

# Monitoring HIV/AIDS Programs: Participant Guide

A USAID Resource for Prevention, Care and Treatment

## Module 10: Monitoring and Evaluating Clinical Care Programs

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Family Health International



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**MODULE 10:**

# **Monitoring and Evaluating Clinical Care Programs**

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## **Learning Objectives**

*At the end of this session, participants will be able to:*

- Understand the components of clinical care programs that should be monitored
- Develop/adapt and use clinical care program indicators for program monitoring
- Use appropriate monitoring and evaluation methodologies and tools
- Better appreciate the different data uses and how they influence data collection and analysis
- Identify possible evaluation questions and determine when an evaluation is necessary

# Overview of Clinical Care Programs

## 1. Definition of Clinical Care

Comprehensive care, support, and treatment for people living with HIV/AIDS requires that a range of mutually reinforcing clinical and community-based services exist in a well-coordinated system. Clinical care refers to any services provided in a clinic setting: prevention of mother-to-child transmission, voluntary counseling and testing (VCT), antiretroviral drug therapy, and treatment of opportunistic infections.

For the purpose of this training module, however, clinical care for HIV/AIDS refers to treatment with antiretroviral drug therapy (ART) and the prevention and management of opportunistic infections (OIs), including tuberculosis (TB). Prevention of mother to child transmission (PMTCT), voluntary counseling and testing (VCT), and related services are addressed in separate training modules.

### Essential Elements of Antiretroviral Drug Therapy (ART) Program:

- Access to HIV counseling and testing services, whether at a voluntary counseling and testing unit within a facility, at a stand-alone center, or as an integrated part of other health services
- Trained clinicians who can diagnose and treat common HIV-related illnesses and manage ART in accordance with national or international guidelines and standards
- Basic medical records systems
- Access to laboratory services capable of performing routine laboratory tests, such as complete blood count and liver function tests, and, if possible, CD4+ count or total lymphocyte count (TLC)
- Secure and consistent supply of affordable ARV drugs, as well as drugs for HIV-related illnesses, palliation, and prophylaxis for certain OIs

As healthcare facilities develop the essential elements outlined above, program implementers must ensure that the following critical elements for comprehensive care are also addressed:

- Involve PLHA and community groups throughout the process, including community treatment preparedness and development of care services
- Develop national standards and guidelines
- Develop standard operating procedures and/or clinical guidelines for HIV care and treatment at the facility
- Create or expand a functional referral system between clinical care and community support services to link PLHA to a continuum of services that address nutrition, mental health, legal and economic support, and psychosocial and spiritual support
- Use initial assessments to strengthen capacity of the healthcare system, such as data management, health commodity management, upgrading infrastructure, and expanding HIV services
- Develop and implement a monitoring and evaluation plan
- Build capacity and support staff through training, monitoring, and mentoring

## Tuberculosis Programs—Technical and Programmatic Approach

A major goal for targeting TB within the HIV continuum of care is to reduce the burden of TB in HIV-infected individuals and in affected communities through three main activities:

- Strengthen the capacity of TB programs
- Expand TB services to HIV-infected populations
- Integrate HIV prevention and care interventions into TB control activities

### Guiding Principles

The guiding principles of a TB control strategy within the continuum of care are to reduce transmission of *Mycobacterium tuberculosis* by detecting and effectively treating all infectious cases and to avert new cases by providing TB preventive therapy to treat latent TB infection. In areas with high HIV prevalence, this strategy must be accompanied by interventions that address the impact of HIV on the natural history of TB and the needs of TB patients living with HIV. Such interventions will involve the following:

- Working at the individual level to assess and address individual health-seeking behaviors, perceptions of TB, and interactions between TB and HIV
- Working at the community level with a behavior change communication (BCC) strategy to change the perception of TB and of the link between TB and HIV, encouraging greater community involvement in the care of TB patients with and without HIV
- Placing emphasis on building local capacity to design, implement, and evaluate effective interventions linking TB and HIV control
- Collaborating with ministries of health (national TB and AIDS control programs), other government agencies, NGOs, donors, and the private sector to design strategies that strengthen TB control activities and integrate TB and HIV control interventions
- Improving the policy environment to secure adequate resources for TB control
- Reducing stigma and discrimination associated with TB and HIV
- Improving the institutional capacity of developing countries to design, implement, and evaluate TB/HIV programs

