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# Evaluation of Program

In order to provide the best service possible to those suffering from MDR TB and to ensure that program improvements are made to the benefit of all involved, it is important to have parameters of programmatic success that may be followed at regular intervals.<sup>1</sup> We have relied on several qualitative and quantitative markers in our Peru program to evaluate project successes and areas which need improvement. These will be briefly described in this chapter.

## 8.1 Using qualitative and quantitative methods for program evaluation

Traditional markers of programmatic success often fall under the realm of the quantitative, where patient and population variables are counted and assessed on a larger scale. Given the pilot nature of the Peru project, we have also relied on the use of more qualitative methods. Qualitative methods are widely used in the social sciences to provide a more in-depth view of program performance.<sup>2,3</sup> Some examples of qualitative methods include participant observation, key informant interviewing, life-history interviewing, and focus-group meetings. These methodologies are complementary and have been used by teams of clinicians, epidemiologists, and anthropologists from both Peru and the United States to evaluate our program.

## 8.2 Individual patient outcomes: Necessary markers of success

Given the clinical focus of this Handbook and of our work in Peru, it is not surprising that we regard individual patient outcomes as the most important markers of program success. If patients are not being cured, then the program is failing. To this end, we closely monitor each patient using the following variables:

- Smear status
- Culture status
- Nutritional status
- Changes in chest radiographs
- Presence of adverse effects
- Proportion of doses given correctly
- Completion of treatment
- Cure
- Patient satisfaction

For each individual patient, the goal is to have the best possible outcomes in each of the fields mentioned above. Thus, for example, if a patient is still smear-positive after five months of treatment, the program is not gauged successful for that patient: nutritional status, progression of chest radiograph, and strength of DOT must all be examined. Changes must be made in the patient's regimen to allow for a better individual outcome. This scrutiny is performed monthly for each individual patient.

### 8.3 Larger scale program evaluation

In addition to the parameters used to mark individual successes and failures, there are multiple program-level variables that are used as well. As an examination of the TB literature shows, there are many levels on which program evaluation can be done.<sup>4,5,6,7,8,9,10</sup> Some program evaluations have used more quantitative data while others have focused on qualitative results. Some of the more commonly evaluated variables include:

- Case finding<sup>11,12,13,14,15,16</sup>
- Case holding<sup>17,18</sup>
- Treatment outcomes<sup>19,20,21,22</sup>
- Adverse effects<sup>23</sup>
- Patient compliance<sup>24,25,26,27</sup>
- Impact on policy<sup>28,29,30,31</sup>
- Health education<sup>32,33,34</sup>
- Economic analyses<sup>35,36,37,38,39,40,41,42</sup>
- Operational research

Each of these – and the ways in which they have been used in the Lima project – will be reviewed in detail below.

#### 8.3.1 Case finding

Case finding refers to the percentage of patients with the disease who are identified and started in therapy for their disease. It has been difficult to specify this number to date in our program in Peru, as there exists no system for screening for MDR TB. Using national data for prevalence of MDR TB greatly underestimates the prevalence in the communities in which we work. Our program has data to suggest that patients who fail DOTS for the first time are likely to have drug-resistant disease and we are working closely with the Peruvian NTP to improve screening with DST for such patients.

#### 8.3.2 Case holding

Case holding refers to the percentage of patients who have remained under the care of our program during treatment. We have assessed this by looking at the number of treatment abandoners on a monthly basis. We have also looked at the number of patients who have completed treatment but are still available for routine smear and culture testing during the post-treatment follow-up period. In addition to these data, qualitative interviews have been done with a series of patients to determine their level of satisfaction with the program. They are also asked about areas of the program that work particularly well and those that are in need of improvement. This qualitative data is used to supplement the numbers described above and to provide information that can be used to make program improvements. These interviews are done with groups of patients on a six- to eight-month basis.

