



MODULE 10:

Monitoring and Evaluating Clinical Care Programs

Monitoring HIV/AIDS Programs

A FACILITATOR'S TRAINING GUIDE

A USAID RESOURCE FOR PREVENTION, CARE AND TREATMENT



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Monitoring HIV/AIDS Programs: A Facilitator's Training Guide

A USAID Resource for Prevention, Care and Treatment

Module 10: Monitoring and Evaluating Clinical Care Programs

September 2004

Family Health International



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MODULE 10:

Monitoring and Evaluating Clinical Care Programs

This Monitoring and Evaluation series is based on the assumption that Core Module 1 (Introduction to Monitoring and Evaluation) is always the first module, that it is followed directly by Core Module 2 (Collecting, Analyzing, and Using Monitoring Data), which is followed by one or more of the optional technical area modules (Modules 4 through 10), and that in all cases the final module is Core Module 3 (Developing a Monitoring and Evaluation Plan). The specified sequence is shown below:

1. *Core Module 1: Introduction to Monitoring and Evaluation*
2. *Core Module 2: Collecting, Analyzing, and Using Monitoring Data*
3. *Optional Technical Area Modules 4 through 10*
4. *Core Module 3: Developing a Monitoring and Evaluation Plan*

Learning Objectives

The goal of this workshop is to increase participants' capacity to plan and conduct monitoring and evaluation of their HIV/AIDS/STI clinical care programs.

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

Session Overview and Schedule

TIME		TOPIC	TRAINING METHOD
8:30-9:00	30 min	A. Welcome and Review	Facilitator Presentation
9:00-10:00	60 min	B. Overview of Clinical Care Programs	Facilitator Presentation
10:00-10:15	15 min	BREAK	
10:15-11:30	75 min	C. Monitoring Clinical Care Programs	Facilitator Presentation, Group Discussion
11:30-12:30	60 min	D. What to Monitor	Facilitator Presentation, Group Discussion, Small Group Activities
12:30-1:30	60 min	LUNCH	
1:30-2:30	60 min	E. Monitoring Methods and Tools	Group Discussion, Small Group Activities
2:30-3:00	30 min	F. Data Analysis and use	Role-Play, Discussion

Session Overview and Schedule

TIME		TOPIC	TRAINING METHOD
3:00-3:15	15 min	BREAK	
3:15-4:00	45 min	G. Evaluating Clinical Care Programs	<i>Facilitator Presentation</i>
4:00-4:15	15 min	H. Wrap-Up	<i>Q & A Session</i>

Materials

- Flipchart paper and stand
- Markers
- Pens or pencils
- Tape or Blue-Tac
- Evaluation Form
- Handout: Monitoring and Evaluation Questions
- Worksheet: What to Monitor for Clinical Care Programs
- Worksheet: Monitoring Questions
- Handout: Operations, Evaluation, Interventions, and Other Research Topics
- Worksheet: Example Goal and Objectives
- Handout: Client Initial Assessment Form
- Handout: Client Record—Follow-up Visit Form
- Handout: Illustrative Indicators List for Monitoring Clinical Care Programs

The training content is based on the assumption that participants have some familiarity with the concepts of opportunistic infections, tuberculosis, and antiretroviral drug therapy and have completed Core Module 1: Introduction to Monitoring and Evaluation and Core Module 2: Collecting, Analyzing, and Using Monitoring Data.

A. Welcome and Review

8:30-9:00	30 min	A. Welcome and Review	Facilitator Presentation
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8:30-8:45 (15 min)

1. Welcome and Review

Thank participants for arriving on time and tell them in a humorous way that anyone who arrives late will be subject to shame and humiliation from the entire group.

Because this module is being delivered after Core Module 1 (Introduction to Monitoring and Evaluation) and Core Module 2 (Collecting, Analyzing, and Using Monitoring Data), participants will be familiar with each other. Therefore, each morning during this time the facilitator can take about 15 minutes to review with participants the material they learned in the preceding modules. This provides an excellent opportunity to generate energy among the group by asking the participants to quiz each other. This review activity can be light, energetic, and even humorous. Encourage participants to stand up or do something else physical as they ask or answer questions.

