Community-based Care for Drug-resistant Tuberculosis

GUIDE FOR IMPLEMENTERS

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About the Cover
Village Health Worker Makutloano Mochaph stands with MDR-TB patient Motsamai Macheli during a home visit in Maseru, Lesotho on April 22, 2015. Macheli has since made a full recovery. (Photo by Merida Carmona / Partners In Health)

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1. INTRODUCTION

Many countries are in the process of establishing or scaling up treatment of drug-resistant tuberculosis (DR TB). Effectively scaling up treatment will require addressing health systems-related issues, such as task shifting to alleviate human resources shortages and greater community engagement.

A principal challenge in establishing or scaling up treatment of DR TB is deciding what model of care to implement. A crucial step is bridging the gap between the hospital and the community to ensure continuity of care. For DR TB treatment to be truly patient-centered, patients should have the option to choose the location of their treatment, including the option to be supported in their homes and communities with monthly visits to the facility for monitoring of treatment and a follow up laboratory monitoring tests.

This guide provides practical, step-by-step guidance on how to organize, implement, and monitor community-based care for DR TB. It is equally useful for program planning or supervision. This guide does not replace other guidelines and documents that contain important medical information, such as Guidelines for the Programmatic Management of Drug-resistant TB (WHO, 2008 and 2011 updates), Management of MDR-TB: A Field Guide (WHO, 2009 and 2016 updates), Delivering Comprehensive Supportive Care to People with Drug-resistant Tuberculosis (USAID 2018), or Treatment Guidelines for Drug-resistant Tuberculosis (WHO, 2016 update). ¹

The target audience for this guide is TB program managers, governments, policy makers, nongovernmental organizations (NGOs), donors and TB advocates.

Context of Implementation of the Community-based DR TB Care Guidelines

Tuberculosis, aside from the clinical effects of the disease, often has social, economic, and psychological effects, which may interfere with a patient’s ability to complete treatment. An episode of TB may further exacerbate poverty or reduce a patient or family’s economic and social conditions. Even if a patient is successfully cured of TB, the experience of TB can magnify health and social disparities and increase the risk of reinfection. A movement towards universal health coverage (UHC) — ensuring that everyone who needs health services can access them without financial hardship — has been growing across the globe. More than 150 world leaders have committed to achieve UHC for their populations by 2030 through the Sustainable
Development Goals (SDGs) agenda. In the context of DR TB, UHC has two interrelated components. First, providing access to the full spectrum of good-quality, essential health services based on specific needs of a given population. Second, financial and social risk protection to safeguard families from impoverishment and other financial hardship associated with out-of-pocket payments for health services. The social risk protection component includes policies and programs designed to reduce poverty and vulnerability by promoting efficient labor markets, diminishing exposure to physical risks, and enhancing capacity to manage economic and social risks, such as unemployment, exclusion, sickness and disability.

The scaling-up of integrated TB and HIV services is critical to end the dual epidemics of Tuberculosis and HIV as TB remains the leading cause of death among people affected with HIV. Community-based DR TB programs should consider TB/HIV and other TB co-morbidities in program design and implementation to ensure continuity of care within existing, possibly disparate, vertical programs.

In the context of the End TB Strategy (ETS) 2015–2035, there is a great emphasis on both universal health coverage and social protection. Furthermore, the ENGAGE-TB approach guidelines from WHO emphasize the importance of an enabling environment, of guidelines and tools, of task identification, of monitoring and evaluation, and of capacity building.

Community-based DR TB care and management considers the End TB Strategy and the ENGAGE-TB guidelines in creating an effective, evidence-based, sustainable strategy for DR TB management at the community level.
Community Health workers conduct home visits to patients in Harper, Liberia on Sept. 24, 2015.

Photo by Rebecca E. Rollins / Partners In Health

2. MODELS OF DR TB CARE

Some countries may implement one or more of the below models of care:

- **Hospitalization**: Patients are hospitalized for the entire period of treatment
- **Ambulatory**: Patients are treated at a health facility on an outpatient basis
- **Community**: Patients are treated at home or closer to their homes and are supported by treatment supporter (e.g. family members, health care workers, co-workers, neighbors, community health workers (CHWs), or village health workers (VHWs))

In cases where a country implements more than one of the above models, a common configuration is as follows:

- **Hospitalization + Ambulatory or Community**: Patients are treated or treatment is initiated at the hospital for a certain period of time or for the entire treatment.

Treatment can be initiated through any of the above models of care; however, community-based care models may serve to overcome human and capital resource barriers encountered with facility-based treatment initiation during program scale-up and serve to minimize nosocomial transmission.
3. CHARACTERISTICS OF COMMUNITY-BASED DR TB CARE

Community-based care:

- **Allows patients to receive DR TB treatment in their own community.** This addresses one key barrier to adherence, travel to a facility\(^2\), and facilitates directly observed treatment (DOT). The World Health Organization recommends that patients with DR TB be treated using mainly ambulatory care rather than models of care based principally on hospitalization.\(^2\) Community-based DOTS-Plus (Directly observed treatment for MDR TB) strategies have been shown to be one-tenth the cost of hospitalization and produce DR TB cure rates up to 83%.\(^3\)

- **Uses compensated, trained, and supervised Community DR TB Supporters.** DR TB treatment is long and complex and can pose insurmountable barriers for an individual. A treatment supporter for people living with DR TB can improve adherence and prevent patient lost to follow up.\(^4\) A treatment supporter can be a family member, health care worker, co-worker, neighbor, CHW, or VHW. DR TB Supporters should receive compensation for their work supporting DR TB patients\(^2\); patients supported by compensated treatment supporters were 1.8 times more likely to complete treatment than those patients receiving standard care.\(^5\)

- **Is compatible with hospital care.** Community-based DR TB care programs should consider patients who may have initiated treatment in a hospital setting to provide continuity of care and ongoing linkages for patients who started treatment as an inpatient or at a facility. An effective and robust referral system should connect patients who began treatment in the hospital setting to high-quality community-based care and should connect patients in community-based care to appropriate hospital-based care as necessary.

- **Empowers communities and households with knowledge** about DR TB and how to mitigate potential health risks. Community-based DR TB care increases community awareness about DR TB, which in turn can be a powerful force in reducing stigma and in changing attitudes and social norms regarding TB patients.

- **Is sensitive to local customs and norms of communities** and respects personal and health rights of individuals within these communities. It activates social and community support systems for addressing stigma and discrimination, thus reducing access barriers to TB diagnostic, care services.\(^6\)

- **Is patient-centered.** Patient engagement and empowerment is a critical part of designing community-based models for DR TB care. A patient-centered approach should guide the intervention around the patient’s rights, preferences, values and needs where the patient is treated as an important partner in care rather than just a recipient of treatment.\(^6\)
4. COMMUNITY-BASED DR TB CARE

4.1 Community-based DR TB Care Framework

The community-based TB care framework provides an overall description of critical elements of an effective community DR TB services delivery system. It makes explicit the foundational systems (supply chain, training, data management and staffing) that are necessary at different program implementation stages (case finding, treatment, and prevention) to help program implementers prioritize high-value interventions to improve patient outcomes. This framework also helps identify areas for monitoring, evaluation, and learning to properly understand and assess program effectiveness and to make refinements to program design in a data-driven manner. The framework can also help facilitate communication among stakeholders by providing a common organizing structure.

Recovered MDR-TB patient Wilfred Jean-François and his wife, Cami Sonya, (right) during a home visit in Belladère, Haiti on April 28, 2016.

Photo by Cecille Joan Avila / Partners In Health
### Critical systems underlying each step:

<table>
<thead>
<tr>
<th>Drug &amp; Supply Chain Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education / Training</td>
</tr>
<tr>
<td>Reporting and Recording</td>
</tr>
<tr>
<td>Staffing</td>
</tr>
</tbody>
</table>

#### ACTIVE CASE FINDING

**Program Strategies / Interventions**
- Household outreach and referral (CHWs)
- Targeted high risk group screening
- Engage local leaders

**Community Activities**
- Household and contact screening (provided by treatment supporters, VHWs, and health care workers)

**Health Facility Activities**
- Inpatient wards
- Outpatient

#### ENROLLMENT & STANDARD EFFECTIVE TREATMENT FOR DR TB

**Program Strategies / Interventions**
- CHW accompaniment / DOT
- Social support (transport, food, housing, cash)
- Manage any other secondary infections
- Patient support services (Counseling, Health Education, School Fees)

#### FOLLOW UP & PREVENTION

**Program Strategies / Interventions**
- Social support (transport, food, housing, cash)
- CHW accompaniment / DOT
- LTFU tracking
- Patient support services (Counseling, Health education, School fees)
- Infection control at the household & facility levels
- Testing for drug resistant TB

**Major Activities**
- Home assessment
- Follow up for support and adherence, monitoring of side effects, identify social problems
- Contact tracing

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**Additional Supportive Services**
- Diagnostics (molecular testing, smear, x-rays, ART initiation, Viral Load testing)
- HIV services for TB patients
- aDSM
4.2 Role of the private sector on DR TB management

As the structure and reach of the private sector varies greatly in different settings, National TB programs should decide on the roles and responsibilities of the private sector in DR TB care. Generally, the private sector should be involved in diagnosis – especially in novel diagnostic tools and equipment – and treatment – especially in drug distribution and the development of novel therapies for DR TB. Critical areas of improvement for the private sector providers, will include reporting and recording and timely case notification to NTP, the partnership can be further strengthened by on the job trainings and monitoring. Successful models can be scaled up and their experience can be shared.

4.3. Roles and responsibilities of the DR TB team

The national TB program should incorporate the management of DR TB into overall TB management. Each level of management – central, sub-national, facility, and community – should engage specified workers with assigned roles. The exact level at which a specific function is provided will depend on the country and the burden of DR TB. The right column in the tables below lists specific responsibilities; the left column lists possible roles that can assume these responsibilities. The exact composition of the DR-TB team will likely vary based on the implementation context, and the below tables serve as options for building the ideal DR TB team for the given setting.