#### 8.3.3 Treatment outcomes

Included in treatment outcomes are the number of patients who are smear-positive and smear-negative, the number of patients who are culture-positive and culture-negative, the number of patients who have died, and the number of patients who have abandoned therapy. These numbers are calculated and reviewed by the team on a monthly basis. In addition to analysis of the group as a whole, smaller subgroups are analyzed as well (e.g. patients with HIV, patients who have failed more than one regimen, children, etc.) so that interventions can be focused on smaller populations of patients that may be particularly problematic (e.g. if there are a larger number of abandoners among children, specific child- and family-focused interventions can be attempted).

#### 8.3.4 *Adverse effects*

As outlined in the previous chapter, a number of adverse effects can be expected during the treatment of MDR TB. We have generated data on a small cohort of the first patients treated demonstrating that adverse effects occur at a lower-than-expected rate among our patients. Patients are constantly being monitored for the presence of adverse effects by community health workers, nurses, and physicians. Standardized reporting forms are analyzed on a quarterly basis. These data are used to not only provide information about the prevalence of adverse effects but also to prompt policy interventions that may be needed as well. For example, at the beginning of the project it was noted that some patients had low levels of potassium and magnesium when these electrolytes were checked: this prompted more routine monitoring of these values and aggressive supplementation as well.

#### 8.3.5 *Patient compliance*

Compliance with therapy is one of the cornerstones in the treatment of MDR TB. In our program this is ensured by strict DOT. Doses missed are immediately reported to the nurse in charge who registers them and puts a plan into action to recuperate the doses. Missed doses are reviewed on a monthly basis. This allows the program to assess how effective DOT is and to identify problematic patients who can then be targeted for more intensive interventions. In addition, a series of qualitative interviews are conducted with groups of patients every six to eight months with a focus on compliance. This information provides a context in which missed doses and abandonment can be better understood. We also focus on barriers to compliance (e.g. long working hours) and work to overcome these barriers as they are identified during the qualitative interviews.

#### 8.3.6 *Policy*

The program's influence on local, national and international policy is closely followed by the team. Multiple meetings have occurred with officials on all these levels since the start of the project so that new guidelines could be established for the identification and treatment of patients with MDR TB. Record systems have been reviewed, and as patient load has increased, the program has moved to a system of electronic medical record-keeping. This system is currently being implemented and the staff being trained in its use.

#### 8.3.7 *Health education*

Each year, a large number of patients, families, community members and health personnel participate in educational seminars, the goal of which is to improve their knowledge about MDR TB and help them identify and overcome barriers to care. As more patients have been enrolled, more training sessions have been planned. These sessions are led by physicians and nurses. We have recently implemented a pre- and post-test to assess participant knowledge before and after training sessions. We are also working on in-depth interviewing with health care practitioners to better identify areas in which training is needed.

#### 8.3.8 *Economic analyses*

Cost-effectiveness analyses are an important indicator of program success. When evaluating MDR TB treatment programs for cost, a number of long-term variables must be taken into account. These include costs of ineffective treatment and re-treatment regimens, costs of amplification for individual patients and in terms of epidemic spread, and cumulative costs of adverse effects among other more traditional analyses. Our team is currently performing an economic analysis of the first cohort of patients treated with a focus on these variables.

### 8.3.9 *Operational research*

A variety of other operational research projects can be part of program evaluation. Currently, we are conducting studies of the execution of DOT, evaluating a scoring system for chest radiographs, and field testing training materials. We are also gauging rates of drug resistance among patients failing DOTS for the first time and evaluating the role of surgical intervention. All these will be key in determining the success of this – and any other – MDR TB treatment programs.

## 8.4 **Conclusion**

Evaluation is a key component of any DOTS-Plus program. This should be done on an individual and programmatic basis using both quantitative and qualitative data. A number of variables that can be assessed have been outlined above and we have found these to be particularly useful in evaluation of MDR TB programs. Other, more operations-focused research is also useful in program evaluation and implementation of changes that will improve care to those suffering from MDR TB.