8:45-9:00 (15 min)

2. Overview of Workshop Objectives and Agenda

The goal of this workshop is to build your skills in monitoring clinical care programs.

At the end of this session, you 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 your program needs an evaluation

There will be a 15-minute mid-morning break, lunch will be from 12:00 to 1:00, and there will be a 15-minute mid-afternoon break. We will finish the workshop by 4:00 p.m.

B. Overview of Clinical Care Programs

9:00-10:00	60 min	B. Overview of Clinical Care Programs	Facilitator Presentation
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Facilitator Note: The purpose of this session is to set the context for the training by introducing essential elements of clinical care, as defined below. The facilitator will take the participants through an overview of clinical care programs using the information in this session.

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.

10:00-10:15	15 min	BREAK
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C. Monitoring Clinical Care Programs

10:15-11:30	75 min	C. Monitoring Clinical Care Programs	Facilitator Presentation, Group Discussion
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Materials

- Worksheet: Example Goals and Objectives

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.

Ask participants to share their clinical care program goals and objectives. Write them on a flipchart. (Take up to five examples.)

Facilitator Note: Use the following to clarify the definition of a goal:

GOAL: A goal is a general statement describing the hoped-for result of a program. Goals are achieved over the long term and through the combined efforts of multiple programs.

For example, UNGASS goal: A reduction in the percentage of HIV-infected infants born to HIV-infected mothers

Ask participants for the specific objectives of their clinical care programs. Write these objectives on a flipchart so that all the participants can see them. (Take up to five examples.)

Ask participants the following questions:

“Based on what you’ve learned in this workshop series”:

- Are these objectives specific. If not, why?
- Are these objectives measurable? If not, can you make them measurable?
- Are these objectives achievable?
- Are these objectives reasonable? What may be the challenges to meeting the objectives?
- Are these objectives time-bound?
- Do these objectives contribute to attaining the overall goals of the program?

Facilitator Note: Use the following to clarify the definition of objectives:

Objective: An objective is a specific, operationalized statement detailing the desired accomplishment of a program.

A properly stated objective is action-oriented, starts with the word “to,” is followed by an action verb, and addresses the questions of what and when, not why or how. Objectives should be stated in terms of results to be achieved, not processes or activities to be performed.

For example, USAID Expanded Response objective: To have 25% of HIV-infected pregnant women in high-prevalence countries receive antiretroviral prophylaxis to prevent mother-to-child transmission

Facilitator Note: The object of this exercise is not to put individuals who offered these objectives on the spot or to criticize them. Keep an atmosphere of support. For example, affirm that part of the objective is good, but it could be even more specific and is an example of how we can all reflect on our programs’ objectives.

2. Definition of Monitoring

Ask participants to define monitoring, and then use the following to clarify and fill in any gaps:

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

Before we talk in detail about what and how to monitor clinical care programs, let us discuss some special considerations that should be kept in mind when 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.

Group Discussion

Ask participants if any of them are currently responsible for monitoring clinical care programs. If there are some, ask them to speak about their experience using national/clinical guidelines in the design of their monitoring system.

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.

Ask participants if they can think of some ways to gather critical monitoring information while still protecting the patient's confidentiality, such as:

- 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

The facilitator should ask participants the following question:

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

Write the participants' responses on a flipchart.

Facilitator Note: Bring up some of the following topics if the participants do not bring them up

- 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.

D. What to Monitor

11:30-12:30	60 min	D. What to Monitor	<i>Facilitator Presentation, Group Discussion, Small Group Activities</i>
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Materials

- Worksheet: What to Monitor for Clinical Care Programs
- Worksheet: Monitoring Questions
- Handout: Monitoring and Evaluation Questions
- Handout: Illustrative Indicators List for Monitoring Clinical Care Programs

1. Developing Monitoring Questions

The facilitator can begin this session by saying:

“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.

Ask participants to list the major areas/issues of clinical care programs that need to be monitored. Write their responses on flipchart paper. Use the following illustrative list to clarify and fill any gaps:

What to Monitor:

- 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

After this brainstorming process, use a flipchart with the following information to further illustrate the points. At the same time, ask participants to make suggestions to fill in the gaps. Distribute Worksheet: What to Monitor for Clinical Care Programs.

