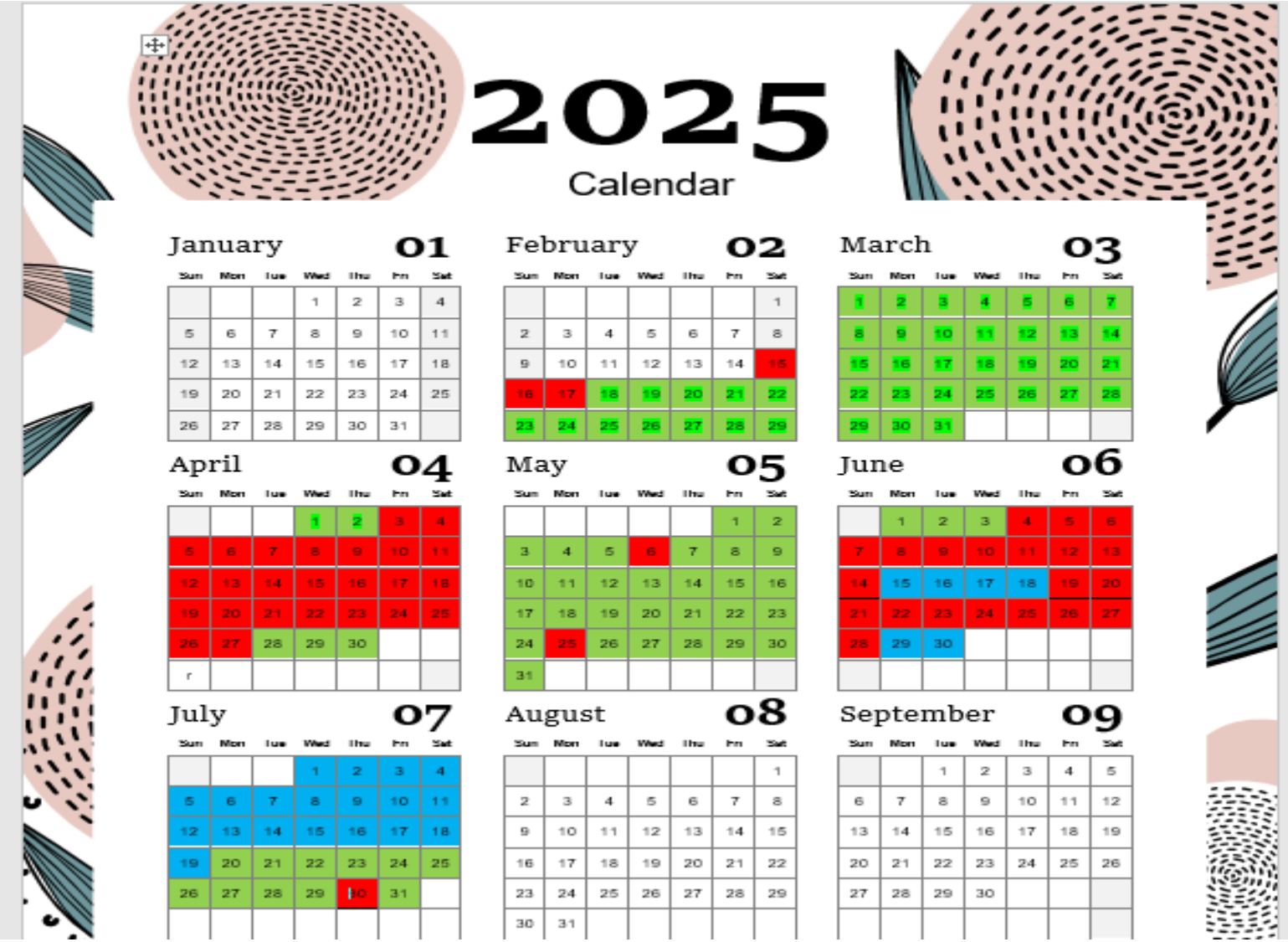
On the fourth day of the challenge, Maria calls with the following complaints:

- Headache
- Rash
- Fever
- Malaise

Because You Don't want Dr. Armitige or Dr. Seaworth To Miss you....