Approaches to TB programs include the following:

- **Strengthening the TB case detection and case-holding capability of national TB programs**  
An effective TB program is essential for controlling TB, especially in high-HIV-prevalence areas. To be effective, such programs must achieve both higher cure and higher detection rates, because both decrease the probability of TB transmission. In addition, higher cure rates prevent the development and transmission of multi-drug resistant strains.
- **Establishing HIV services at TB service points**  
Most TB patients in high-HIV-prevalence countries are HIV-infected and do not have easy access to HIV education, VCT, or services to help them manage HIV-related illnesses. Establishing HIV services within TB service points will address the needs of most TB patients. HIV VCT will help alleviate the anxiety of most TB patients (many are aware of the link between TB and HIV) and motivate HIV-negative patients to adopt life-saving skills and behaviors. Knowing their status makes it possible for HIV-positive people to plan for the future and to alter their behavior to protect others. It also makes HIV more visible in communities, thus reducing stigma. HIV education, by filling gaps in knowledge and dispelling misunderstandings, also can reduce stigma and discrimination. Providing appropriate HIV care will also boost the credibility of health workers in TB programs.

- **Introducing TB control activities at HIV service delivery points**  
The majority of HIV-infected people living in areas where TB is prevalent are likely to develop TB during their lifetime. Introducing TB control activities at HIV service points will help strengthen TB programs by increasing TB case detection and cure rates and by reducing the number of people who develop TB from reactivation of latent infection.
- **Managing HIV-related TB through training and capacity-building**  
This program area's objective is to build capacity for effective and sustainable HIV-related TB services by increasing understanding of the interaction between TB and HIV.

### **Opportunistic Infections**

An opportunistic infection (OI) is defined as an infection caused by organisms that would not cause disease in a person with a properly functioning immune system. OIs may be bacterial, viral, fungal, or protozoan. People with HIV/AIDS are especially susceptible to OIs due to the following:

- Immune system suppression
- Psychological stress that can affect the immune system
- Nutritional depletion

Co-infections with pathogens such as TB and malaria increase the HIV viral burden and accelerate progression of HIV. Many people first learn about their HIV-positive status when they are diagnosed with an OI, and this usually does not occur until the patient is at an advanced stage of disease. The natural history of HIV involves a progressive loss of CD4 T lymphocytes, and as the CD4 level declines, the risk of contracting OIs increases.

The context for OI prevention in resource-constrained countries is very different from what exists in a non-resource-constrained environment. Common OIs in resource-constrained countries include:

- Tuberculosis
- Pneumococcal disease
- Non-typhoid salmonellosis
- Cryptococcosis
- PCP
- Bacterial infections
- Penicilliosis

Indications for prophylaxis in resource-constrained countries include use of the World Health Organization clinical stages and, where possible, CD4 count and viral load.

## **Monitoring Clinical Care Programs**

### **1. Setting Program Goals and Objectives**

Without clear objectives, monitoring and evaluation is difficult and, in some cases, impossible. As you remember from the earlier modules, the first step in developing a monitoring and evaluation plan is to set program goals and objectives that provide the framework around which a monitoring and evaluation plan is designed.

### **2. Definition of Monitoring**

Monitoring involves tracking the key elements of an ongoing program over time (inputs, process, outputs, and assessing quality). Monitoring answers the questions: "To what extent are planned



activities actually realized? How well are these services provided?” Monitoring also assesses the extent to which the way a program is undertaken is consistent with its design or implementation plan.

### 3. Special Considerations Regarding Monitoring Clinical Care Programs

#### A. Using national guidelines and standard operating procedures for monitoring clinical care programs

The focus of this module is on monitoring and evaluating clinical care services from the program management perspective, including monitoring patients’ individual health outcomes. The methodologies used to conduct clinical monitoring of patients vary from country to country and are determined at national level consultations by stakeholders, including the Ministry of Health, physicians, service providers, and HIV/AIDS experts. Guidelines are usually based on the World Health Organization’s *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Guidelines for a Public Health Approach* (June 2002).