What to Monitor	Facilitator says, to illustrate:
<ul style="list-style-type: none"> Overall project implementation and management 	
<ul style="list-style-type: none"> Guidelines and procedures 	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"> Infrastructure and supplies 	Clinical/counseling space, commodities management, and procurement
<ul style="list-style-type: none"> Human resources 	Staff training and management
<ul style="list-style-type: none"> Quality of services 	
<ul style="list-style-type: none"> Patient health status and outcomes 	
<ul style="list-style-type: none"> Referral systems 	

Facilitator Note: Using the above “What to Monitor” categories is encouraged because these categories will be referred to throughout the day in each part of the training.

After filling in the box, ask the group if this list covers all of the areas that they named above; let them help you adjust it as necessary.

Group Exercise

Divide participants into six small groups and ask each group to generate five M&E questions for each assigned area. Tell them they have 10 minutes.

Group 1: Guidelines and procedures
 Group 2: Infrastructure and supplies
 Group 3: Human resources
 Group 4: Quality of services
 Group 5: Patient health status and outcomes
 Group 6: Referral system

When time is up, reconvene the full group. In a joint discussion session, ask each group to read aloud each of the questions generated. Take comments from the whole group while making clarifications. Ask the full group the following questions:

- What are some of the things you noted?
- What did you learn from the exercise?
- Was it useful? Why?

Facilitator Note: Make sure you include some questions related to USAID-required process indicators (e.g., questions regarding coverage, how many people with advanced HIV are receiving ARV drug treatment, and how many people are reached by community-based care services in the past 12 months) from Handout: List of Indicators for Monitoring Clinical Care Programs.

2. Selecting and Using Monitoring Indicators

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

In this session, we will use the objectives and monitoring questions to review mandatory (required) and other illustrative indicators for clinical care programs listed below.

The facilitator can begin this session by saying:

“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.

Minimum Indicator List for Clinical Care Programs

trainings conducted on clinic-based care
individuals trained in providing clinic-based care
trainings conducted on the provision of OI services
health providers trained to provide OI services
trainings conducted on the treatment of TB/HIV co-infection
healthcare professionals trained in treating TB/HIV co-infection
trainings on the provision of TB prophylaxis
service providers trained in the provision of TB prophylaxis
trainings in other infectious diseases (other than TB) and HIV
service providers trained in treating HIV-infected individuals with infectious diseases other than TB
Total # trainings
Total # service providers trained
current HIV patients less than 15 years old previously enrolled
% current previously enrolled patients that are less than 15
current HIV patients age 15 to 19 previously enrolled
% current previously enrolled HIV patients that are age 15 to 19
current HIV patients age 20 to 24 previously enrolled
% current previously enrolled HIV patients age 20 to 24
current HIV patients age 25 and older previously enrolled
% current previously enrolled HIV patients age 25 and over
Total # current patients previously enrolled
new HIV-positive patients less than 15 years old enrolled
% new patients less than 15 years old enrolled
new HIV patients age 15 to 19 enrolled
% new patients 15 to 19 years old enrolled
new HIV patients age 20 to 24 enrolled
% new patients age 20 to 24 enrolled
new HIV patients age 25 and older enrolled
% new patients age 25 and older enrolled
Total # new patients enrolled
HIV-positive patients less than 15 years old who died
% patients less than 15 years old who died
HIV-positive patients age 15 to 18 who died
HIV-positive patients age 19 to 24 who died
% patients age 20 to 24 who died
HIV-positive patients age 25 and older who died
% patients age 25 and older who died
Total # patients who have died
Total # current HIV-positive patients served
current positive patients eligible for ART
% current positive patients eligible for ART
individuals with advanced HIV infection receiving ART
% eligible patients on ART
patients on ART who received or are receiving adherence counseling
% patients on ART who received or are receiving adherence counseling
people receiving nutritional care and support services
% people receiving nutritional care and support services
people receiving food assistance
HIV-infected individuals receiving treatment for infectious diseases other than TB
individuals receiving drugs for prevention or treatment of OIs
% current patients on OI prophylaxis
patients referred for STI care
% all patients referred for STI care