- You get a second consult.
- This time the recommendation is to re-start the challenge but to substitute Rifabutin for Rifampin





Rifabutin and EMB from 6/29 to 7/5

INH, Rifabutin and EMB from 7/6 to 7/12

INH, Rifabutin, EMB and PZA from 7/12 to 7/19

Do you count the doses of a drug challenge?

If so, when would you start counting doses?

Does the patient need to start treatment over?

How many doses of therapy has Maria completed?

I have been on treatment since February. I don't want MORE...

- Maria does not want to continue therapy because she has been on treatment for 8 months.
- How would you encourage Maria to continue her therapy?
- You have received the susceptibilities, and the specimen is found to be PAN sensitive
- Maria took almost 3 months to convert her culture.
- Maria's CXR in April showed minimal improvement
- Maria's CXR in June showed improvement as compared to the April CXR but the cavitary lesion can still be seen
- Today's CXR shows complete resolution of the cavitary lesion.
- Decision is made to treat for 9 months and to repeat the CXR before Maria completes therapy

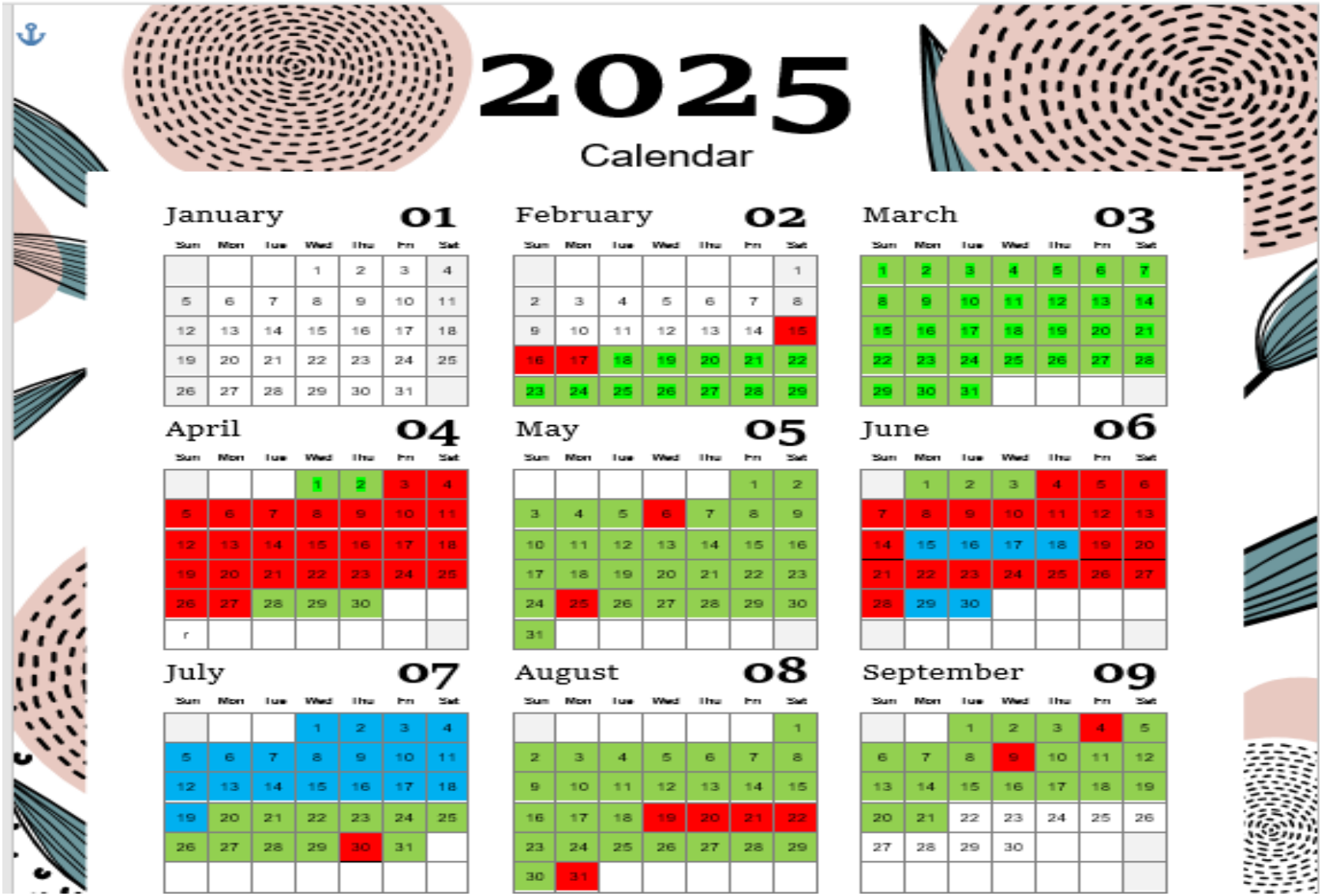
Can we advance to the Continuation Phase, yet???

