Drug Use Review Programs: Approach to Ensure Rational Use of Anti-TB Drugs

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What is a Drug Use Review Program?

DUR is a quality assurance intervention that, in a step-by-step manner, identifies and remedies problems related to drug use by collecting, analyzing, and interpreting data through organized, ongoing, systematic, and criteria-based reviews.
Why is it Needed?

The objectives of drug use evaluations include:

• Ensuring that drug therapy meets current standards of care
• Preventing problems related to medication
• Evaluating the effectiveness of drug therapy
• Identifying areas of practice that require further education of health care providers
• Controlling drug cost
Why is it Needed for TB?

- When medicines used to treat TB are misused or patient care is mismanaged:
  - The patient’s health condition may worsen
  - Drug resistance can develop or amplify
  - The patient may stop taking anti-TB medicines because of side effects
  - Severe side effects of anti-TB medicines may threaten patients’ health or life, if not managed correctly
  - Patient can continue to spread TB
  - Cost of TB therapy increases
DUR Guidelines for Anti-TB Drugs

Instructions
- Plan
- Conduct
- Improve
- Assess

Annexes
- Criteria
- Data collection forms
- Implementation activity tracker
- Data summary tools
- Hepatotoxic, nephrotoxic, neurotoxic, and ototoxic drugs
- Drugs that prolong QT interval
- Overlapping ARV toxicities
Step 1: Establish responsibility
Step 2: Develop policies and procedures
Step 3: Define all departments where anti-TB drugs are used
Step 4: Orient TB staff to the program
Step 5: Access resources available for the program
Step 6: Prepare data collection forms
Step 7: Orient data collectors
Step 8: Collect data
Step 9: Tabulate data
Step 10: Interpret data
Step 11: Make recommendations for improvement
Step 12: Disseminate results and discuss improvement strategy
Step 13: Implement the strategy
Step 14: Conduct a follow-up DUR
Step 15: Review and discuss follow-up data
Step 16: Evaluate the program
Step 17: Plan and implement the next cycle
Phase 1: Plan the DUR Program

- Establish responsibility for the DUR process
- Develop policies and procedures
- Orient TB staff to the program
- Assess resources available for the program
- Establish criteria for DUR
- Prepare data collection forms
- Orient data collectors
Definition of Criteria

Predetermined parameters of drug prescribing and use established in a DUR program for comparison to actual practice
Criteria for DUR for Anti-TB Drugs

• I. Justification for use
• II. Process
  – Contraindications
  – Dosing and administration
  – Monitoring
  – Storage and handling
  – Drug interactions
  – Patient counseling
• III. Complications that could occur during therapy and how to respond if the complication presents
  • Adverse drug reactions
References for DUR Criteria

• Medicine package inserts
• WHO TB treatment guidelines
Definition of Threshold (or Target)

A percentage, established by the DUR committee, that identifies the point at which a drug therapy problem exists.
Phase 2: Conduct the DUR

• Collect data
• Tabulate data
• Interpret data
## Data Collection Form

### Kanamycin Drug Use Review - ADULT

**Name of Institute**

<table>
<thead>
<tr>
<th>Case Reviewed</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>DR-TB Case Number</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Threshold %</th>
<th>Y (Yes), N (No), NA (Not applicable)</th>
</tr>
</thead>
</table>

### Process Criteria

1. Appropriate dosing for adult patients is used - 15 – 20 mg/kg once daily to a maximum of 1000 mg

2. Pregnancy status is documented for female patients of childbearing potential prior to starting treatment

3. Audiometric testing conducted prior to starting treatment

4. Renal function testing conducted prior to starting treatment

5. Serum potassium testing conducted prior to starting treatment

6. Patient is not co-administered or sequential potentially nephrotoxic, neurotoxic, or ototoxic drugs (annex F)
Data Analysis

<table>
<thead>
<tr>
<th>CRITERIA (LEVOFLOXACINE)</th>
<th>TOTAL NUMBER MET</th>
<th>THRESHOLD MET</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB is microbiologically diagnosed (e.g., smear; culture; WHO endorsed rapid diagnostics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and Drug susceptibility testing (DSkT) document the organism resistant to at least rifampicin</td>
<td>120</td>
<td>0</td>
<td>100 100</td>
</tr>
<tr>
<td>Patient history has been reviewed for:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. levofloxacin allergy</td>
<td>92</td>
<td>28</td>
<td>95 77</td>
</tr>
<tr>
<td>b. quinolone antimicrobial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate levofloxacin dosing for adult patients 500-1000 mg by mouth daily</td>
<td>108</td>
<td>12</td>
<td>100 90</td>
</tr>
<tr>
<td>Serum glucose of diabetic patients is monitored</td>
<td>12</td>
<td>3</td>
<td>95 80</td>
</tr>
<tr>
<td>Patients are advised to drink plenty of beverages</td>
<td>100</td>
<td>20</td>
<td>95 83 Patient information sheets are not available at the clinic.</td>
</tr>
<tr>
<td>Diarrhea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Dehydration is assessed; initiate rehydration if indicated</td>
<td>39</td>
<td>5</td>
<td>95 88</td>
</tr>
<tr>
<td>• Anti-diarrheal therapy is initiated (e.g., aluminum hydroxide [not given within 2 hours of levofloxacin], loperamid)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Lactobacillus or food such as yogurt (not given within 2 hours of levofloxacin) is administered</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Phase 3: Implement Improvement Strategy

• Make recommendations for improvement
• Disseminate results and discuss strategy for improvement
• Implement the strategy
Interventions or Corrective Actions (1)

- Educational interventions:
  - In-service or continuing education programs
  - Informal and formal counseling
  - Letters to health care providers
  - Newsletters, guidelines on medicine use, and other informational materials
Interventions or Corrective Actions (2)

• Operational interventions:
  – Changes in treatment facility policies and procedures
  – Formulary additions and deletions
  – Implementing or revising standard treatment guidelines
  – Purchasing new equipment
Phase 4: Assess Effectiveness of the Program

- Conduct a follow-up DUR
- Review and discuss follow-up data
- Evaluate the program
- Plan and implement the next cycle
Follow-Up DUR

• Check that recommendations have been implemented
• Re-evaluate DUR to see if problems with pharmaceutical therapy have been resolved
Benefits of DUR Program

- DUR program can contribute to improving use of anti-TB medicines
- Health care workers can use the guidelines as a complete and concise source of anti-TB medicine information
- DUR can be made a part of operational research activities
THANK YOU