(continued on next page)

HIV-infected individuals receiving TB prophylaxis
 % HIV-positive patients receiving TB prophylaxis
 # HIV-positive patients diagnosed with active TB
 % HIV-positive patients diagnosed with active TB
 # HIV-infected individuals receiving TB treatment
 % HIV-positive patients receiving TB treatment
 # HIV-positive patients receiving treatment for other infectious diseases
 % HIV-positive patients receiving treatment for other infectious diseases
 # patients receiving psychosocial support
 # people referred to a TB clinic
 # USAID-assisted ART programs

Small Group Exercise

Ask participants to return to the groups they used for the exercise on developing monitoring questions. Ask each group to pick two monitoring questions identified in the previous exercise.

Have each group select appropriate indicators for their two questions. Questions they should ask themselves while they are selecting their indicators include: What does it measure? Are data practical and easy to collect? How will they be analyzed? Is a qualitative or quantitative measure the most appropriate?

Call time, reconvene the full group, and clarify any issues and concerns.

12:30-1:30	60 min	LUNCH
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E. Monitoring Methods and Tools

1:30-2:30	60 min	E. Monitoring Methods and Tools	Group Discussion, Small Group Activities
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Materials

- Handout: Client Initial Assessment Form
- Handout: Client Record—Follow-Up Visit Form
- Worksheet: Monitoring Questions
- Handout: Monitoring and Evaluation Questions

Facilitator Note: Start this session by referring to the main areas of monitoring for clinical care programs identified earlier in the day. Make references to the areas of monitoring questions and indicators requiring quantitative and qualitative methodologies during this presentation.

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.

Refer to the flipchart, the list of monitoring questions developed by the group exercise earlier, and the handout on monitoring and evaluation questions. Indicate quantitative monitoring questions and indicators.

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

Monitoring and Evaluation Tools

Review with the participants some of the issues that they must take into consideration when developing or adapting tools (e.g., the size of the program, specific program components, language and literacy level of program staff, budget, and reporting requirements of the national health management information system).

Group Discussion

Let participants review examples of the data collection tools presently in use in some clinical care sites (see appendix):

- Handout: Client Initial Assessment Form
- Handout: Client Record—Follow-Up Visit Form

Take comments from the group and clarify as necessary. While wrapping up the session, tell participants that information collected on these forms can be useful in analyzing trends over time.

Other items/questions to include in the wrapping-up discussion include: Have any of the participants used similar data collection tools? Do they have difficulties using the tools? Do they find them useful? Are the tools user-friendly?

Invite participants to share thoughts about the data collection and reporting tools, formats, and procedures at their respective sites. Discuss barriers to data collection, recording, and reporting as they are relevant to these interventions.

F. Data Analysis and Use

2:30-3:00	30 min	F. Data Analysis and Use	Role-Play, Discussion
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The facilitator should begin this session by saying:

“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.”

Using Monitoring Data

Playing the role of a Project Monitor (and identifying yourself as such) who is helping an agency in the design phase to plan a monitoring plan, ask the group to answer the following four questions for each of the five scenarios that follows:

1. What kind of data are needed?
2. Where can I find those data?
3. What are the next steps to take based on the data findings?
4. How do you initiate the feedback process with the implementing agency, clinical staff, or project?

Scenario 1: Patients are reporting that they spend too much time waiting to be seen when they come for follow-up visits.

Scenario 2: Health providers are emotionally and physically exhausted and have asked managers to re-examine schedules to find ways to better distribute the workload.

Scenario 3: Although there is money available to purchase medications, the clinic frequently runs out of the drugs it uses in the first-line ARV drug regimen.

Scenario 4: The majority of patients do not adhere to their antiretroviral, TB, or OI drug regimen when they are taking the medication at home.

Scenario 5: Clinical sites make referrals to community services for orphans and vulnerable children, home-based care, and psychosocial support. The clinics want to know if patients are using these referrals and what services they are receiving.