Things we know:

The organism is PAN-susceptible

Maria's X-ray and symptoms are improving.

We have found a regimen that Maria can tolerate, and we are supporting her cultural beliefs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12 13 14 15 16 17 18
19 20 21 22 23 24 25
26 27 28 29 30 31
August 08
Sun Mon Tue Wed Thu Fri Sat
1
2 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
September 09
Sun Mon Tue Wed Thu Fri Sat
1 2 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

Let's do some math

How many doses has Maria taken since starting her treatment?

56 doses

In how many weeks did she finish the initial phase of therapy?

56/7=8 (Doses/# of expected observed doses per week = weeks)

How many weeks and how many doses of therapy would Maria have finished if she had only received 48 doses?

42/7= 6 Maria has finished 6 weeks of therapy

8-6= 2 Maria has two weeks left to finish her initial phase of therapy

2x7 = 14 Maria has 14 doses left to complete the initial phase of therapy

If Maria misses 5 doses, will she complete the initial phase of therapy in the 12 weeks that are required per our calendar?

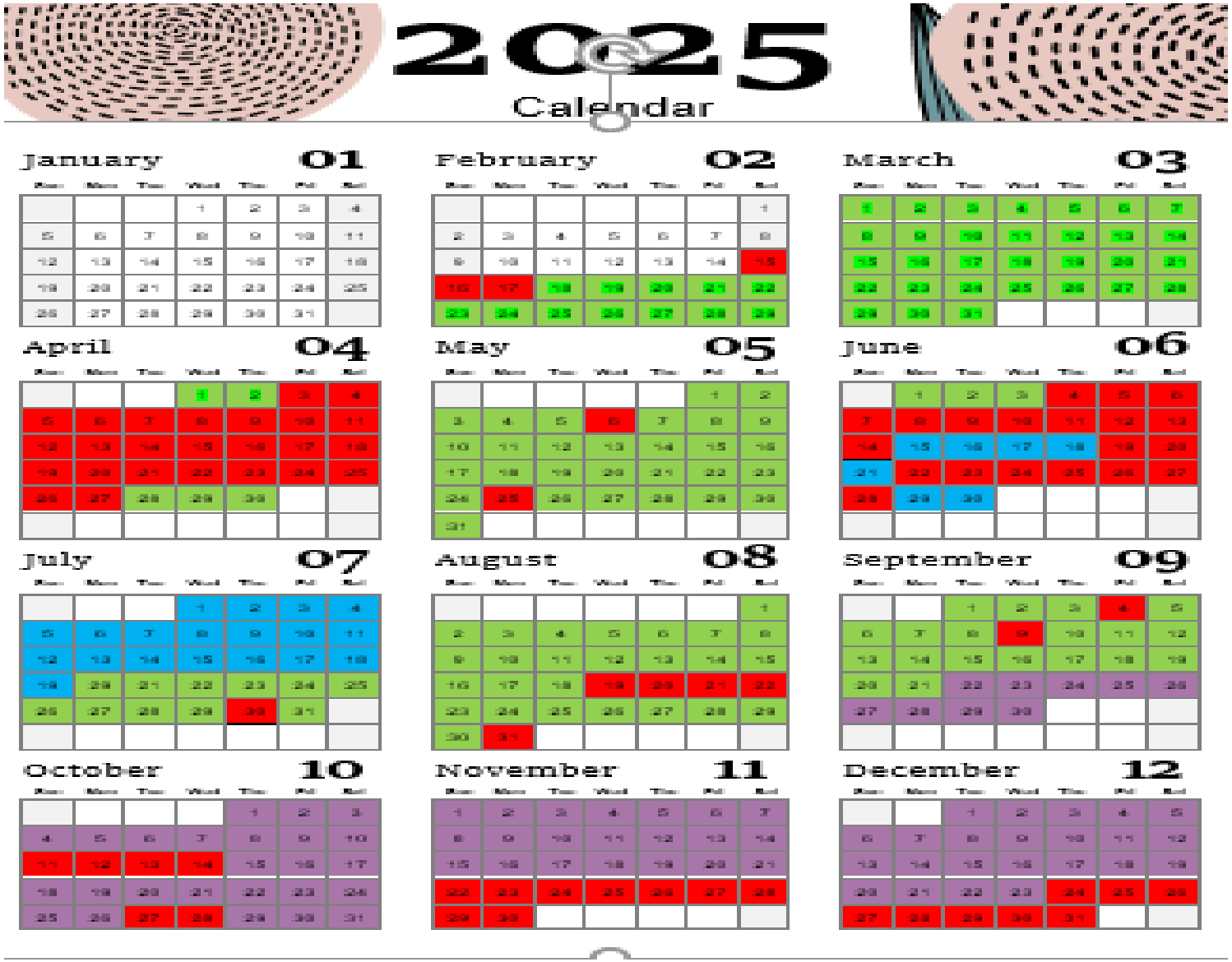
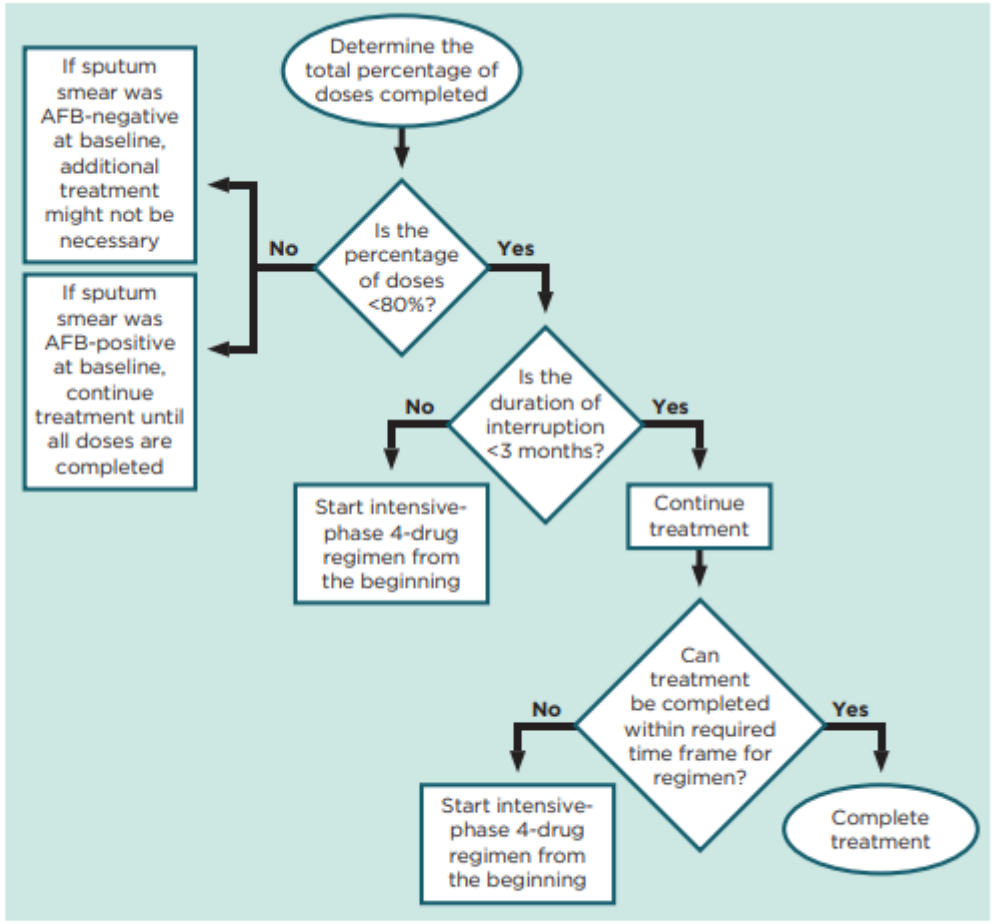

2025
Calendar
January 01
February 02
March 03
April 04
May 05
June 06
July 07
August 08
September 09
October 10
November 11
December 12

Figure 5.3
Algorithm for Management of Continuation Phase Treatment Interruptions



Abbreviation: AFB, acid-fast bacilli.