- The first step in designing a monitoring and evaluation plan for your clinical care program is to make sure that you have copies of your country’s national guidelines, standard operating procedures, and any clinical protocols that are being used at the health facilities you are monitoring. These documents will contain criteria and standards for important clinical issues such as:
  - When to start antiretroviral (ARV) drug therapy
  - Tests used for laboratory monitoring of patients on ARV drugs and when/how often they should be used
  - When patients should change ARV drug regimens
  - Lists and descriptions of ARV drug regimens
  - ARV drug regimens and considerations for special populations: pregnant women, children, injecting drug users, and people with TB co-infections
  - How to manage and treat opportunistic infections
  - Referral and linkage issues
  - Commodity management Issues
- In designing your monitoring plan, you should focus on the program and clinical performance indicators that are most useful and necessary for adequately monitoring the program.
- You should also keep in mind that treatment regimens and recommendations continue to evolve and may change as the result of research findings, changing resources or capacity at the country level, and the availability of drugs and equipment.

#### B. Confidentiality of Clinical Records

Much of the information collected by health facilities about individual patients is confidential. Any efforts to monitor and evaluate clinical care programs must above all else respect this confidentiality. It is important to ensure that the monitoring system does not increase the risk that an individual patient’s name or health status will be revealed. Review of clinical records containing the names of patients should be restricted to the healthcare providers of the specific facility concerned.

Some ways to gather critical monitoring information while still protecting the patient’s confidentiality include:

- How many people have changed their antiretroviral drug regimens this month?
- What are the most common side effects cited by people on the first-line antiretroviral drug regimen this month?
- How many people have experienced treatment failure (as defined by clinical guidelines) this month?

### C. Management Information Systems

The facilities you are monitoring may or may not have an electronic clinical management information system (MIS) or database for collecting and storing patient data. Patients are assigned a code number so that no names appear in the clinical management information system. The database can be programmed to run reports on selected indicators, thus simplifying reporting and monitoring while protecting patients' personal information.

### D. Involvement of People Living with HIV and AIDS (PLHA) in Planning and Monitoring Services

Ensuring that services meet patients' needs means involving patients in the monitoring of services. How can PLHA be involved in monitoring? At the same time, it is important to consider the potential stigma patients might experience from being associated with the clinic or being known to seek services there.

### E. Other Ethical and Special Issues

What are some other ethical and special issues that should be considered when developing a monitoring and evaluation plan for clinical care services?

- Selection of criteria for beginning ART and development of an individualized ART plan: Can the patient afford lifelong treatment? Are the patient's other HIV care and support needs being met? Can the patient tolerate and adhere to the regimen?
- Cost-effectiveness of monitoring ART protocols.
- Equitable access to ART and treatment for opportunistic infections.
- When to start opportunistic infection/tuberculosis prophylaxis (for adults and children).
- Other issues around stigma.

## What to Monitor

### 1. Developing Monitoring Questions

After setting program objectives, and bearing in mind issues to consider when monitoring (as illustrated in the previous session), it is time to develop monitoring and evaluation questions. If these questions are well defined, they will facilitate the development of your M&E system. M&E questions should focus on each component of the program.

The major areas/issues of clinical care programs that need to be monitored include:

- Program implementation, management, and capacity
- Use of/adherence to protocols and guidelines

- Clinical monitoring of individual patients
- Cost effectiveness
- Adequacy of resources or inputs (e.g., trained personnel, private examination area, testing facilities, equipment, and supplies)
- Staff development, training, supervision, and support
- Management information system
- National guidelines/standards (e.g., appropriateness, awareness, and acceptability to providers)
- Service utilization
- Service delivery: treatment and follow-up; referral system for comprehensive care and support; nutrition, psychosocial, and prevention counseling/education for patients and families; and laboratory services
- Behavior change communication/promotion of clinical services
- Referral system to other support services