In summary, what can all of these data be used for? Ask the group for their thoughts, and include the following if they are not brought up by the group:

- Improving performance (e.g., hire more staff, train staff, and/or buy more supplies)
- Feedback to program staff (e.g., hold regular staff meetings, including field staff)
- Decision-making about future direction of the program such as scaling-up services/ expanding coverage (e.g., identify new geographical areas and/or other services to be added to program)
- Reporting to donors and policymakers

- Communicating the program’s successes and challenges to the community (e.g., newspaper articles, press conference, or town hall meeting)
- Fund-raising (proposal writing)

Ask participants to share their own experiences with reporting on their programs’ performance and on communicating with donors, government officials, and the community. Identify obstacles and possible solutions to the feedback process.

3:00-3:15	15 min	BREAK
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G. Evaluating Clinical Care Programs

3:15-4:00	45 min	G. Evaluating Clinical Care Programs	<i>Facilitator Presentation</i>
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Materials

- Handout: Operations, Evaluation, Interventions, and Other Research Topics

Ask participants to provide suggestions about monitoring challenges and the next step after monitoring.

Continue by saying:

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

The following are some take-home points about evaluation:

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

Using the Handout: List of Operations, Evaluation, Interventions, and Other Research Topics, discuss standardized outcome indicators.

Encourage participants to decide if an evaluation of their program is recommended. If the answer is yes, discuss the kinds of evaluation questions that should be asked and how, when, where, and by whom will the evaluation be conducted

If time allows, lead a discussion of other areas for inquiry, such as the following:

- Evaluation of clinical guidelines
- Quality of life
- Process evaluation

H. Wrap-Up

4:00-4:15	15 min	H. Wrap-Up	Q & A Session
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Materials

- Handout: Evaluation Form

Ask participants for two major lessons they learned during the workshop.

Write each of the lessons mentioned on a flipchart (or ask a participant to do so).

Distribute the Evaluation Form to participants and ask them to fill it out and submit it before leaving the classroom.

Appendix

Module 10: Monitoring and Evaluating Clinical Care Programs

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Monitoring and Evaluation Questions

1. Have the activities been carried out as planned? If not, why?
2. What population is being reached? Is this our targeted population?
3. Have the targets been met? Have targets been set that are based on population in need?
4. If there are problems with implementation, what are the obstacles? (e.g., lack of inputs; staff performance or attitude; or lack of accessibility, affordability, acceptability, or awareness by the targeted population)
5. Is the commodity management system working well?
6. Are all drugs, laboratory supplies, and equipment available?
7. Is laboratory equipment in good working order?
8. Are the costs of the project within budget?
9. Is this ART/clinical care program cost-effective?
10. Is there a need for technical assistance or other resources?
11. Are financial, supervisory, and program reports complete and timely?
12. Are the needs of patients/clients addressed?
13. Are the resources (infrastructure, trained staff, equipment, ARV drugs, test kits required by protocol, storage, supplies, waste disposal, and commodities) consistently available and in place to meet minimal standards of ART care?
14. What is the average workload for each category of staff (doctors, nurses, counselors, etc.)?
15. What training is necessary for staff (according to job description)?
16. Is the service accessible in terms of location, travel time, and means of transportation?
17. Is the service user-friendly (registration, privacy, cleanliness, efficient procedures, waiting time, hours of operation, and location)?
18. Is there a data recording system (i.e., use of unique identifiers or codes) to ensure the confidentiality of the clients?
19. Do the registration processes afford client privacy?
20. Does the registration process collect the usual demographic data needed, including name, sex, marriage status, occupation and reason for coming to clinic?
21. Are there written policy and procedures in place to protect client confidentiality?
22. Are all staff aware of these policies, and do they follow them?
23. Are condoms available (adequate and consistent supply), affordable, and accessible to the targeted population?

Service Utilization and Activity

24. Who is using the services? (demographic and personal information)
25. Are significant populations or groups not being reached?
26. Are patients being selected for ART/OI prophylaxis and treatment based on national or program guidelines?
27. How many clients are attending each service?
28. Are clients compliant with the monitoring plan?
29. Are clients adhering to their drug regimen?
30. Is there a change in demand for VCT?
31. Are stakeholders involved in planning or monitoring the services?
32. Is the service affordable? How much does it cost for clients to receive ART services (fees, travel costs, and hours of work lost)?
33. Is the service acceptable to the clients (operating hours, service flow, counseling and testing procedures, privacy, confidentiality, waiting time, attitude of staff, information provided, and emotional support)?