Am I done YET???

- The patient completed
- 56 doses /7 days a week of RIPE = 8 weeks
- 78 doses/7 days a week of IR= 11 weeks

Total weeks completed =18

How many weeks does the patient have left?

39 weeks (9 months) -18 weeks of completed doses = 21 more weeks of therapy

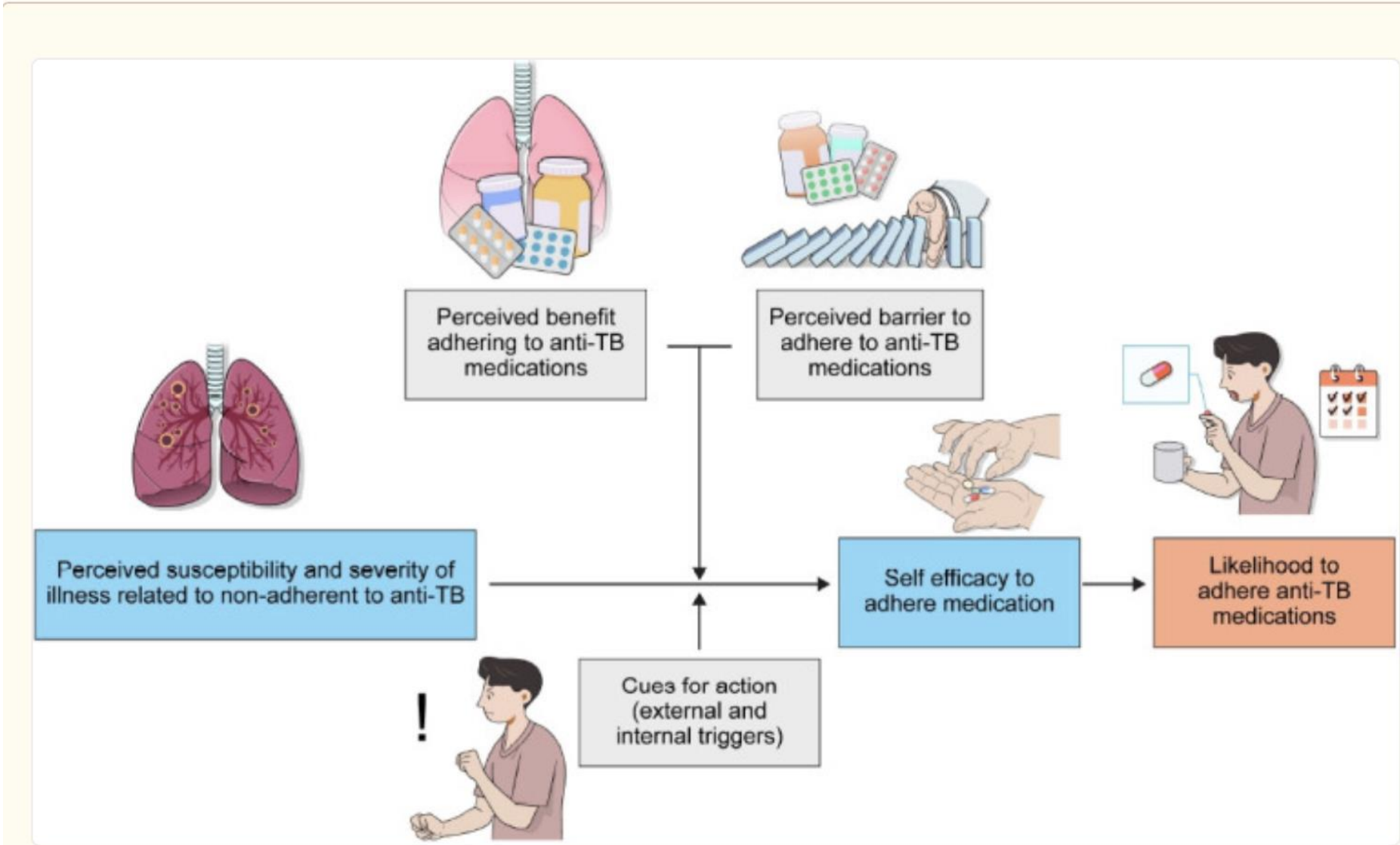
How many more doses does Maria have left?

