TREATMENT ADHERENCE AND COMPLETION

LEARNING OBJECTIVES

Upon completion of this session, participants will be able to:

1. Provide strategies for dose counting
2. Provide strategies for management of treatment interruptions
3. Identify clinical assessment tools to ensure successful treatment completion

INDEX OF MATERIALS

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<th>PAGES</th>
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<tr>
<td>1. Treatment adherence and completion – slide outline</td>
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<tr>
<td>Presented by: Lana Kay Tyer, RN, MSN</td>
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SUPPLEMENTAL MATERIALS

**ADDITIONAL REFERENCES**


Treatment Adherence and Completion

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TB Nurse Consultant
WA State Department of Health

Objectives

• Practice strategies for dose counting
• Demonstrate strategies for management of treatment interruptions
• Integrate clinical assessment tools to ensure successful treatment completion
What is the responsibility of the case manager?

- Ensure the patient adheres to appropriate and adequate treatment
- Ensure patient receives essential medical evaluations, including routine clinical monitoring
- Ensure patient’s response to treatment is evaluated regularly
- Serve as a source of information to patient and family

Treatment Adherence

- Define adherence vs compliance
- How is it demonstrated by the patient?
- How is it assessed?
How is Treatment Completion Determined?

• Completion of treatment =
  - Positive response to treatment
  - Negative sputum/specimen culture
  - Improved chest radiograph
  - Diminished or resolved symptoms
  - Weight gain
• AND total number of doses taken in recommended timeframe

ATS Treatment of TB Guideline
ATS Treatment of TB Guideline

• Recommendation 2: We suggest using directly observed therapy (DOT) rather than self-administered therapy for routine treatment of patients with all forms of tuberculosis.
  • Challenges to DOT?

Which patients does your clinic have the ability to offer DOT (in-person or electronic)?

• MDR-TB patients
• Sputum smear positive TB disease patients
• Sputum smear negative pulmonary TB patients
• TB patients with pulmonary to and HIV
• Extra pulmonary TB disease patients
• Household contacts under 5 years old
• Household contacts with immunosuppressive conditions
• MDR TB contacts
• Others?
Treatment adherence and completion

TB Case Management and Contact Investigation Intensive

Appropriate Intervals

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Drug</th>
<th>Intensive Phase</th>
<th>Continuation Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>INH</td>
<td>7 d/wk for 56 doses (8 wk)</td>
<td>INH RIF 7 d/wk for 126 doses (18 wk), or 5 d/wk for 90 doses (18 wk)</td>
</tr>
<tr>
<td>2</td>
<td>INH</td>
<td>7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)</td>
<td>INH RIF 3 times weekly for 54 doses (18 wk)</td>
</tr>
<tr>
<td>3</td>
<td>INH</td>
<td>3 times weekly for 24 doses (8 wk)</td>
<td>INH RIF 3 times weekly for 54 doses (18 wk)</td>
</tr>
<tr>
<td>4</td>
<td>INH</td>
<td>7 d/wk for 14 doses then twice weekly for 12 doses</td>
<td>INH RIF Twice weekly for 36 doses (18 wk)</td>
</tr>
</tbody>
</table>

Target Timeframe

National Tuberculosis Indicators Project (NTIP)

- Treatment Initiation- For TB patients with positive acid-fast bacillus (AFB) sputum-smear results, increase the proportion who initiated treatment within 7 days of specimen collection. 97%
- Completion of Treatment- For patients with newly diagnosed TB disease for whom 12 months or less of treatment is indicated, increase the proportion who complete treatment within 12 months. 95%

What are reasons to extend treatment and are not included in this measure?


Curry International Tuberculosis Center
May 8-11, 2018
What is “Appropriate Treatment”? 

- Drug susceptibility testing
- Drug-o-gram

What is a Countable Dose? 