What to Monitor	Facilitator says, to illustrate:
<ul style="list-style-type: none"> <li>• Overall project implementation and management</li> </ul>	
<ul style="list-style-type: none"> <li>• Guidelines and procedures</li> </ul>	For treating OIs and TB, ARV drug treatment regimens, clinical procedures, laboratory procedures, systems for maintaining client records, and quality control
<ul style="list-style-type: none"> <li>• Infrastructure and supplies</li> </ul>	Clinical/counseling space, commodities management, and procurement
<ul style="list-style-type: none"> <li>• Human resources</li> </ul>	Staff training and management
<ul style="list-style-type: none"> <li>• Quality of services</li> </ul>	
<ul style="list-style-type: none"> <li>• Patient health status and outcomes</li> </ul>	
<ul style="list-style-type: none"> <li>• Referral systems</li> </ul>	

## 2. Selecting and Using Monitoring Indicators

Monitoring indicators are developed based on objectives and monitoring questions developed during program planning.

Indicators are a necessary component for monitoring clinical care programs. Without indicators, it becomes impossible to monitor program benchmarks (the facilitator should explain benchmarks here). We learned how to select good indicators earlier in this workshop series, and now we will review international-, national-, and program-level clinical care indicators.

This training module is concerned primarily with program-level monitoring. However, when selecting indicators you must be mindful of the international- and national-level indicators for which you will be required to provide data through your routine reporting activities. That is, in addition to collecting data from the indicators you select for monitoring your program, you should ensure that your monitoring systems also collect data in the format and timeframe required by USAID and other international organizations, national programs, and UNAIDS/UNGASS.

## Monitoring Methods and Tools

### 1. Quantitative Monitoring

**Quantitative** monitoring (measuring how much, how many, quantity) tends to document numbers associated with the program, such as how many posters were distributed, how many counseling sessions were held, how many times a promotional radio spot was aired, and so on. Quantitative monitoring focuses on which and how often program elements are being carried out. Quantitative monitoring tends to involve record-keeping and numerical counts. The activities in the project/program timeline of activities should be closely examined to see what kinds of monitoring activities might be used to assess progress. The method for monitoring and its associated activities should be integrated into the project timeline.

### 2. Qualitative Monitoring

**Qualitative** monitoring (quality) asks questions about how well the elements are being carried out. Questions many include: How are people's attitudes changing toward stigma, family planning, care and support? What is the influence of program activities on real or incipient behavior change? How does information permeate communities "at risk"? and so on. To obtain this type of information—something that can also work as a part of the feedback system—such qualitative methods as in-depth interviews and focus group discussions are often used.

### M&E Methods Specific to Clinical Care Programs

Monitoring and evaluation methods specifically for clinical care programs can include (but are not limited to) the following:

- Periodic site assessment visits
- Key informant interviews with patients (e.g., clinic-based exit interviews)
- Chart audits and case reviews using established guidelines to monitor quality of care
- Client surveys
- Special studies to review issues such as factors influencing adherence and factors influencing service utilization
- Laboratory record review
- Periodic assessment of commodity management issues

## Data Analysis and Use

Systematic analysis of program outputs and outcomes helps identify major gaps in effectiveness and efficiency. For example, regularly assessing what proportion of women are tested, initiate antiretroviral therapy, receive nutritional counseling, and comply with antiretroviral therapy helps identify and act upon the major obstacles to the effectiveness of prevention of mother-to-child transmission programs. To later expand a program, it is important to identify successes and to analyze the reasons for successes.

## Evaluating Clinical Care Programs

Evaluation answers the following questions: What outcomes are observed? What do the outcomes mean? Does the program make a difference?

Demonstrating benefits through evaluation will help to verify whether:

- The intervention is successful
- The intervention reaches the beneficiaries
- The intervention benefits the targeted population

Review the essential steps to designing evaluation studies:

- Identify program goal and objectives
- Define the scope of the evaluation
- Define evaluation questions and indicators
- Define methodology
- Design instruments and tools
- Carry out the evaluation
- Analyze data and write report
- Disseminate and use data