At the central level:

<table>
<thead>
<tr>
<th>POSSIBLE ROLES</th>
<th>SPECIFIC RESPONSIBILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• National TB Control Program Manager</td>
<td>The central unit will plan, assess needs, implement, monitor, and evaluate the DR TB program.</td>
</tr>
<tr>
<td>• National TB/HIV Coordinator</td>
<td>• Establish guidelines, norms and procedures for the control of DR TB.</td>
</tr>
<tr>
<td>• National Monitoring, Evaluation and Quality (MEQ) Officer</td>
<td>• Manage budgets, work plans, reporting, and quality improvement initiatives.</td>
</tr>
<tr>
<td>• National AIDS Program</td>
<td>• Advocate for community care.</td>
</tr>
<tr>
<td>• National Laboratory Services</td>
<td>• Strengthen collaboration between HIV/TB programs.</td>
</tr>
<tr>
<td></td>
<td>• Coordinate operational research on community care.</td>
</tr>
<tr>
<td></td>
<td>• Coordinate lab services and procurement including drugs and lab reagents</td>
</tr>
<tr>
<td></td>
<td>• Establish the training program, communications plan and data management.</td>
</tr>
</tbody>
</table>
At the sub-national level (provincial, regional, district):

<table>
<thead>
<tr>
<th>POSSIBLE ROLES</th>
<th>SPECIFIC RESPONSIBILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Regional TB Coordinator</td>
<td>• Organize, coordinate, and regularly supervise TB and DR TB diagnosis and treatment.</td>
</tr>
<tr>
<td>• District TB Coordinator</td>
<td>• Coordinate with the central level, other institutions, e.g., NGOs and patient support systems.</td>
</tr>
<tr>
<td></td>
<td>• Integrate DR TB with other services, e.g., HIV and maternal services.</td>
</tr>
<tr>
<td></td>
<td>• Supervise data collection reporting and recording.</td>
</tr>
</tbody>
</table>

At the hospital level:

<table>
<thead>
<tr>
<th>POSSIBLE ROLES</th>
<th>SPECIFIC RESPONSIBILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>DR TB Clinical Service:</td>
<td><strong>Inpatient</strong></td>
</tr>
<tr>
<td>• Doctor or other clinician</td>
<td>• Diagnosis of DR TB, ensure quality of treatment, prescription, and initiation, and clinical follow-up during treatment.</td>
</tr>
<tr>
<td>assigned the responsibility for</td>
<td>• Manage inpatients with severe disease and complications from treatment.</td>
</tr>
<tr>
<td>clinical management of DR TB</td>
<td>• Share responsibility with the DR TB Clinician of the health care facility in management of inpatients with DR TB.</td>
</tr>
<tr>
<td>in the district</td>
<td>• Supervise administration of inpatient treatment.</td>
</tr>
<tr>
<td>• Nurses and supportive staff</td>
<td>• Begin patient care plan development and education to avoid initial LTFU and LTFU during transition to outpatient and community-based care</td>
</tr>
<tr>
<td>with specific training in</td>
<td></td>
</tr>
<tr>
<td>management of DR TB patients</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Outpatient</strong></td>
</tr>
<tr>
<td></td>
<td>• Coordinate with the DR TB Nurse on outpatient admission and discharging inpatients.</td>
</tr>
<tr>
<td></td>
<td>• Monitor outpatients for problems that may arise during treatment, e.g., side effects, adherence problems, etc.</td>
</tr>
<tr>
<td></td>
<td>• Coordinate clinical support services.</td>
</tr>
<tr>
<td>Lab Services</td>
<td>• Provide laboratory services for DR TB patients, including monitoring tests for side effects.</td>
</tr>
<tr>
<td>• Laboratory technician</td>
<td></td>
</tr>
<tr>
<td>• Laboratory assistant</td>
<td></td>
</tr>
<tr>
<td>Data Management</td>
<td>• Maintain database (register) of all DR TB patients in the region/district.</td>
</tr>
<tr>
<td>• Data clerk</td>
<td>• Keep track of follow-up appointment dates for all DR TB patients.</td>
</tr>
<tr>
<td></td>
<td>• Store outpatient records of all DR TB patients.</td>
</tr>
<tr>
<td></td>
<td>• Produce timely reports according to the national guidelines.</td>
</tr>
<tr>
<td>Drug Management</td>
<td>• Manage second-line drug stock and ancillary drugs for side effects (inventory, forecasting, and drug supply) for the region/district.</td>
</tr>
<tr>
<td>• Pharmacist</td>
<td>• Prepare pediatric anti-TB drug doses.</td>
</tr>
<tr>
<td>• Pharmacy technician</td>
<td></td>
</tr>
<tr>
<td>• Pharmacy assistant</td>
<td></td>
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</tbody>
</table>
At the health center level:

<table>
<thead>
<tr>
<th>POSSIBLE ROLES</th>
<th>SPECIFIC RESPONSIBILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Service:</strong>&lt;br&gt;- Clinician assigned the responsibility for clinical management of DR TB in the district</td>
<td>• Monitoring outpatients on treatment&lt;br&gt;• Submit regular samples for clinical monitoring of patients&lt;br&gt;• Identify side effects&lt;br&gt;• Supply monthly medication</td>
</tr>
<tr>
<td><strong>Community DR TB Team:</strong>&lt;br&gt;- Nurses, nurse assistants, social workers, and others who are responsible for managing DR TB patients in the community</td>
<td>• Coordinate all DR TB community activities.&lt;br&gt;• Perform home visits in case of medical or adherence problems or as otherwise necessary (older adults, people with disabilities).&lt;br&gt;• Assess and improve TB infection control in the home.&lt;br&gt;• Identify and address socioeconomic problems.&lt;br&gt;• Supervise DR TB Supporters.&lt;br&gt;• Coordinate with clinical, data, and pharmacy staff.&lt;br&gt;• Implement proper infection control measures.</td>
</tr>
<tr>
<td><strong>Lab Services</strong>&lt;br&gt;- Laboratory technician&lt;br&gt;- Laboratory assistant</td>
<td>• Provide laboratory services for DR TB patients, including screening tests for side effects.</td>
</tr>
<tr>
<td><strong>Data Management</strong>&lt;br&gt;- Data clerk</td>
<td>• Maintain database (register) of all DR TB patients in the region/district.&lt;br&gt;• Keep track of follow-up appointment dates for all DR TB patients.&lt;br&gt;• Store outpatient records of all DR TB patients.&lt;br&gt;• Produce timely reports according to the national guidelines.</td>
</tr>
<tr>
<td><strong>Drug Management</strong>&lt;br&gt;- Pharmacist&lt;br&gt;- Pharmacy technician&lt;br&gt;- Pharmacy assistant</td>
<td>• Manage second-line drug stock (inventory and drug supply) for the patient followed at the health center.&lt;br&gt;• Prepare pediatric second line anti-TB drug doses.&lt;br&gt;• Prepare drug packs for each DR TB patient and deliver them to the community team.</td>
</tr>
</tbody>
</table>
In the community:

<table>
<thead>
<tr>
<th>POSSIBLE ROLES</th>
<th>SPECIFIC RESPONSIBILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>DR TB Supporter who is trained, monitored and supervised</td>
<td>• Supervise all doses of second-line TB drugs in the community.</td>
</tr>
<tr>
<td></td>
<td>• Identify possible side effects or complications and report them promptly to the DR TB Nurse.</td>
</tr>
<tr>
<td></td>
<td>• Support patient to attend all medical consultations.</td>
</tr>
<tr>
<td></td>
<td>• Support the patient in collecting sputum samples monthly.</td>
</tr>
<tr>
<td></td>
<td>• Screen household contacts for TB and refer them for testing.</td>
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<tr>
<td></td>
<td>• Help facility track patients lost-to-follow up.</td>
</tr>
<tr>
<td></td>
<td>• Continue to provide education and psychosocial support for the patient and family.</td>
</tr>
<tr>
<td></td>
<td>• Identify any issues interfering with the DR TB treatment.</td>
</tr>
<tr>
<td></td>
<td>• Implement proper infection control measures.</td>
</tr>
<tr>
<td></td>
<td>• Ensure that the patient is adhering to drugs for comorbidities.</td>
</tr>
<tr>
<td>• Family member</td>
<td></td>
</tr>
<tr>
<td>• VHW/CHW</td>
<td></td>
</tr>
<tr>
<td>• Neighbor</td>
<td></td>
</tr>
<tr>
<td>• Coworker</td>
<td></td>
</tr>
<tr>
<td>• Community Leaders</td>
<td>• Convene meetings and events to provide information, education and communication around DR TB and its prevention</td>
</tr>
<tr>
<td></td>
<td>• Reduce stigma</td>
</tr>
<tr>
<td></td>
<td>• Mobilize the community to support community members with DR TB</td>
</tr>
<tr>
<td>• Patients</td>
<td>• Work with the DR TB Supporter to take medication and to report adverse events.</td>
</tr>
<tr>
<td></td>
<td>• Visit the DR TB clinic monthly for consultations, discussion about treatment plan, and blood and sputum testing</td>
</tr>
<tr>
<td></td>
<td>• Discuss infection control measures as guided by a health care provider</td>
</tr>
</tbody>
</table>
4.4 Responsibility of the DR TB Nurse

DR TB service coordination is essential. Sufficient, trained human resources will strengthen the patient’s psychosocial, economic and medical support network, contributing to improved health outcomes. The DR TB Nurse is central to DR TB service coordination and is responsible for coordinating care for DR TB patients in the community. The DR TB Nurse is based at the facility (hospital and health center) and works as part of a team that may include clinicians and nursing assistants, as well as non-clinical staff such as social workers, drivers, and nutritionists. Clinical activities, such as the referral of medical emergencies, are an important part of the daily activities of the DR TB Nurse. The DR TB Nurse supports patients to adhere to treatment to have the best outcome possible. A sample job description for a Community DR TB Nurse can be found in Appendix I.

Responsibilities include but are not limited to the following:

- **Performing or supporting home visits in case of medical or adherence problems**
  - Assessing the home and family at the beginning of treatment.
  - Visiting the patient in case of medical problems, including adverse drug effects.
  - Screening family members for HIV and TB.
  - Educating the family and community about DR TB.
  - Tracking those who have been lost to follow up.

- **Identifying, reporting, and addressing socioeconomic problems.**
  - Providing counseling and psycho-emotional support.
  - Helping patients obtain social and material support.

- **Supervising DR TB Supporters.**
  - Finding an acceptable DR TB Supporter for each patient (see Section 4.1).
  - Training the DR TB Supporter (initial and refresher training).
  - Communicating with the DR TB Supporter in case of emergencies.
  - Monitoring the DR TB Supporter monthly.
  - Conducting surprise visits to patients’ homes to assess quality of DOT.