- DOT & VDOT
- Partial doses during re-challenging
- Interval doses
- Treatment completion counted in weeks
Treatment adherence and completion

TB Case Management and Contact Investigation Intensive

RVCT Manual: DOT

<table>
<thead>
<tr>
<th>Option (select one)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, totally self-administered</td>
<td>No doses of medication were given under direct supervision.</td>
</tr>
<tr>
<td>Yes, totally directly observed</td>
<td>Response applies if DOT was used for all doses for a patient who was taking medication 1–5 times a week. Response also applies if the patient was taking medication 7 times a week and DOT was used for at least 5 of those doses (i.e., patient self-administered the dose[s] during weekends and holidays).</td>
</tr>
<tr>
<td>Yes, both directly observed and self-administered</td>
<td>Response applies if the patient self-administered any dose while taking medication 1–5 times a week. Response does not apply if the patient was taking medication 7 times a week and DOT was used for at least 5 of those doses (i.e., patient self-administered the dose[s] during weekends and holidays). Response also applies if patient took several months of self-administered therapy and several months of DOT.</td>
</tr>
<tr>
<td>Unknown</td>
<td>It is not known whether any doses were given under direct supervision.</td>
</tr>
</tbody>
</table>

Total DOT vs. Both DOT and SA

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Total Direct Observed Therapy (DOT)</th>
<th>Both Direct Observed Therapy + Self-Administration (SA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5x per week</td>
<td>All treatment DOT</td>
<td>If any treatment is SA</td>
</tr>
<tr>
<td>7x per week</td>
<td>DOT at least 5x per week</td>
<td>SA more than 2x per week</td>
</tr>
</tbody>
</table>
RVCT Manual: Counting weeks

<table>
<thead>
<tr>
<th>Option (select one)</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of weeks of directly observed therapy (DOT)</td>
<td>Based on the total number of regimen-appropriate weeks and doses ingested under directly observed supervision (e.g., 026)</td>
<td>The total number of DOT weeks must be less than or equal to the time between Date Therapy Started (item 36) and Date Therapy Stopped (item 43).</td>
</tr>
</tbody>
</table>

Lapse in Treatment vs Treatment failure

• Timing of interruption:
  • Intensive phase
  • Continuation phase
• Earlier and longer the duration of interruption the more serious and greater need to restart treatment
• Dangerous interruptions: during intensive phase & 3 months or more
• Know when to consult with TB clinician for assessment of non-adherence
Why is the timing of the interruption so important?

- Intensive Phase - Highest bacillary load
  - Drug resistance
- Continuation Phase - lower bacillary burden
  - Effectiveness
  - Possibility of reoccurrence

Interruptions in Treatment

- Intensive phase vs continuation phase
- How extensive is the disease?
  - Cavitary?
  - Grade of smear positivity
  - Drug resistance
  - Do you have culture conversion?
- Assess for measures of response to treatment
  - Gaining weight
  - Resolving symptoms
  - Sputum conversion
  - Chest radiograph improvements
Initial Phase Treatment Interruptions

1. Treatment is interrupted
2. Is it for <14 days?
   - No: Start over from the beginning
   - Yes: Can the initial phase treatment be completed within 3 months?
     - No: Start over from the beginning
     - Yes: Continue treatment to complete total doses required

Continuation Phase Treatment Interruptions

1. Determine the total percentage of doses completed
2. Is the percentage of doses <80%?
   - No: Is the duration of interruption <3 months?
     - No: Start initial phase 4-drug regimen from the beginning
     - Yes: Continue treatment
   - Yes: Can treatment be completed within the required time frame for regimen?
     - No: Start initial phase 4-drug regimen from the beginning
     - Yes: Complete treatment
Returning a patient to treatment

• Collect sputum cultures for repeat drug susceptibility
• Obtain new chest radiograph
• Duration of interruption was more or equal to 3 months
  • Continue to complete a full course
  • Positive culture - restart treatment regimen while waiting for DST
  • Negative culture - continue therapy to complete regimen within 9 months of original start date
• Duration of interruption was less than 3 months
  • Positive culture - Continue with 4 drug while waiting for DST
  • Negative sputum cultures - consider stopping if patient has received a total of 9 months of therapy.

Multi-drug Resistant TB Interruptions

• Once DST reveals resistance regimen is modified
  • What is a countable dose?
• NTNC Manual says if culture positive after a treatment interruption start multidrug regimen while waiting for DST with 2 new agents - fluoroquinolone and injectable.
In all cases...