34. Is the service adequate? What do clients need that is not being provided?
35. If there are fees involved, is this service affordable for those with little income?
36. What is being done for PLHA who are not eligible for ART?
37. Are clients/patients experiencing an improved quality of life due to the program?
38. What programs are in place to provide care for caregivers?

Staff Development, Training, and Support

39. What are the standards for necessary clinical care program staff training?
40. Has the staff received the necessary training?
41. What training has been provided to staff? How many staff members have been trained?*
42. What kind of training has been provided in supervision?
43. Are continuing education and training available to the clinical care staff at least annually?
44. Are counselors well informed about other issues relevant to clinical care services (MTCT, care and support, TB, etc.)?
45. Are there written job standards and/or position descriptions?
46. Are performance evaluations based on demonstration of competencies specific to the setting?
47. How well does staff follow the protocol?
48. Are the case managers or community lay workers appropriately supervised?
49. How often are all staff meetings held? What are the major issues discussed during these staff meetings?
50. What mechanisms are in place to help staff solve problems?
51. What mechanisms are in place to help staff deal with stress and burnout?
52. How are we caring for caregivers?

Clinical Care: TB/OI

53. Is there a protocol in place that meets national guidelines or, if not available, WHO guidelines?
54. Do the local or national standards meet international standards?
55. Do clinicians accept the protocol?
56. Are the necessary inputs available as required by the protocol?
57. What are the monitoring procedures for patients receiving treatment for OI/TB? Is there a checklist provided for the basic monitoring level?
58. How is adherence defined?
59. What is the rate of adherence to OI/TB prophylaxis and treatment?
60. What measures are in place to improve adherence?
61. Are drug regimens prescribed according to protocol for specific groups (adults/adolescents, children, infants, women of childbearing potential or who are pregnant, people with TB and HIV co-infection, injecting drug users)?
62. What are the levels of drug toxicity or allergies to prophylaxis drugs or treatment drugs?
63. What is the prevalence of OIs for which we are providing prophylaxis (i.e., rates of PCP and Toxoplasmosis if cotrimoxazole is given)? What are the rates of active TB?
64. What is the prevalence of other OIs?
65. Are the local eligibility criteria effective?
66. Do programs follow the eligibility standards?
67. What kind of training has been provided for lab technicians?
68. What is the definition of TB "cure"?
69. Is VCT being provided for TB patients?

70. What training has been provided in DOTS (directly-observed treatment for TB, short course)?

Clinical Care and Monitoring: ART

71. Is there a protocol in place that meets national guidelines or, if not available, WHO guidelines?
72. Do the local or national standards meet international standards?
73. Are the protocols/guidelines accepted by clinicians?
74. Is care being given according to the guidelines or protocol?
75. Are the necessary inputs available as required by the protocol?
76. What are the monitoring procedures? Is there a checklist provided for the basic monitoring level?
77. How is adherence defined?
78. Are drug regimens prescribed according to protocol for specific groups (adults/adolescents, children, infants, women of childbearing potential or who are pregnant, people with TB and HIV co-infection, and injecting drug users)?
79. Does the protocol allow for "drug vacations"?
80. What is the clinical response to ART?
81. What about toxicity?
82. Are the local eligibility criteria effective?
83. Do programs follow the eligibility criteria?
84. How is resistance monitored and reported?

Laboratory

85. What are the current testing procedures (HIV screening, diagnostics, ART monitoring)?
86. Does the testing protocol meet national or local guidelines/standards?
87. How consistently is the laboratory testing protocol used?
88. How long must clients wait to receive their test result?
89. How much does the testing protocol cost? Is it cost-effective?
90. Is the HIV testing protocol the most appropriate given local conditions? If not, how can it be improved?
91. How is client confidentiality managed throughout the blood collection, testing, and reporting procedures?
92. Are the standard operating procedures for the laboratory being observed?
93. Is the laboratory functioning as planned?
94. What quality assurance mechanisms are in place for the laboratory?
95. How are the commodities (lab kits, reagents, drugs, etc.) being managed? Are they available?