- **Coordinating with clinical, data, and pharmacy staff**
  - Arranging for hospital admission for patients in case of medical emergencies.
  - Coordinating patients’ transitions from the hospital to community-based DR TB care.
  - Coordinating the patients’ next outpatient clinic visits.
  - Managing outpatient clinic schedules with the data team.
  - Ensuring that patient has the correct treatment and care for comorbidities.
  - Working with the pharmacy team to deliver medications to patients.
4.5 Participation of the DR TB Nurse in the outpatient clinic

The DR TB Nurse should participate in the outpatient clinic activities to assess and supervise the DR TB Supporters. The duties of the DR TB Nurse during outpatient treatment will differ in each setting but may include the following:

- **Organizing follow-up of DR TB patients:**
  - Using the Appointment System (see Section 4.8), collecting the files of the patients who are expected that day from the Records Team before the clinic opens.
  - Measuring patients’ weights and vital signs.
  - Sending patients to collect blood and sputum samples.
  - Inspecting Treatment Cards and transferring tick records to the copy of the Treatment Card in the clinic files.
  - Discussing community/adherence issues with the DR TB Clinician.
  - Updating the Register for second-line drug treatment.

- **Arranging evaluation of new patients, such as those who are referred to the clinic as presumptive for DR TB:**
  - Reviewing the referral form.
  - Ensuring that the required tests are done (e.g., chest X-ray, blood and sputum samples) before the patient is seen by the DR TB Clinician.

- **Facilitate linkage to social support services:**
  - Organize distribution of food packages, transportation reimbursements (via SMS, mobile cash transfers, post office transfers, etc.), and DR TB Supporter compensation (see Section 5.5).

- **Assessing and supervising DR TB Supporters:**
  - Conducting monthly performance evaluation of each DR TB Supporter (see Appendix II) and correcting problems that are discovered.
  - Conducting refresher training for all DR TB Supporters at least quarterly (see Section 5.4).

- **Ensuring that patients are given the right quantity of prescribed drugs:**
  - Sending prescriptions to pharmacy dispensing area.
  - Receiving patient packs from Pharmacy Team and checking quantities.
  - Educating patients and DR TB Supporters about regimen changes.
4.6 Integrated care for DR TB patients

Patients who suffer from co-morbid conditions should receive care for these other conditions within the DR TB program as is possible within the given TB program. Integrated care should be encouraged to the extent possible through building linkages with other services to provide coordinated care.

- **Other chronic diseases (HIV, diabetes, etc.) should be managed during the routine DR TB outpatient clinic visits.**
  - The patient drug pack prepared by the Pharmacy Team should include all medications prescribed for other conditions as well.
  - The Community DR TB Team should be trained in the management of other common chronic diseases (such as diabetes, HIV and hypertension) in addition to DR TB.

- **Advantages of integrated care:**
  - It is more convenient for the patient. Because many DR TB patients are debilitated and struggling with side effects, integrated care decreases the likelihood of them abandoning therapy.
  - It reduces medical error and drug interactions, as one clinical team manages all the different medications for the patient.
  - It decreases the risk of transmission to other patients, because infectious patients are not required to visit multiple clinics.

- **Integrated care is particularly important in the case of HIV co-infection. All HIV-related services (antiretroviral therapy, screening for opportunistic infection, etc.) should be provided in the DR TB clinic or at community level as is feasible and appropriate in the given setting.**

- **Family planning is a particularly important part of integrated care for DR TB patients, who should not become pregnant while being treated for DR TB. Female DR TB patients of reproductive age should be counseled and assisted in finding an appropriate family planning method.**
4.7 Communication with the community

• **The DR TB Nurse should provide an emergency phone number to the DR TB Supporter**
  - The DR TB Nurse should write his or her contact number in the DR TB Supporter DOT book (see Appendix III).
  - Patients and families should be instructed to contact the DR TB Supporter immediately in case of emergency.
  - The DR TB Supporter can be instructed to send an SMS or “flash” the DR TB Nurse, and then receive a call back.

• **If the patient has any problems or concerns, the DR TB Supporter should call the DR TB Nurse immediately. These problems may include:**
  - Side effects
  - Missed doses
  - Running out of drugs early
  - Unable to attend the clinic for any reason

• **In case a patient experiences life-threatening side effects, all DR TB Treatment Supporters should have the regional coordinator or hospital staff’s phone number.**
4.8 Appointment system

Patients should be evaluated at the DR TB clinic every month.

- All appointment dates should be communicated to a Data Management Team (preferably at the facility that coordinates the patient’s care) that keeps track of all appointments in a calendar database.

- On DR TB clinic days, the Data Management Team should send a list of patients expected to be seen to the Pharmacy Team and Clinical Team as appropriate.

- Patients who are discharged from the hospital can be given an appointment for the next DR TB clinic day.
4.9 TB infection control in the community

The World Health Organization recommends that DR TB be treated using mainly ambulatory care rather than hospitalization. Treatment of DR TB via hospitalization increases the risk of airborne DR TB infection, which jeopardizes the health of both patients and health care workers. Studies have shown that hospitalization is a significant risk factor for patients developing MDR TB, especially in low-resource settings that often have substandard infection control infrastructure.

- **The best method of infection control is effective treatment.** Early diagnosis and rapid initiation of effective treatment should be the priority for any TB control program. Access to early rapid diagnostic tools including molecular testing, supported by an effective sputum transportation system, is essential.

- **The home visit is an excellent opportunity for the DR TB Nurse to assess and improve infection control in the home. They should:**
  - Conduct an infection control assessment with the Home Assessment Form (Section 6.1)
  - Educate the patient and family about how to avoid further spread of TB in the household; explain the most recent results of the sputum analysis.
  - Improve natural ventilation and exposure to sun within the home.
  - Screen family members for symptoms of TB.
  - Offer HIV testing to all family members in high HIV-prevalence settings, or if the patient is HIV positive.
  - Advise patients on cough hygiene, such as covering their mouths with tissues, handkerchiefs, or surgical masks when coughing.
  - Advise patients to minimize contact with infants and children during the initial months of treatment.
  - Advise patients to sleep in a separate, well-ventilated room during the initial months of treatment if possible.
  - Advise patients to collect their sputum in a plastic bag or jar and teach them how to bury or dispose of it.

- **DR TB Supporters are at increased risk for occupational disease. The following steps should be taken to reduce risk.**
  - DR TB Supporters should know their HIV status
  - DR TB Supporters should be offered HIV testing when they begin supporting patients; after three months if they initially tested negative, and then again annually.
  - DR TB Supporters should not have a health condition that could lead to immune-suppression
  - DR TB Supporters should know the sputum status of their patient. If the sputum culture is positive, this means the patient is still infectious and particulate respirators should be considered.
  - Each DR TB Supporter should receive two disposable particulate respirators (N95 or FFP2) monthly if the patient is culture-positive and be trained on how and when to use them.
4.9 Caring for caregivers

• **Health workers are at risk for DR TB in high-burden TB settings because they are constantly exposed to infectious TB patients.**
  - Health workers should be trained in infection prevention and control when they start working in high-burden TB settings. Written infection control policies, procedures and job aids should be made available to them.
  - Health workers should be provided with the personal protective equipment necessary for caring for DR TB patients.
  - All health workers who are diagnosed with TB should have sputum sent for drug susceptibility testing.

• **Health workers living with HIV are at the highest risk for developing TB and DR TB, so HIV testing is an important part of occupational safety.**
  - Health workers (especially doctors and nurses) often do not want to know their status, but this should be a priority of the occupational health and safety program.
  - All health workers should be offered HIV testing before starting to work with TB patients, three months later, and annually while this work continues.

• **Health workers who develop TB or DR TB disease may have legal protection or recourse. It is the responsibility of the employer to ensure that health workers have priority access to occupational health and safety programs and appropriate diagnosis and treatment.**
5. DR TB SUPPORTERS

5.1 Profile of a DR TB Supporter

• Young and preferably female DR TB Supporters are recommended for pediatric patients; the parents or family members of the child should be avoided as much as practically possible to supervise doses.

• DR TB Supporters should live near the patient. This makes twice-daily DOT feasible. Additionally, in case of medical emergencies, the family should be able to contact the DR TB Supporter quickly. A neighbor is ideal.

• DR TB Supporters should be compensated, trained, and linked with a professional health worker responsible for ongoing skills-building and supportive supervision. DR TB Supporters should have the ability to make use of mobile phones and mHealth treatment support solutions as required.

A DR TB Treatment Supporter:

• Is someone from the patient’s community;
• Is chosen by or is acceptable to the patient and his or her family;
• Should preferably be selected from existing community health workers; but can may include a family member, coworker, neighbor, etc.
• Is active, strong and not too old to work;
• Is available to support the patient at any time during the day or night;
• Can observe confidentiality of the patient’s records;
• Has a stable living situation near the patient;
• Has basic literacy skills (should be able to read and write);
• Is motivated to care for DR TB patients;
• Is committed to supporting the patient for the full length of treatment;
• Should not have a health condition that could lead to immune-suppression; *
• Has received basic TB training and DR TB-specific training sufficient to provide patient education.

* The most common type of immunosuppression is HIV/AIDS, but chronic illnesses such as diabetes also suppress the immune system and are a risk factor for TB infection and disease.
5.2 Tools for the DR TB Supporter

It is recommended to provide DR TB Supporters with these materials:

- Treatment Card
- Lockable container at home (to keep confidential documents)
- Reliable means or funding for urgent transportation
- Identification
- Mobile phone (or other means of communication) and adequate airtime
- Pens or pencils
- Ruler
- Umbrella
- Torch
- Waterproof bag
5.3 Initial training for DR TB Supporters

DR TB Supporters should receive specific training in DR TB, which is necessary to provide DOT; complete training can generally be accomplished within two weeks (less if they have had previous training on TB and HIV).

- **The WHO’s Training plan for a new community TB treatment supporter is an excellent foundation for initial training for DR TB Supporters.** The training should cover:
  - Basic information about TB and HIV.
  - Information about drug regimens, phases of treatment and treatment duration.
  - Role and responsibilities of the DR TB Supporter on an individual basis and as part of the broader clinical team.
  - How to talk to DR TB patients in the first encounter.
  - How to read the treatment card.
  - How to give DOT.
  - How to mark the treatment card.
  - Common side effects and how to identify them.
  - Ancillary drugs used to treat side effects.
  - How to encourage the patient to continue coming to the clinic for TB treatment follow ups.
  - How and when to make referrals for medical evaluation.
  - What to do if a patient misses a scheduled treatment.
  - How to obtain a resupply of drugs.
  - Appropriate storage of drugs.
  - What to do if the patient or the DR TB Supporter must be away for a few days.
  - When to send the patient back to the health facility for follow-up.
  - The importance of sputum and blood tests every month.
  - Infection control at home, including universal precautions and needle disposal.
  - How and when to use and store a particulate respirator (N95 or FFP2).
  - TB screening for adults and children.
  - Patient rights and patient confidentiality.