• Consult with an expert to manage treatment interruptions-
  • Infectious disease provider
  • TB clinical team
  • State TB program
  • Curry Warm line (ADD NUMBER)

Medication Counting Exercises

Tips:
• 6 months standard treatment is 26 weeks
• Keep a tally of DOT, SA and missed doses
• IDEA: use a calendar for complex cases or all cases
• Must extend treatment to make up missed doses to equal total dose count requirements
References


• U.S. Department of Health and Human Services Centers for Disease Control and Prevention: Tuberculosis Core Curriculum, Chapter 6: Treatment of TB Disease.

**TB Elimination**

**Treatment of Latent Tuberculosis Infection: Maximizing Adherence**

**Introduction**

Latent tuberculosis infection (LTBI) is the presence of *M. tuberculosis* organisms (tubercle bacilli) without symptoms or radiographic or bacteriologic evidence of TB disease. Approximately 90-95% of those infected are able to mount an immune response that halts the progression from LTBI to TB disease. However, because prevention of TB has major public health implications, the Centers for Disease Control and Prevention (CDC) and the United States Preventive Services Task Force (USPSTF) recommend testing populations that are at increased risk for TB infection and treating those for whom TB disease has been ruled out. Health care providers must communicate the risks and benefits of treatment to their patients and encourage adherence and treatment completion.

**Communicating the Value of Latent TB Infection Treatment**

A patient’s acceptance of LTBI treatment is often influenced by the initial approach of the health care provider. When discussing the risks and benefits of treatment it is important to explain that:

- As long as TB germs are in the body, they can begin to multiply and cause disease
- Certain individuals are at especially high risk for progression to TB disease. They include persons with recent TB infection and certain medical conditions, and those taking medication that may alter immunity
- Completing treatment for latent TB infection can reduce the risk of TB disease by 90%
- Treatment decisions are based on the results of scientific research
- TB infection is treated with one or two drugs, whereas TB disease initially requires four drugs

**Identifying Barriers to Adherence**

Many variables affect a patient’s adherence to the recommended treatment regimen, including:

- Appointment hours that conflict with patient’s schedule
- Misinformation about TB
- Health beliefs and practices
- Limited financial resources
- Co-existing medical conditions
- Medication side effects
- Language barriers
- Real or perceived stigma related to latent TB infection treatment

**Strategies for Maximizing Adherence**

**Collaboration with community agencies**

Partner with local health departments and community-based organizations that can provide:

- *Case management* to ensure continuity of services
- *Directly observed therapy (DOT)*, whereby a health care worker observes the ingestion of medication; highly recommended when using intermittent regimens and for high-risk patients, such as those whose treatment has been interrupted or who often miss appointments for medication refills
Incentives, which are small rewards that encourage or motivate patients. Local businesses and organizations may be a resource for incentives such as grocery store vouchers, nutritional supplements, movie tickets, or restaurant coupons.

Enablers such as free van transportation or bus tickets, reminder letters or phone calls, and other assistance that makes it easier to keep appointments.

Effective patient education

- Have materials available in patient’s primary language and at appropriate literacy level.
- Include patient’s family in health education whenever possible, because they can offer support.
- Reinforce educational messages at each visit.
- Give clear instructions regarding side effects and when to report them to a health care provider.
- Allow opportunities for questions and answers.

Patient-focused strategies

- Obtain patient’s agreement to complete treatment before actually starting (patient contract).
- Recommend reminders such as watches, alarm clocks, notes to self, pill boxes with days of the week.
- Schedule monthly appointments to monitor progress.
- Reinforce importance of treatment completion at each visit to help maintain patient’s commitment.
- Tailor treatment regimen to patient’s needs (daily vs. intermittent dosing, alternate regimens).

- Recommend taking medication at same time every day and associate it with a daily activity such as mealtime, brushing teeth, etc.
- Recommend taking isoniazid with food if gastrointestinal upset is a problem.

References

ATS/CDC. Targeted tuberculin testing and treatment of latent TB infection. MMWR 2000;49 (No. RR- 6). http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm


Additional Resources


http://www.cdc.gov/tb