Nutritional Counseling and Services

96. Do patients on ART receive nutritional assessment and counseling at each visit (or according to protocol)?
97. Does the nutritional status of patients receiving nutritional assessment and counseling at each visit improve?
98. How many of the patients receive nutritional support or are enrolled in food/nutrition programs?

Patient and Family Education and Counseling (Prevention, Care, and Support)

99. Are patients receiving education and counseling services according to guidelines?
100. What topics or issues are covered in these sessions?

101. What is the quality of this counseling?
102. Are patient educational and counseling needs met?

Support Systems

103. How are clients monitored or supported outside of the clinical setting?
104. Is the monitoring system working?
105. What are the adherence rates? What are the major reasons that clients do not adhere to the regimen?
106. What interventions or activities are in place to promote adherence? Are they effective?

Referral System and Coordination of Community Services

107. Does the referral system include:
 - TB diagnosis and treatment?
 - Opportunistic care (including STIs)?
 - Hospital in-patient care?
 - Nutrition (feeding programs, counseling/education)?
 - Palliative treatment?
 - Psychosocial counseling?
 - PLHA support groups?
 - Spiritual care?
 - Legal expertise?
 - Home-based care?
 - Family support/respite care?
 - Clinical care services?
 - Income generating activities?
108. Does the service site have a list of local healthcare providers and institutions that agree to treat and care for HIV-positive persons?
109. Are clients empowered to inform their healthcare providers about their HIV status?
110. If their HIV-positive status is known, does stigma prevent patients from going to the referral sites for other kinds of care services?
111. Is there a method to follow-up client referrals?
112. What follow-up or case management services are provided at the VCT sites or elsewhere in the community?
113. If the testing is anonymous, do the referral sites accept the codes?
114. How many people are being referred to clinical care services?
115. How do they access the clinical care site?
116. Is this system working? How are referrals followed up?
117. How are people made aware of the service? How are they referred?
118. Are there technical working groups, forums, or meetings for service providers or district advisory teams in place? If so, how often do they meet and what are the major issues or topics discussed? If problems are identified, how are they addressed?

Behavior Change Communication/Service Promotion

119. How is the service being promoted or publicized? How aware are clients of the service? What are the referral sources?
120. What communication channels or methods are being used to inform the public about clinical care?

121. Do the messages reduce stigma and discrimination, convey the availability of high quality clinical care services, and encourage the targeted population to use the clinical care service by explaining the benefits?
122. What materials have or are being developed? Who is the targeted audience? Is the targeted audience based on epidemiological or site data? What is the process for designing the materials?
123. How many materials have been distributed?
124. Does the service disseminate information on behaviors that improve health?
125. How is this information disseminated (print, radio, television, Internet, outreach workers, pamphlets, posters, street plays, and/or discussion groups)?
126. Is information targeted to specific populations?
127. Is the media's use of the information tracked?
128. Has there been collaboration with the local media to develop news or features?
129. Does the clinical care service sponsor community meetings or group educational sessions?

Evaluation of Intervention and Effectiveness of ART Programming

130. Does an ART program help to normalize HIV and promote community acceptance? Is stigma reduced?
131. Is this ART intervention making a difference (quality of life)?
132. Is ART feasible in this setting? Can it be sustained?
133. What is the cost effectiveness of the ART program?
134. How can this ART introduction program be brought to scale?
135. How acceptable is the ART program to clients attending VCT centers and patients attending HIV clinics at the hospital?
136. What are the appropriate criteria (clinical, biological, social, and economic) for starting, switching, and stopping treatment?
137. What are feasible ways to implement surveillance for drug resistance?
138. What is the most efficient way to order, stock, secure, distribute, and use ARVs in resource poor settings?
139. What is patients' willingness and ability to pay for the ART interventions?
140. What is the feasibility of the ART program in a resource poor setting?
141. How can ongoing financing of ART be developed?
142. What is the impact of the ART program on the community perception of HIV or on stigma?
143. What are the determinants for improving ART adherence?