- **In the beginning of the program, DR TB Supporters can receive initial training one-on-one from a medical health care worker (e.g., nurse or clinical officer).** As the number of patients grow, it is more efficient to systematically train all potential DR TB Supporters in each community. Countries can adjust the training to fit their needs and local regulations.

- **The DR TB Supporter should also be mentored during the first few weeks of treatment.** The DR TB Nurse should provide supervision of the DR TB Supporter’s tasks.
• The use of mobile technology will play a big role in patient follow-up, adherence and monitoring. This can be through SMS reminders for appointments, Video-DOT (V-DOT), Video Psychological Support and Counseling.

5.4 Additional training for DR TB Supporters

• One-on-one training will include:
  - Preparation of daily dose of medication
  - Documentation of observed treatment on the Treatment Card

• At each monthly clinic evaluation, the DR TB Nurse should identify knowledge and skills gaps and reinforce the following:
  - How DR TB manifests and how it is transmitted
  - Drugs used in the treatment of DR TB
  - Distinction between intensive and continuation phases
  - Roles and responsibilities of all members of the DR TB team
  - How to encourage patients to take treatment
  - Side effects
  - When to refer patients for medical evaluation prior to their next scheduled appointment (e.g., in the case of severe or concerning adverse events, deteriorating health)
  - Importance of monitoring treatment with sputum and blood tests
  - Risk factors for loss to follow up
  - Screening household contacts for TB
  - Principles of infection control, include disposal of hazardous materials
  - Patient rights and patient confidentiality
5.5 Models of Payment for DR TB Supporters

The DR TB Supporter should be reimbursed for all costs incurred as part of the execution of their duties, including (but not necessarily limited to) the cost of transportation to the monthly and unscheduled medical consultation if needed and any additional expenses required for medical emergencies.

- In addition to reimbursement for expenses, DR TB Supporters should be recognized and compensated for their time and services. Previous work has shown that patients who were supported by treatment supporters who received financial incentives were 1.8 times more likely to complete treatment than those receiving standard care.\(^5\)
  
  - Monetary payment may be referred to as a stipend or allowance, rather than a salary, which implies contractual employment.
  
  - Non-monetary compensation may be used as an alternative to monetary payment. Examples include: food packages, bicycles, priority or free access to health and human services (e.g., health insurance), livestock, additional training, and clothing.

- Monetary compensation should be tied to performance, as assessed during monthly supervision and evaluation (see Appendix II). During the monthly evaluation of the patient, the DR TB Nurse will also evaluate each DR TB Supporter. If his or her performance is acceptable, the DR TB Supporter receives the monthly compensation.
  
  - The DR TB Nurse will not compensate DR TB Supporters unless they perform all of the above responsibilities during the preceding month.
  
  - If performance is not acceptable for two months in a row, the DR TB Nurse will immediately find an alternate DR TB Supporter for the patient.

- If the DR TB Supporter cannot supervise treatment, he or she should inform the DR TB Nurse in advance, so that another supervisor can be found, and no doses are missed.

- If the DR TB Supporter does not fulfill his or her responsibilities for two months in a row, he or she should be replaced immediately. This should be made clear to the DR TB Supporter from the outset.
5.6 Monitoring DR TB Supporters

- The DR TB Nurse should make an unannounced visit to the patient’s home first to ask the patient and his or her family about the DR TB Supporter. The DR TB Supporter should then be called to discuss any issues and reinforce teaching points.

- Pill counts should be done at monthly evaluations or during spot visits. The DR TB Nurse should count the remaining pills and compare this number to the number of pills that should be remaining based on the number of days since the medication bag was replenished. If there are any extra or missing pills, the DR TB Supporter should explain.

- The patient should regularly be asked about the DR TB Supporter (e.g., “Is the DR TB Supporter prompt? Does he or she have a good attitude? Does he or she work around the patient’s schedule? Is the relationship still a good one?”).

- The DR TB Supporter should be asked to assess his or her own performance at monthly evaluations (e.g., “How do you think you are doing? What are you struggling with?”).

- The DR TB Supporter should keep the treatment card, even if the TB medications are kept in the patient’s home. The DR TB Supporter should read the exact treatment regimen listed on the Treatment Card and tick immediately after observing the morning or evening dose.
Natalia Sidorenko and Nataliya Smolina, of PIH’s Sputnik team, bring food to the home of Alexander in Tomsk, Russia on April 26, 2016. Alexander was successfully treated for TB.

Photo by Elena Devyashina for Partners In Health

6. SOCIAL SUPPORT

6.1 Home Assessment

The DR TB Nurse should perform a home assessment at the beginning of treatment for all patients. This allows the clinical and public health teams to understand the social and family environment and conditions of TB transmission for each patient. This sample assessment form may be adapted to specific countries.

<table>
<thead>
<tr>
<th>Social</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many people are sharing the household with the patient?</td>
</tr>
<tr>
<td>How many are HIV positive or suffer from another chronic disease?</td>
</tr>
<tr>
<td>How many are below 5 or above 50 years of age?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Economic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient have a regular source of income (grant/work)? Yes</td>
</tr>
<tr>
<td>From what material is the patient’s residence constructed?</td>
</tr>
<tr>
<td>What is the ratio of employed persons versus unemployed persons in the household?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Habits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient smoke? Yes</td>
</tr>
<tr>
<td>Does the patient drink alcohol or take drugs? Yes</td>
</tr>
<tr>
<td>Does anyone else in the household drink or take drugs? Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TB Knowledge</th>
</tr>
</thead>
</table>

24
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do the patient and the family understand how TB is transmitted?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the family understand the need to be screened for TB?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Infection Control</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the house have adequate light and ventilation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient sleep in a separate room?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient socialize in outdoor spaces while sputum positive?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hygiene</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the patient able to demonstrate good cough hygiene?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient know how to safely dispose of sputum?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.2 Food packages
There is strong evidence \(^{(10)}\) that food packages influence DR TB patient outcomes both by improving patient nutritional status and acting as powerful adherence enablers. Food packages should be considered a part of the treatment regimen, and just as important as medications.

- Because patients often share their food packages with their families, the size of the food package may need to be adjusted according to the number of family members. The food package should be increased if it is not enough for the whole family and there is no other source of income.

- Food packages should be designed according to World Food Program (WFP) guidelines for HIV patients starting antiretroviral therapy and TB patients starting treatment. \(^{10}\)

- The exact composition of the food package will depend on the country, but may include:
  - Cereals (maize, rice, wheat bulgur, sorghum, millets, etc.)
  - Pulses (peas, beans, lentils, etc.)
  - Oil
  - Fortified blended foods
  - Sugar, salt
  - Animal products (canned fish, beef and cheese, and dried fish)
  - Dried skimmed milk

- In certain cases it may be more prudent to provide food vouchers instead of actual packages, and this should be considered for the specific implementation context
6.3 Transportation
DR TB patients often are asked to make many trips to the hospital, clinic or laboratory. For this reason, they may have more out-of-pocket expenses due to transportation than other TB patients.

- **Every effort should be made to consolidate the trips required each month.**

- **Reimbursement for transport expenses is an important enabler for DR TB treatment.**
  - Patients should be reimbursed for transportation expenses based on individual need (geographic location and method of transport).
  - If the DR TB Supporters accompany the patient to a clinic visit, they should receive reimbursement for transport.
6.4 Financial support

As many DR TB patients experience economic hardship National TB Programs should consider introducing targeted monetary support plans to reduce treatment adherence barriers. Evidence suggests that financial incentives may enable people to continue treatment by overcoming the financial barriers caused by absence from work to attend appointments, or costs from travel or medical expenses. \(^{11}\)

Studies have found that financial incentives can drive return appointment attendance through a direct cash incentive or free or reduced prices on services. \(^{12, 13, 14}\) It is important to consider adequate targeting and conditions in the design and implementation of the cash transfer schemes so that they are appropriate and have a positive impact on patients. \(^{15}\)

Countries can choose any of the financial support models that are appropriate and feasible for their settings.

6.5 Temporary accommodation

While it is usually best for patients to live with or near their families, there are situations when it is in the interest of the patient to move closer to the treatment facility. National TB programs may arrange such accommodation, or may collaborate with other agencies and stakeholders to do so.

- **Temporary accommodation or hostels may be needed for DR TB patients who:**
  - Live in very remote areas;
  - Need to be monitored closely;
  - Are too ill to go home, but too well to be in the hospital; or
  - Are homeless or have very difficult family situations.

- **Temporary accommodation may be outfitted with all the necessities of living:**
  - Bed and other simple furniture
  - Bedding and blankets
  - Long-lasting insecticide-treated bed nets
  - Cooking stove and fuel
  - Pots and other cooking implements
  - Washing basin, soap (laundry and bath)
  - TV or radio

- **Additional to food packages, cleaning and cooking should be provided for very weak or ill patients.**
6.6 Work

TB usually affects patients during their most productive years. Nearly all TB patients contribute to their family income. The stress of needing income often means that many patients work until their health has completely deteriorated.

- **Patients should be sputum culture negative before returning to work.**
  - Patients should be encouraged to resume work as soon as their sputum is culture negative and they feel physically able to work. This allows patients to reintegrate into society and earn money for their families.
  - Some patients will not want to return to work even if they are in good health, for fear of falling sick again. These patients need counseling and psychological support to facilitate their return to the workforce.

- **Those without skills or jobs should be encouraged to engage in income generating activities such as:**
  - Sewing circles
  - Gardening
  - Raising chickens or pigs
  - Operating phones
  - Shops

- **It may also be a worthwhile investment to pay for school fees for school-age children, or for additional vocational training for adults, such as sign language classes for patients with injectable-related hearing loss.**

- **National TB programs may implement such social support themselves, or may collaborate with other agencies and stakeholders to manage income-generating activities, job training, and education projects.**
Diego* is a patient with drug-sensitive TB and a participant of our endTB project. He receives advice, orientation, and treatment from community health worker, Verónica Quispe, and field technician, Yecela Rodríguez, at the Punchauca Health Center in Carabayllo, Peru on Mar. 17, 2016.
*Name changed

Photo by William Castro Rodríguez / Partners In Health

7. ADHERENCE SUPPORT

Treatment for DR TB is long and often complicated. Success of treatment relies heavily on adherence, which in turn requires:

- A good understanding by the patient of the fundamentals of DR TB and its treatment;
- Commitment from the patient to participate in treatment;
- Support of the patient by the family; and
- Good communication among the provider, the patient, and the family.
7.1 Treatment Support

Patients should be educated on how treatment for DR TB is administered in the given context. Intake of TB medication must be observed throughout treatment and recorded on the Treatment Card. The DR TB Supporter should notify the DR TB Nurse within 24 hours of a missed dose.

