Assessing the management of anti-TB medicines and supplies

Management of anti-TB medicines and supplies

Objectives: at the end of the assessment reviewers should comment on –

- the availability of anti-TB medicines (including anti-TB medicines for children and for treating drug-resistant TB) and past shortages of medicines;
- the availability of supplies and the occurrence of stock outs;
- the overall management of anti-TB medicines and supplies;
- the measures that need to be taken to improve the management of medicines and supplies.

Background:

Good TB strategy requires that adequate quantities of internationally quality assured medicines be available whenever they are needed by patients and health workers, and that good quality laboratory and other supplies for diagnosis be uninterrupted. The process of managing the supply of anti-TB medicines includes taking essential steps to select, procure, distribute and rationally use the medicines.

Selection: The five essential medicines for first-line anti-TB treatment – ethambutol, isoniazid, pyrazamide, rifampicin and streptomycin – should be available in different formulations and packages, including blister packs, fixed-dose combinations (FDCs) and kits for treating individual patients.

Procurement: Procurement procedures should use accurate demand forecasting of the need for anti-TB medicines to ensure that the correct quantities of medicines are available at the right time at affordable prices, and that they are of an acceptable quality. Procurement should be centralized, and medicines should be ordered annually.

Distribution and storage: The steps for ensuring that the distribution and storage of medicines and supplies are adequate includes managing the importation of medicines, including port and customs clearances, and registering the medicines; establishing good storage practices, ensuring that staff are appropriately trained, and that storage conditions are adequate; regularly distributing medicines and supplies from the central level to the regional and peripheral levels; establishing an inventory-management system that includes a safety stock and information for forecasting needs for medicines and supplies; conducting regular physical quality checks; and organizing kits of medicines for treating individual patients.
**Rational use of medicines**: Access to medicines must be accompanied by measures to ensure they are used rationally, including taking action to limit the misuse of first-line and second-line medicines outside the national TB programme. Such measures may include improving and enforcing regulations on prescribing and dispensing medicines.

Most activities at the basic management unit focus on ordering, distributing, storing and rationally using anti-TB medicines. Selection and procurement are done at the central level or the regional or provincial levels of the national TB programme.

**Location:** central, regional or provincial medicine and supply warehouse; basic management unit or pharmacies at TB clinics and private pharmacies

**Staff to be interviewed:** TB coordinators, pharmacists, staff at the medicine and supply warehouse

**Assessment**

a. Who is in charge of ordering and receiving anti-TB medicines and supplies? If the person is available, ask about the procedures used to verify and document the quantities received.

   i. Does the facility use a register for medicines or supplies to track the delivery, receipt and movement of each item? Are expiry dates monitored?

   ii. Where are orders for medicines and supplies fulfilled (for example, from a regional store or central store, or directly from suppliers or wholesalers)?

   iii. What procedures have been established to ensure that health facilities receive medicines and supplies regularly? How often are supplies received? Who determines what supplies are needed and places the order?

   iv. Are kits of medicines for treating individual patients available? How are they supplied?

b. Are first-line anti-TB medications available? If yes, which ones?

c. Are second-line medicines available? If yes, which ones?

d. Are laboratory supplies and reagents kept at the store? If not, where are they kept? Are expiry dates monitored?

e. How does the facility keep track of medicines and supplies (that is, with a stock register or a card)?

   i. If the facility uses a register or card, does it include information on:

      • the quantities of medicines and supplies used by patients during the most recent period;
• the quantities ordered but not yet received;
• the quantities received from previous orders;
• the quantities loaned to other health facilities that need to be replaced;
• the expiry dates of the medicines in stock.

ii. Do the amounts of supplies and medicines in stock correspond to the amounts recorded on the register or card? (Count the supplies and medicines in stock and compare the totals with the amounts recorded on the stock register or card. If there is no stock register or card, compare the quantities with receipt records and the TB treatment register.)

f. What is the medicine storage area like?

   i. What is the temperature of the area? Is the area humid? Are medicines exposed to direct sunlight?
      • Inspect some of the tablets: are the colours of the medicines appropriate? Has the colour faded? Are the tablets crumbling, or do they smell unusual?