21x7= 147 doses

Remember the Kids???

- Which children should be your priority for evaluation? Why?
- Do any of the children require window prophylaxis?
- Why would a pediatric TB provider need to know and keep bugging you about the adult susceptibilities
- What information would be important for you to share with the pediatric provider?

Your homework will be to familiarize yourself with the dosing of TB meds for kids !


Perceived benefit adhering to anti-TB medications
Perceived barrier to adhere to anti-TB medications
Perceived susceptibility and severity of illness related to non-adherent to anti-TB
Self efficacy to adhere medication
Likelihood to adhere anti-TB medications
Cues for action (external and internal triggers)

Remember the factor?

There is a lot that you as nurse case manager can do to help the patients modify their behavior.

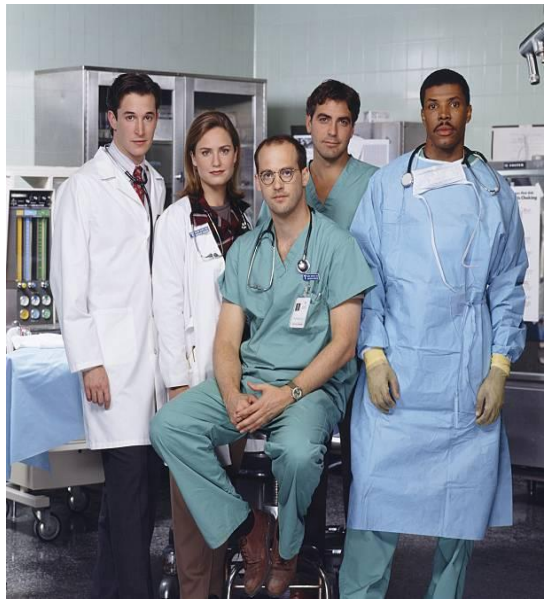
The Four Pillars of Nursing:

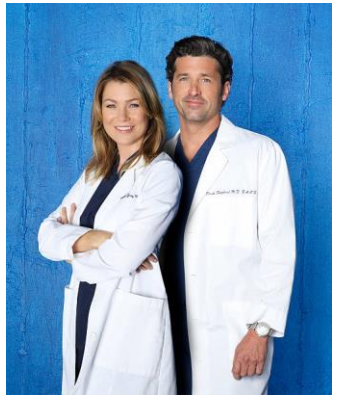
- **Clinical Practice**
- **Education**
- Research
- Leadership

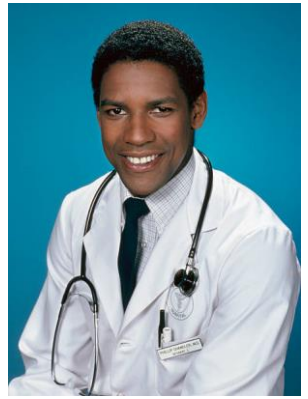
You are your patient's voice!

Patient Advocacy is a *core* and *essential* function of nursing.

It is fundamental to ethical practice and patient-centered care

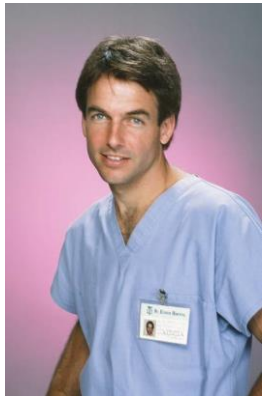






DOCTORS ARE ONLY

HUMAN



Thank you for all you do every day for those who may not have a voice!

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Questions and Contact Information

Contact Information: Barbarah.Martinez@bcm.edu or bxmart23@texaschildrens.org
Work cell: 346-257-1275
Office Number: 832-824-4324