- **DOT should be organized in accordance to the needs of the patient.**
  - The DR TB Supporter generally supervises doses in the patient’s home, but in exceptional cases the patient may visit the home of the DR TB Supporter, for example, for reasons of confidentiality.
  - DOT may occasionally be administered in other places, such as the patient’s workplace. Where available, a workplace health facility may be used. In such cases, employers play an important role in supporting adherence and should be engaged as part of the team.

- **In fully community-based DOT:**
  - All doses are observed by a DR TB Supporter in the patient’s home.
  - During the injectable phase, a nurse or another qualified individual should inject the patient at a suitable location.

- **In combined facility/community-based DOT:**
  - Facility health workers supervise the morning dose. The facility should be the one closest to the patient’s home. During the injectable phase, a facility nurse should inject the patient each morning.
  - A DR TB Supporter supervises doses during the evenings, weekends, and holidays.

- **A program may use both DOT strategies, depending on the patient’s situation.**
  - Some patients cannot visit a facility can benefit from community-based DOT. A differentiated approach should be used for patients suffering from physical or mental disability or those with severe illness, or side effects. In addition, vulnerable patients such as children and the elderly should be considered for community-based DOT. Lastly, patients with complex work schedules, or rural patients, far from the facility may be supported by community-based DOT as well.

- **New technologies and tools (e.g. V-DOT, SMS reminders, and different mobile applications) can be used as an alternative method for DOT.**
  - Additional training for health care workers, community health workers and patients will be required.
  - The extent of the use of new technology will depend on resources available.
7.2 Managing side effects and monitoring treatment

Side effects are a major reason for loss to follow up. Side effects can occur at any time during treatment. In most cases these are mild, but occasionally they can be severe. It is important to detect and resolve them early and quickly.

With the advent of Delamanid and Bedaquiline, there are new options for regimen substitution or modification to increase retention in care among DR TB patients. Implementation of active TB drug safety management (ADSM) and monitoring should be in place.

- DOT is an opportunity for early detection of side effects. The DR TB Nurse and the DR TB Supporter should be conversant about the potential side effects that could be produced by the regimen that the patient is receiving. The DR TB Supporter should be able to easily contact the DR TB Nurse 24 hours a day.
  - If side effects are mild, the DR TB Nurse can monitor and manage them with pre-established protocols.
  - If side effects are severe, the DR TB Nurse should arrange for appropriate medical referral and inform the hospital.

- The DR TB Supporter should also monitor for signs that the patient’s condition is improving.
  - Signs that treatment is working includes:
    o Decreased cough and sputum production
    o Weight gain
  - If the patient is having fevers or night sweats, difficulty breathing or hemoptysis, the DR TB Supporter should notify the DR TB Nurse, who will arrange for appropriate medical referral.
7.3 Patient retention and prevention of loss to follow up

Patients should be provided with all the necessary support to keep them retained in care. Social support for adherence and retention in care is particularly needed for vulnerable patients including patients with physical or mental disabilities as well as children, the elderly and those from minority groups. The Practical Guide entitled *Delivering Comprehensive Supportive Care to People with Drug-resistant Tuberculosis* by USAID describes a toolkit for providing supportive care services to people with DR-TB and should be consulted for developing a full supportive care package. Support can be provided through:

1. **Home visits.** Home visits and a home assessment help identify clinical and social challenges that can interfere with retention while on treatment. In addition, many patients with DR TB may have been sick for a long time and may be physically disabled by their disease. The home visit can help identify modifications in the home that may be necessary to help the patient or family in performing activities for daily living.

2. **Early and aggressive management of side effects.** Side effects are the most common reasons for loss to follow up. Early detection will allow the patient to receive timely treatment and will boost retention.

3. **Psychosocial counseling.** Early psychosocial assessment and counseling helps to identify and treat patients with underlying mental illness or those who develop Central Nervous System (CNS) side effects of the medications. Through psychosocial support, patients will be empowered to address social issues pertinent to TB and to TB treatment.

4. **Support and address economic problems.** Many patients are unable to work when they are ill, and they may be the primary wage earners for their family. Patients should be connected to housing, food and clothing services through partners, NGOs and social welfare programs.

5. **Provide support and address substance abuse.** Identify early signs of alcohol and drug abuse. Patients should be encouraged to stop or decrease alcohol/drug consumption as it will interfere with their treatment.

6. **Create a team-based approach with healthcare personnel and the DR TB Supporter.** Ensure that there is a positive relationship between the patient and their healthcare providers. The patient should be treated respectfully and considered part of the DR TB team.

7. **Involve the family and community.** Family is the most important source of psychosocial support for the patient. Community and religious leaders can be helpful if there are community-wide issues such as stigma toward DR TB patients. Patient confidentiality should be protected at all times.

8. **Assessment of patient perspectives is critical.** Administering qualitative surveys to patients, their families, community health workers, and health providers to gather their opinions of the mix of interventions within the community-based model for DR TB care can be used.
8. DRUG SUPPLY CHAIN MANAGEMENT

8.1 Centralized control of second-line TB drugs

TB drugs are ordered and procured by the National TB Program directly or through sub-contracted third parties agencies. Sub-national levels will request drugs based on projected numbers to be enrolled or active patients on treatment. A three-month buffer supply is recommended on the subnational level.

- **At the DR treatment facility, monthly patient drug packs should be assembled by the Pharmacy Team and delivered to the nearest health center or DR TB Supporter.**
  - The pharmacy team is responsible for providing and packing drugs for each individual patient as prescribed. A 30-day supply should be packed for each second-line TB drug and should include drugs for other chronic conditions like HIV and diabetes. The Community Team should verify each patient pack (see Pharmacy Logbook in Appendix IV).

- **All extra drugs, including those from patients who have died during the month, should be brought back to the DR TB treatment facility by the DR TB Supporter.**
8.2 Standardized prescription form

A standardized prescription form can reduce clinician and pharmacy error. The DR TB Clinician fills out the form and passes it to the Pharmacy Team, which prepares the patient drug pack. This form can also be included as part of DR TB clinic follow-up forms and hospital discharge summaries.

The prescription form should include the most commonly prescribed TB and other medications; blank spaces are included at the bottom for uncommonly prescribed medications. The below example is not exhaustive; programs in different countries may choose to add other commonly used drugs.

<table>
<thead>
<tr>
<th>Drug</th>
<th>DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Morning (mg)</td>
</tr>
<tr>
<td><strong>TB Therapy</strong></td>
<td></td>
</tr>
<tr>
<td>Isoniazid</td>
<td></td>
</tr>
<tr>
<td>Rifampicin</td>
<td></td>
</tr>
<tr>
<td>Ethambutol</td>
<td></td>
</tr>
<tr>
<td>Pyrazinamide</td>
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<tr>
<td>Kanamycin</td>
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</tr>
<tr>
<td>Capreomycin</td>
<td></td>
</tr>
<tr>
<td>Levofloxacin</td>
<td></td>
</tr>
<tr>
<td>Moxifloxacin</td>
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</tr>
<tr>
<td>Prothionamide</td>
<td></td>
</tr>
<tr>
<td>Cycloserine</td>
<td></td>
</tr>
<tr>
<td>Linezolid</td>
<td></td>
</tr>
<tr>
<td>Clofazimine</td>
<td></td>
</tr>
<tr>
<td>PAS</td>
<td></td>
</tr>
</tbody>
</table>
### HIV Therapy

<table>
<thead>
<tr>
<th>Drug</th>
<th>Morning (mg)</th>
<th>Mid-day (mg)</th>
<th>Afternoon (mg)</th>
<th>Midnight (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT-3TC - EFV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDF-3TC-EFV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDF-3TC-NVP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZT -3TC -NVP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC-3TC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Adjunct TB Therapy and drugs for common side effects

<table>
<thead>
<tr>
<th>Drug</th>
<th>Morning (mg)</th>
<th>Mid-day (mg)</th>
<th>Afternoon (mg)</th>
<th>Midnight (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopramide</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levothyroxine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delamanid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bedaquiline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imipenem-Cilastatin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meropenem</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin-Clavulanate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.3 Projection of second-line TB drug demand and consumption

- Projection and procurement of second-line TB drugs is a very important activity that is done at the central level by the National TB Program and pharmaceutical agencies in the country.
  - The National TB Program needs to place orders taking into account the lead time needed for second-line medication.
  - Some of the second-line drugs have short shelf-lives, including cycloserine and capreomycin. Deliveries of these drugs should be staggered in order to avoid expiration.
  - For new TB drugs, like Bedaquiline and Delamanid, the National TB Program should work closely with the Global Drug Facility (GDF) to place orders on time. The GDF’s second-line drug projection and procurement tools can be found here: http://www.stoptb.org/gdf/drugsupply/psmtools.asp

- Below are example formulas to calculate orders of second-line drugs. They assume that patients are evenly distributed across weight classes. Once the program has grown, the actual weight distribution of patients in the program can be used for these calculations.

<table>
<thead>
<tr>
<th>Drug (unit)</th>
<th>Quantity to Order</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyrazinamide (500 mg tab)</td>
<td>3 x D x P</td>
<td>Mean consumption is 1500 mg/day</td>
</tr>
<tr>
<td>Kanamycin (1 gr vial)</td>
<td>1 x D x P</td>
<td>Will discard unused portion of vial</td>
</tr>
<tr>
<td>Capreomycin (1 gr vial)</td>
<td>1 x D x P</td>
<td>Will discard unused portion of vial</td>
</tr>
<tr>
<td>Ethionamide (250 mg tab)</td>
<td>3 x D x P</td>
<td>Mean consumption is 750 mg/day</td>
</tr>
<tr>
<td>Cycloserine (250 mg tab)</td>
<td>3 x D x P</td>
<td>Mean consumption is 750 mg/day</td>
</tr>
<tr>
<td>Levofloxacin (250 mg tab)</td>
<td>D x (P/2)</td>
<td>Half the patients are &lt;50 kg (750 mg/day)</td>
</tr>
<tr>
<td>Levofloxacin (500 mg tab)</td>
<td>3 x D x (P/2)</td>
<td>Half the patients are &gt;50 kg (1000 mg/day)</td>
</tr>
<tr>
<td>Clofazimine (100mg caps)</td>
<td>1 x D x P</td>
<td>Children dose 1mg/kg/Day</td>
</tr>
<tr>
<td>Bedaquiline (100 mg tab)</td>
<td>1 x D x P +20 tabs</td>
<td>First Two weeks 400 mg daily, then 200 mg 3 times/week</td>
</tr>
<tr>
<td>Delamanid (50 mg tabs)</td>
<td>4 x D x P</td>
<td>For 6 months</td>
</tr>
</tbody>
</table>

D = Number of days that patients receive treatment in the time period for which you are ordering
P = Number of patients taking the drug
8.4 Don’t forget to budget for…

- **Syringes, needles, and water for injection.** Approved needle disposal containers are also needed for each DR TB Supporter who is providing injections. These disposal containers need to be collected and disposed by the Community DR TB Team according to national protocol.