   ii. Have medicines been organized on the shelves so that it is easy to read the product’s name and expiry date?

   iii. Does air circulate in the storage area? Is there an air conditioner? Are there windows that can be opened? Is there an exhaust fan? Are there spaces between the shelves?

   iv. Is the storage area secure? Has a lock been installed on the door, and do staff use it? If there are windows, can they be locked, or have bars been installed to prevent access?

   v. Are medicines stored on the floor of the storage area? Are containers of medicines stacked one on top of another?

   vi. Are there any insects, rodents or other pests in the storage area?

   vii. Is there potential for stock to be destroyed by rain or floods? Is there a fire extinguisher with a valid expiry date? Is the fire extinguisher easily accessible? Have staff been trained to use it?

g. Is stock rotated using the first expiry, first out (FEFO) principle? (Inspect a few kits to ensure that FEFO is being followed for the kits)

h. Are kits of medicines used to treat individual patients? If yes, how are they organized?

   i. Do they contain fixed-dose combination (FDC) blister packs?
Framework for conducting reviews of tuberculosis programmes

ii. Are the kits easy to access on the shelf or in the storage area?

iii. How many months of treatment are included in one kit?

iv. Are syringes and other supplies (for example, sterile water for injections) included in the kits for retreatment patients?

v. Are kits adjusted for a patient’s weight? Are medications adjusted as a patient’s weight increases?

vi. Are patients’ names listed on the outside of the kits?

vii. Is the shortest expiry date for all the medicines listed on the outside of the kit?

viii. What is done with medicines from the kits that are not used?

i. Is there a buffer or safety stocks of anti-TB medicines? If yes, how long should the buffer stock last (for example, 3 months)?

j. Have there been any medicine stock-outs during the past year? If so, which medicines were affected, and for how long? (Explore the reasons for the stock-outs; for example, determine whether the incorrect amount was ordered, or deliveries arrived late from the regional or central store, or whether some medicines expired.)

- Were any anti-TB medicines borrowed from a nearby facility during the past year? Have any facilities borrowed medicines during the past year from the facility being reviewed?

k. Have there been any excess stocks of anti-TB medicines during the past year? If so, which medicines were affected, and what quantities? Did any medicines expire before they were used? (Explore the reasons for excess stock; for example, determine whether the incorrect amounts were ordered or there were changes in the number of patients, regimens, or formulas.)

l. How are orders for anti-TB medicines calculated? How are quantities of buffer or safety stocks calculated?

m. What anti-TB medicines are available for children? Are paediatric formulations available, or are adult tablets broken in half for children?

n. What is the source of the anti-TB medicines? Do the medicines come from an international quality assured source? Are the medicines received from the Global Drug Facility or from domestic manufacturers?

o. Are stored medicines sampled and tested regularly?

p. What is the procedure for handling expired anti-TB medicines?
### Indicators for: Assessing the management of anti-TB medicines and supplies

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Calculation</th>
<th>Source of information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of months that will be covered by the existing buffer or safety stock at a TB clinic or treatment centre</td>
<td>Quantities of anti-TB medicines available for the number of TB patients expected to be treated within the coming months</td>
<td>TB treatment register, individual stock registers</td>
</tr>
<tr>
<td>Second-line medicines dispensed as kits for individual patients by the central pharmacy to the point of care</td>
<td>Number dispensed monthly, number dispensed quarterly</td>
<td>Interview with pharmacist</td>
</tr>
<tr>
<td>Percentage of time anti-TB medicines were out of stock</td>
<td>Numerator: total number of stock-out days for all first-line medicines × 100 Denominator: 365 × number of anti-TB medicines usually in stock</td>
<td>TB treatment register, individual stock registers</td>
</tr>
<tr>
<td>Value of expired anti-TB medicines during the most recent quarter</td>
<td>Sum of the number of units expired for each medicine × unit cost for each medicine</td>
<td>Order receipt</td>
</tr>
</tbody>
</table>