- **A small supply of first-line TB drugs.** The National TB Program should estimate the small percentage of patients who:
  - Are susceptible to some of the first-line TB drugs. Isoniazid or rifampicin susceptibility is rare, but there will be a few patients who will be using these drugs.
  - Need high-dose isoniazid, a “third-line” drug of unclear efficacy.
  - Do not have DR TB, but are using second-line TB drugs because of allergies to first-line TB drugs.

- **Ancillary drugs for side effects.** Some may be available widely because they are considered essential drugs, but many are not. The National TB Program should ensure that Pharmacy Teams at facility levels have access to sufficient quantities of commonly used ancillary drugs:
  - Anti-emetics: metoclopramide, prochlorperazine
  - Anti-depressants: sertraline, fluoxetine
  - Anti-convulsants: phenytoin
  - Anti-psychotics: haloperidol, risperidone
  - Antihistamines: chlorpheniramine
  - Anti-diarrheals: loperamide
  - For neuropathic pain: amitriptyline
  - Family planning
  - For physical pain and air hunger: opioids
  - For hypothyroidism: thyroxine

- **Ensure that customs processes are started well in advance of the needed arrival of second-line TB drugs and lab reagents.** This will help prevent delays and potential expiration of the drugs.

- **Monitoring tests.** Instruments for most of the basic blood tests for screening and treatment of side effects are available in any hospital. However, additional funds may be necessary for these tests, especially in hospitals where there are DR TB inpatients who require frequent monitoring. The National TB Program should ensure that Laboratory Teams at all facilities have sufficient equipment and reagents to perform all necessary tests (see Section 8).

- **Approved particulate respirators (N95 or FFP2) for hospital staff, laboratory staff, community staff, and DR TB Supporters.**
8.5 Storage conditions in the community

- **For storage packs or containers for second-line TB drugs, consider the following options:**
  - Wooden boxes are durable, but can be difficult to take to and from the pharmacy.
  - Canvas bags are light and convenient, but may tear after several months, so a sufficient supply of replacement bags will be necessary.
  - Synthetic bags are heavier but more durable than canvas bags. Some are insulated and may help protect the drugs from extreme temperatures and direct sunlight.
9. CONSIDERATIONS FOR LABORATORY SERVICES

Decentralized and easily accessible laboratory services will improve diagnostic capabilities and reduce turnaround time (TAT) for receiving patient results. An effective sample transportation network is critical for successful program implementation.

9.1 Ensuring quality sputum sample storage and transportation

- **A well-structured system for sputum collection and transportation should be established.**
  - A sample condition and handling protocol should be established and followed.
  - Sputum samples should be cultured within 72 hours (3 days).
  - For specimens that can be cultured in fewer than 72 hours: Refrigerate at +4 °C until transport or immediately transport to the laboratory for processing.
  - For specimens that will be cultured more than 72 hours after collection: use a 1 percent cetylpyridinium chloride (CPC - CPC; solution of 1% CPC in 2% sodium chloride) to preserve the specimen for up to two weeks. Specimens with CPC in them should not be refrigerated as the CPC will crystalize and be ineffective.
  - CPC tubes should be provided to health facilities on a regular basis, along with instructions on how to prepare sputum samples for transport to the laboratory.
  - CPC is not permitted for liquid media; therefore, specimens decontaminated with CPC cannot be used if the laboratory does susceptibility testing on liquid media.
  - Samples collected in CPC should be cultured on solid media.

- **For areas that are remote from a culture laboratory**, new methods appropriate for peripheral laboratories (e.g., Xpert MTB/RIF®) are becoming more available. These technologies should be implemented to reduce the TAT of test results, however programs need to address the issues of reliable electricity supply and ensure availability of consumables and each specific supply management system.

- **Adequate supplies should be available to ensure test are done when needed and not delayed due to stock outs.**

- **Programs need to ensure all required monitoring tests are available and accessible in order to minimize and provide timely management of adverse events.**
9.2 Improve retention in care among DR TB presumptive cases

A robust system should be established to communicate GeneXpert, LPA and drug susceptibility testing (DST) results in a timely fashion to requesting clinicians at all levels. Different systems may use paper result forms, text messages (SMS, WhatsApp), or the Internet.

- Without a strong communication system, DST results may be lost in transit between the national TB laboratory and the district-level clinicians who ordered the test. The national TB laboratory may not be able to find the clinician who originally ordered the DST.
- The communication systems used and the personnel involved must ensure the safety and confidentiality of patient information.
- The National TB Program should regularly review the records of the national TB laboratory at least monthly for any new patients who have been diagnosed with DR TB. These names and addresses should be communicated to the appropriate person in the respective region/district/facility who will trace the patients and make sure that they are started on appropriate treatment.
- DST results may arrive many months after they are ordered, making it difficult for district-level clinicians to track the patient for whom the DST was ordered.
- The national TB laboratory should routinely inform the district hospital of the newly diagnosed DR cases for tracing and treatment management plan.
- A register (see Appendix V) can be used at district-level facilities to make sure that all DR TB suspects are accounted for and DST results have been received. The Community DR TB Team can evaluate turn-around-time on a regular basis.
9.3 Monitoring tests for side effect screening

- **WHO guidelines recommend screening for side effects that can be caused by second-line TB drugs.** These side effects include acute renal failure, hypokalemia, hepatitis, QTC prolongation and hypothyroidism. The following tests should therefore be available, preferably at the district level:
  - Urea, creatinine, and electrolytes
  - Liver function tests
  - Full blood count
  - Thyroid stimulating hormone
  - Electrocardiogram (ECG)
  - CD4 counts (HIV positive case every 6 months)
  - Pregnancy testing (at baseline and whenever indicated)
  - Blood sugar

- **Point-of-care testing is an excellent way to improve screening for side effects.** When blood tests are done at the district or regional hospital, blood samples may be lost and results may be delayed or lost. For some analyses, handheld devices using cartridges allow results to be read instantly and appropriate treatment started quickly. Some devices are portable and can be taken along to home visits. Specific tests depend on the manufacturer, but the following tests are often available:
  - Urea, creatinine, and electrolytes - Hemoglobin
  - TSH (Thyroid stimulating hormone - rapid test)
  - Pregnancy testing

- **Patients receiving injectables should have their hearing tested during their regular clinic visits, as per guidelines.**

- **ECG should be used for patients receiving Bedaquiline and Delamanid for detection of qtc interval prolongation**
10. QUALITY OF CARE

High-quality services are of the utmost importance for successful, ethical management of DR TB. Acceptable, evidence-based, and rights-based approaches are central to fulfilling the goals of the End TB Strategy. Components of high-quality services include:

- **Assessing quality of care at each step in the care cascade**: Quality improvement projects, run charts and other quality assessments help teams can be used to achieve high standards and maintain quality care.
- **Diagnosis** should be accessible and timely, minimizing the patient’s need to wait in long lines or return to clinic. The scale-up of GeneXpert and LPA as well as the systems needed to inform patients of their results in a timely fashion are critical. The diagnostic tests should be assessed for quality control regularly (See Section 9 Laboratory Section). The turn-around time between taking the sample, informing the patient of his or her diagnosis should be monitored regularly.
- **Initiating treatment**: The time from diagnosis to initiation of treatment is also a critical step in providing quality of care and should be minimized.
- **The prompt and correct management of side-effects** is important to minimize default and improve patient experience and outcomes.
- **Care for the patient**: A patient-centered approach is imperative to providing quality TB care. This means understanding the patient’s experience and assuring that they are treated with respect.
- **Robust supply chain of TB drugs and drugs for secondary effects** is a critical component of a high-quality TB program.

Among other considerations, the following factors are important to providing high-quality, human rights-centric care:

- Managing the conflict between preventing disease transmission and patients’ rights to demand a supportive care environment or to refuse treatment
- Response to stigmatization attached to TB
• Understanding of long treatment periods and the resultant challenges with adherence
• Understanding the risk to health care workers
• Implementation of palliative care and end of life care when treatment options are not effective
• Consideration of research and interventional priorities

10.1 Package of DR TB Services at the Community-Level
The Community-Based DR TB Care Framework in Section 4.1 provides an overall description of critical elements of an effective community DR TB services delivery system. Whereas the previous framework outlines foundation systems - supply chain, training, data management and staffing at different program implementation stages - the following should be considered an essential package of services for DR TB care at the community-level, a selection of which will be relevant or feasible in the given implementation context:

• Access to rapid diagnosis of DR TB
• Access to quality-assured medications for DR TB and their uninterrupted drug supply
• Clinical and laboratory monitoring during the whole duration of therapy
• Management of adverse reactions and other medical conditions
• Trained treatment supporters at the community level
• Psychological and social support and accompaniment to patients throughout therapy
• Efforts to provide community awareness and reduce of stigma
• Infection control and prevention of transmission
• Monitoring and evaluation of DR TB services
• Availability of financial resources and political support
11. CONTINUITY OF CARE

Countries using a hospitalization model for treatment initiation should put more effort and systems to support the patient’s adherence after discharge. It has been documented that there is a risk for a higher loss to follow up after such discharge.

NTPs should develop a discharge protocol, referral forms and systems, a checklist for discharge, and appointment cards for patient follow-up visits. As well, NTPs should establish communication system between community-based health workers and patients and establish social support systems for the patient.

11.1 Discharge from the hospital

- **NTPs should describe the process for patients being discharged from receiving care in a hospitalization model to receiving care in a community-based model in the national guidelines.** A protocol for discharging patients should be included in each hospital or facility treating DR TB patients with a checklist for discharging patients. Clear communication with the nearest health facility and referral system should be established. Decisions should be made regarding where the discharged patients will get their regular monitoring tests and follow up visits. A duplicate discharge note should be sent to the receiving facility and the second copy should remain the patient’s medical record.

- **It is essential that there is good communication before discharge among representatives from the hospital (e.g., clinician or hospital nurse), DR TB Nurse, DR TB Supporter, patient, and family. All parties should:**
  - Agree that the patient is medically stable for discharge.
  - Agree to where the patient should be sent (home or other housing situation such as temporary accommodation).
  - Ensure the pharmacy prepares the correct patient pack before discharge.
  - Prepare transportation from the hospital.
  - Agree on the discharge plan and complete a hospital discharge summary (see Appendix VI).
  - Plan for social support for the patients
  - Provide date for next follow-up visit and monitoring tests
  - Provide the patient with infection prevention and cough hygiene training

- **The DR TB Nurse should perform a home assessment prior to discharge for all patients (see Section 6.1). If adherence issues are identified, then the DR TB Nurse will conduct a follow-up home assessment focusing on adherence issues.**
11.2 Household contact tracing

Upon diagnosis, a list of household contacts should be developed and kept in the patient’s clinical record until the home assessment. During the initial home assessment, the DR TB Nurse screens all household contacts; thereafter, it is the role of the DR TB Supporter to regularly screen identified household contacts.

- **Household contacts of DR TB patients are people living in the same household. These may include:**
  - People spending nights in the same room as the patient, including spouses, children, caretakers, etc.
  - People spending time in common living areas.

- All household contacts should receive HIV counseling and testing in high HIV prevalence settings, or if the patient is HIV-positive.

- All children below five years of age should receive a baseline chest X-ray and evaluation by a clinician, even if they are asymptomatic.

- **Adult close contacts who answer yes to any question on the symptom screen should receive:**
  - A chest X-ray
  - A sputum smear, culture, and drug susceptibility test
  - An evaluation by a clinician, preferably the DR TB Clinician. The evaluation should include a history and physical examination.

**Close Contacts**

- Close contacts of DR TB patients should receive careful clinical follow-up for a period of at least two years, especially children. If active TB develops, appropriate DR TB treatment should be initiated.

- Additionally, a list of close contacts from outside the household should be developed and kept in the patient’s clinical record until the home assessment. These contacts include individuals with frequent contact with the patient.

- The routine use of second-line drugs for chemoprophylaxis in DR TB contacts is currently not recommended.
11.3 Follow-up after completion of treatment

After completing treatment, each patient should be followed for the next two years with clinical and bacteriologic screening in accordance with the National TB Program guidelines.

- **Patients should be instructed to return to the health facility for evaluation in case they experience recurrence of TB symptoms.**

- **Household contacts should be instructed that the risk of developing DR TB continues after the patient has been cured and that they should report to the health facility if they develop any TB symptoms.**

- **Proper referrals for other medical and social services should be put in place prior to discharge from treatment. Patients should be referred to the nearest clinic for follow-up of chronic medical conditions (such as HIV or diabetes) that were managed by the DR TB clinical team during treatment.**
11.4 Palliative care

Despite availability of effective treatment options, DR TB remains a life-threatening condition associated with high mortality rate. When all treatment alternatives fail and there is no cure possible, TB programs increasingly recognize palliative and end of life care as an important part of the continuum of care for DR TB patients, though with introduction of BDQ and DLM there are more options for such patients.

Palliative care programs proved to be effective not only in hospital settings but at patient’s home. Community based palliative care models are emerging increasingly, hospice programs in countries with a long history of palliative care provision have good capacity and experience in providing home-based services to patients with far advanced illness and their families. Establishment of effective linkages with primary care, local pharmacies, hospital services and social care providers is necessary for providing home and community based palliative care. Community resources should also be mobilized for adequate patient and family support, availability of separate sleeping arrangement and a suitable caregiver is critical to support the patient.

**Key elements of highly-functional palliative care programs include:**

- Comprehensive assessment, including documentation of prognosis (can be prior to admission), functional assessment, screening for physical and psychological symptoms, and assessment of social and spiritual concerns.
- Pain Treatment
- Screening for Physical Symptoms (pain, dyspnea, nausea, and constipation)
- Dyspnea Screening and Management
- Discussion of Emotional or Psychological Needs
- Discussion of Spiritual/Religious Concerns
- Discussion end of life care options
- Discussion of preferred place for end of life care: hospital, home, hospice, nursing-home
- Family Evaluation of Palliative Care
11.5 Additional considerations

Some patients may need special protocols and considerations for treatment. These protocols should be developed at a national level and disseminated to all regions or districts. Groups of patients may include:

- People living with HIV
- Children
- Pregnant women
- Older adults
- People living with diabetes
- People who abuse alcohol or drugs
- Segregated communities (Prisoners, soldiers, displaced persons, etc.)
- Health workers
12. MONITORING AND EVALUATION FRAMEWORK

12.1 Monitoring, Documenting and Reporting

- All NTPs should develop a monitoring and evaluation framework for DR TB which includes community-based care for DR TB with minimum requirements on recording and reporting tools according to WHO recommendations and the National DR TB guidelines.

- Programs should add qualitative and quantitative indicators to capture information on patient adherence (e.g. adverse events (AEs), severe adverse events (SAEs), drugs, other clinical information, HIV, DM, hypertension).

- Establishing quality indicators is highly recommended (i.e. Number of doses missed by patient and others). High treatment success and low unfavorable treatment outcomes for community-based DR TB models can be used as a proxy for successful community-based programs.

12.2 Treatment Card for patients receiving second-line TB drugs

There should be two copies of the Treatment Card:

- One copy should be given to the DR TB Supporter, who is responsible for recording all doses. Generally, the patient should not keep the Treatment Card, but this will depend on the National TB Program protocol.

- One copy is kept in the clinic outpatient file.

- At each monthly medical consultation, the information from the treatment card kept by the DR TB Supporter should be transferred to the treatment card kept at the clinic.

- Any changes to the treatment regimen should be noted on both Treatment Cards.
12.3 Use of technology

The DR TB cascade of care can be centralized, unified, and made more efficient with the implementation of mHealth tools. mHealth stands as a cost-effective solution to reduce user error, to increase patient adherence, and to manage co-morbid conditions in a cohesive manner with minimal additional burden to pharmacists, providers, and patients, especially in comparison to manual alternatives.

In the 2017 update of the WHO Guidelines for treatment of drug-susceptible tuberculosis and patient care the use of mobile technology will continue to play a large role in patient follow-up, treatment adherence and monitoring. Examples can be SMS reminders for appointments, Video Psychological Support and Counseling as well as V-DOT or Video observed treatment (VOT). VOT may replace DOT when the video communication technology is available and it can be appropriately organized and operated by health-care providers and patients. Geo-mapping of DR TB patients electronically is another useful tool for TB programs, to address hot zones and design interventions accordingly based on patient’s locations.

NTPs should evaluate the available technologies and make their choice based on cost, effectiveness and possibility of scale up.
13. COSTING AND VALUE-ADDED OF COMMUNITY-BASED CARE FOR DR TB

NTPs are advised to develop or modify a costing tool for financing community-based care for DR TB as well as demonstrating the value-added of providing treatment and care for DR TB at the community level. For national planning and budgeting the WHO’s Planning and Budgeting Tool for Tuberculosis Control: User Manual is recommended. Additionally, The Global Fund’s impact evaluation has been used to demonstrate deaths averted and lives saved.
14. FREQUENTLY ASKED QUESTIONS

- **Does treating patients at home pose a risk to the community?**
  In reality, by the time the majority of patients have been diagnosed with DR TB, they have been infectious for months or even years. This means that their close household contacts may already be infected. Taking the patient out of the home does not change this fact. Rather, it is important to explain to the family members how to decrease the risk of developing active TB disease, to explain the symptoms of active TB, and to implement a system of screening household contacts of DR TB patients.

- **Isn’t it important to isolate patients with DR TB?**
  Isolation is less important than treatment. It is very difficult to truly isolate a TB patient. Hospitals, even those designated for the treatment of DR TB, are usually not adequately equipped for isolation of patients with airborne infections. Nosocomial transmission is very common, and is dangerous for other patients as well as hospital staff. Effective treatment, on the other hand, results quickly in a non-infectious patient, no matter where the patient is.

- **Is daily treatment support necessary?**
  DOT is especially important for DR TB treatment. Second-line TB drugs have many side effects and DR TB treatment is very long. Most patients will default without daily support. It is also important to monitor patients for serious side effects. DOT should be provided in a supportive, rather than punitive, manner.

- **What is compensation for DR TB Supporters?**
  DR TB Supporters should be compensated for their time and effort in supporting patients. Sometimes DR TB Supporters are given means to accomplish their duties (e.g., transport reimbursement, basic tools and materials); this is NOT compensation. Compensation is above and beyond reimbursement of the out-of-pocket costs of doing the job.

- **Why do DR TB Supporters need to be compensated for their work?**
  Reciprocity is an ethical principal to reward (“compensate”) someone who does a service for benefit of the community. It is true that there are some people who will participate in community health work – even to expose themselves to significant risk – for no compensation. However, in many communities, this is not feasible as a long-term strategy, because people need a way to put food on the table. Compensation of DR TB Supporters creates a more effective community-based program. It is expensive to continually recruit and train new people to replace those who left because their work was not sufficiently rewarded.
• **Do enablers such as food packages and transportation reimbursement improve TB treatment outcomes?**

Yes. One of the most important TB treatment outcomes is patient adherence. There is credible evidence that food packages and transportation reimbursement are powerful enablers that improve patient adherence to TB treatment. There are numerous ongoing studies that are looking at the effect of nutritional supplements on TB treatment outcomes. Additionally, food packages ensure that TB patients and their family, who may not have a source of income due to TB disease, still have access to food. Transportation reimbursement allows consistent access of the patient to treatment facilities which helps enable adherence.

• **Why are shorter MDR-TB regimens needed?**

The duration of the longer MDR-TB treatment regimens and the toxicity of certain agents composing them discourage many patients from completing the treatment as prescribed. As well, the high cost associated with the implementation of the regimens poses a problem at the health systems level. Attempts to reduce the length of treatment and to use a combination of medicines which is more tolerable, more effective and less expensive have been ongoing for several years. More recently, a standardized treatment regimen lasting 9 to 12 months has been reported to give relapse-free cure in more than 85% of selected MDR-TB patients, with adverse reactions typical of those expected when using these second-line TB medicines.

• **Which is the shorter MDR-TB regimen that WHO recommends?**

The regimen recommended by WHO has been used more recently in different geographical sites and in the STREAM trial. The regimen contains kanamycin (an injectable agent), moxifloxacin, prothionamide, clofazimine, isoniazid, pyrazinamide and ethambutol, given together in an initial phase of 4 months (with the possibility to extend to six months if the patient remains sputum smear positive at the end of month 4), followed by 5 months of treatment with four of the medicines (moxifloxacin, clofazimine, pyrazinamide, and ethambutol). Earlier cohorts used gatifloxacin instead of moxifloxacin when this medicine was still available on the market.

In summary: 4-6 Km-Mfx-Pto-Cfz-Z-Hhigh-dose-E / 5 Mfx-Cfz-Z-E

• **When should the shorter MDR-TB regimen be used?**

In the STREAM Trial – a small but well-designed study – the shorter regimen (9 month) failed to demonstrate equivalence with the conventional regimen (20 months). Based on these results, it is prudent not to use the shorter regimen empirically and to use utmost caution when recommending the regimen. This caution includes that:

1. All patients receive individualized DST
2. If a patient is found to be resistant to K, Z, E or prothionamide—the shorter regimen should not be used.
3. Additionally, if a patient has failed Category II the shorter regimen (based on HZE) is not likely to be effective. Further studies are needed with new drugs to discern whether another shorter regimen could be designed.
• **What is the dosage of medicines to use in the WHO-recommended shorter MDR-TB regimen?**

Medicines are taken once per day, all days of the week. If the intensive phase is prolonged the injectable agent is only given three times a week after the fourth month.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Weight group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Less than 30 kg</td>
</tr>
<tr>
<td>Gatifloxacin</td>
<td>400 mg</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>400 mg</td>
</tr>
<tr>
<td>Clofazimine</td>
<td>50 mg</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>800 mg</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>1000 mg</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>300 mg</td>
</tr>
<tr>
<td>Prothionamide</td>
<td>250 mg</td>
</tr>
<tr>
<td>Kanamycin*</td>
<td>15 mg per kg body weight (maximum 1 g)</td>
</tr>
</tbody>
</table>

*For adults over 59 years of age, the dose will be reduced to 10 mg/kg (max dose 750 mg)*

• **Can all MDR-TB patients be treated with the WHO-recommended shorter MDR-TB regimen?**

No. The shorter MDR-TB regimen may be used in MDR-TB patients who do not have the following conditions:

- Confirmed resistance, or suspected ineffectiveness, to a medicine in the shorter MDR-TB regimen (excluding resistance to isoniazid)
- Previous exposure for more than 1 month to a second-line medicine included in the shorter MDR-TB regimen
- Intolerance to one or more medicines in the shorter MDR-TB regimen or increased risk of toxicity (e.g. drug-drug interactions, cardiotoxicity)
- Pregnancy
- Extra pulmonary disease
• How are Bedaquiline and Delamanid used?

Both drugs are used in combination with MDR-TB therapy.

Bedaquiline is a bactericidal drug against *M. tuberculosis* administered first at a loading dose of 400 mg orally once daily for two weeks, followed by 200 mg orally three times weekly for a total treatment duration of only 24 weeks.

Delamanid is a new TB drug with No cross-resistance with any anti-TB drugs, administered 100 mg twice daily (200 mg total daily dose) 7 days per week for 24 weeks. Delamanid can be taken at the same time as the other anti-TB drugs and it should be taken with a light meal.
15. REFERENCES


Additional Resources

16. APPENDICES

1. Sample community health nurse job description
   A nurse located at a health center or facility that will:
   • Coordinate all initiation and treatment of DR TB patients
   • Follow up on all pediatric cases in the community
   • Conduct home assessments for all newly enrolled patients
   • Supervise and train community health workers and treatment supporters
   • Identify patients with any social problems and connect them to appropriate services
   • Submit monthly, quarterly and annual reports
   • Participate in all program activities including planning and reviews
   • Coordinate program activities with other partners and stakeholders in the field
II. Sample monthly performance evaluation

The DR TB Nurse should evaluate the DR TB Supporter monthly. This can be done during the clinic visit at the outpatient facility with both the patient and DR TB Supporter, or it can be done during a home visit.

<table>
<thead>
<tr>
<th>Understands</th>
<th>Circle the appropriate number: 1=poor, 5=excellent</th>
<th>N/A (tick)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient’s TB treatment regimen (names and doses)</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Common side effects of the TB treatment regimen</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>All other drugs taken by the patient and why</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Whether the patient is infectious (smear or culture positive)</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Patient’s HIV status/CD4 count</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Performance (during the past month)</th>
<th>Circle the appropriate number: 1=poor, 5=excellent</th>
<th>N/A (tick)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment card filled properly/good condition</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Patient’s appraisal of the supporter: punctuality, assiduity, supportiveness</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>DOT book filled properly/good condition</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Medication bag kept in good condition</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Provided DOT correctly</td>
<td>1 5</td>
<td></td>
</tr>
<tr>
<td>Notified DR TB Nurse in case of any problems</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Addressed any social problems</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Up to date on own HIV testing</td>
<td>1 5</td>
<td></td>
</tr>
<tr>
<td>Household contact screening</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>
### Sample DOT book

The DOT Book is a notebook kept by the DR TB Supporter. The DR TB Supporter records all medications administered, including side effect medications, prophylaxis, and antiretroviral therapy.

<table>
<thead>
<tr>
<th>Date</th>
<th>Drug</th>
<th>Morning</th>
<th>Evening</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>15/9/07</td>
<td>Z</td>
<td>[●●●●●]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15/9/07</td>
<td>ETO</td>
<td>[●●]</td>
<td>[●]</td>
<td>[CsmyL]</td>
</tr>
<tr>
<td>15/9/07</td>
<td>OFX</td>
<td>[●●●●●]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15/9/07</td>
<td>CS</td>
<td>[●●]</td>
<td>[●]</td>
<td>[CsmyL]</td>
</tr>
<tr>
<td>15/9/07</td>
<td>PAS</td>
<td>[●]</td>
<td>[●]</td>
<td>[CsmyL]</td>
</tr>
<tr>
<td>15/9/07</td>
<td>AZT-3TC</td>
<td>[●]</td>
<td>[●]</td>
<td>[CsmyL]</td>
</tr>
<tr>
<td>15/9/07</td>
<td>EFV</td>
<td></td>
<td>[●]</td>
<td>[CsmyL]</td>
</tr>
<tr>
<td>15/9/07</td>
<td>CTX</td>
<td>[●]</td>
<td></td>
<td>[CsmyL]</td>
</tr>
<tr>
<td>15/9/07</td>
<td>B6</td>
<td></td>
<td>[●●●]</td>
<td>[CsmyL]</td>
</tr>
</tbody>
</table>
IV. Sample pharmacy logbook for preparation of DR TB patient medication packs

The Logbook should be maintained by the Pharmacy Team and kept in the area used to prepare patient drug packs.

<table>
<thead>
<tr>
<th>Date</th>
<th>Patient Registration Number</th>
<th>Time case file Received</th>
<th>Prepared by (Pharmacy Team)</th>
<th>Checked by (Pharmacy Team)</th>
<th>Received by (Community Team)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
## V. Sample testing registrar

<table>
<thead>
<tr>
<th>Name</th>
<th>Sex</th>
<th>Age</th>
<th>DR TB Suspect Number</th>
<th>Date</th>
<th>Sputum Collected</th>
<th>Sputum Sent to Lab</th>
<th>Received Date</th>
<th>Smear Results</th>
<th>DST Results</th>
<th>HIV Test Results (Pos/Neg/Refused)</th>
<th>Treatment Start Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 2
VI. Sample hospital discharge summary

Patient name______________________Registration number____________________

Age__________________Sex__________________

Address______________________________________________________________

Telephone ____________________________

Date of admission_______Date of discharge__________

Facility where the patient will receive outpatient care___________________________

Hospital course:

Procedures received while hospitalized:

Discharge diagnosis:

Follow-up (appointments, labs):
<table>
<thead>
<tr>
<th>Drug</th>
<th>DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Morning (mg)</td>
</tr>
<tr>
<td>TB Therapy</td>
<td></td>
</tr>
<tr>
<td>Isoniazid</td>
<td></td>
</tr>
<tr>
<td>Rifampicin</td>
<td></td>
</tr>
<tr>
<td>Ethambutol</td>
<td></td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td></td>
</tr>
<tr>
<td>Kanamycin</td>
<td></td>
</tr>
<tr>
<td>Capreomycin</td>
<td></td>
</tr>
<tr>
<td>Levofloxacin</td>
<td></td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td></td>
</tr>
<tr>
<td>Prothionamide</td>
<td></td>
</tr>
<tr>
<td>Cycloserine</td>
<td></td>
</tr>
<tr>
<td>Linezolid</td>
<td></td>
</tr>
<tr>
<td>Clofazimine</td>
<td></td>
</tr>
<tr>
<td>PAS</td>
<td></td>
</tr>
<tr>
<td>HIV Therapy</td>
<td></td>
</tr>
<tr>
<td>AZT-3TC - EFV</td>
<td></td>
</tr>
<tr>
<td>TDF-3TC-EFV</td>
<td></td>
</tr>
<tr>
<td>TDF-3TC-NVP</td>
<td></td>
</tr>
<tr>
<td>AZT -3TC -NVP</td>
<td></td>
</tr>
<tr>
<td>ABC-3TC</td>
<td></td>
</tr>
</tbody>
</table>
Adjunct TB Therapy and drugs for common side effects

<table>
<thead>
<tr>
<th>Drug</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Metoclopramide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levothyroxine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delamanid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bedaquiline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imipenem-Cilastatin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meropenem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amoxicillin-Clavulanate</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
VII. Sample monthly report of community-based activities

Report for _____ / _____ (month/year)

<table>
<thead>
<tr>
<th>New patient enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number started on treatment</td>
</tr>
<tr>
<td>Number of new DR TB patients who are HIV-positive</td>
</tr>
<tr>
<td>Number started at home</td>
</tr>
<tr>
<td>Number started in the hospital</td>
</tr>
</tbody>
</table>

List of districts with new DR TB patients:

<table>
<thead>
<tr>
<th>Home visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number started on treatment</td>
</tr>
</tbody>
</table>

List of districts with new DR TB patients:

<table>
<thead>
<tr>
<th>Temporary accommodation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient name</td>
</tr>
<tr>
<td>---------------</td>
</tr>
</tbody>
</table>

List of emergencies (provide a brief explanation of each):

List of patients who were discharged from treatment:

List of patients who died at home:
VIII. Sample transfer form

Patient name ___________________________ Registration number __________

Age ________________ Sex ________________ Date of transfer __________

Receiving clinician __________________________

Date discussed with receiving clinician ________________

Contact information of receiving clinic __________________________

__________________________________________

Reason for transfer:

Presenting symptoms and treatment course:

Please find attached photocopies of the patient’s treatment card and most recent bacteriology and drug susceptibility testing results. For additional information, please contact us.

Clinician’s Name ___________________________ Signature ___________________________

Clinician’s Contact Information __________________________