Illustrative Indicators List for Monitoring Clinical Care Programs

trainings conducted on clinic-based care
individuals trained in providing clinic-based care
trainings conducted on the provision of OI services
health providers trained to provide OI services
trainings conducted on the treatment of TB/HIV co-infection
healthcare professionals trained in treating TB/HIV co-infection
trainings on the provision of TB prophylaxis
service providers trained in the provision of TB prophylaxis
trainings in other infectious diseases (other than TB) and HIV
service providers trained in treating HIV-infected individuals with infectious diseases other than TB
Total # trainings
Total # service providers trained
current HIV patients less than 15 years old previously enrolled
% current previously enrolled patients that are less than 15
current HIV patients age 15 to 19 previously enrolled
% current previously enrolled HIV patients that are age 15 to 19
current HIV patients age 20 to 24 previously enrolled
% current previously enrolled HIV patients age 20 to 24
current HIV patients age 25 and older previously enrolled
% current previously enrolled HIV patients age 25 and over
Total # current patients previously enrolled
new HIV-positive patients less than 15 years old enrolled
% new patients less than 15 years old enrolled
new HIV patients age 15 to 19 enrolled
% new patients 15 to 19 years old enrolled
new HIV patients age 20 to 24 enrolled
% new patients age 20 to 24 enrolled
new HIV patients age 25 and older enrolled
% new patients age 25 and older enrolled
Total # new patients enrolled
HIV-positive patients less than 15 years old who died
% patients less than 15 years old who died
HIV-positive patients age 15 to 18 who died
HIV-positive patients age 19 to 24 who died
% patients age 20 to 24 who died
HIV-positive patients age 25 and older who died
% patients age 25 and older who died
Total # patients who have died
Total # current HIV-positive patients served
current positive patients eligible for ART
% current positive patients eligible for ART
individuals with advanced HIV infection receiving ART
% eligible patients on ART
patients on ART who received or are receiving adherence counseling
% patients on ART who received or are receiving adherence counseling
people receiving nutritional care and support services
% people receiving nutritional care and support services
people receiving food assistance
HIV-infected individuals receiving treatment for infectious diseases other than TB
individuals receiving drugs for prevention or treatment of OIs
% current patients on OI prophylaxis
patients referred for STI care

- % all patients referred for STI care
- # HIV-infected individuals receiving TB prophylaxis
- % HIV-positive patients receiving TB prophylaxis
- # HIV-positive patients diagnosed with active TB
- % HIV-positive patients diagnosed with active TB
- # HIV-infected individuals receiving TB treatment
- % HIV-positive patients receiving TB treatment
- # HIV-positive patients receiving treatment for other infectious diseases
- % HIV-positive patients receiving treatment for other infectious diseases
- # patients receiving psychosocial support
- # people referred to a TB clinic
- # USAID-assisted ART programs

Illustrative Cost-Effectiveness Indicators

- # PLHA who can pay for ART, OI, or TB treatment
- % patients eligible for ART program who are able to pay the service fees
- Number and percent of sites that apply cost-sharing and user-fee schemes
- Costs of each component (e.g., training) have been calculated
- Cost of ARVs: free or partial cost recovery
- Cost of treating OI and related illnesses (e.g., Candidiasis, Toxoplasmosis)
- Cost of treating common illnesses (e.g., malaria, upper respiratory tract infections)
- Cost of providing simple diagnostic services (e.g., full blood count)
- Cost of hospitalization and medical consumables
- Sources of funding

Illustrative Outcomes, Effectiveness of Programs, and Impact

1. Number of incident cases of OIs in patients taking ART
2. Number and percent of patients presenting toxicity or adverse reaction from ART
3. Percent of patients having increased CD4 counts after starting ART
4. Number and percent of patients who die during ART
5. Number of hospitalizations in patients on ART compared to those not on ART
6. Clinical response: mean CD4 count or other laboratory monitoring data, body mass, nutritional status
7. Pathological events during follow-up
8. Adherence per regimen
9. Determinants of adherence
10. Mortality due to HIV-related illnesses in those on ART compared to those not on ART
11. Adherence measurements in OI prophylaxis and ART
12. Disease progression profiles
13. Incidence of immune reconstitution syndromes
14. Secondary resistance in patients on ART
15. Incidence/prevalence of TB
16. Incidence/prevalence of OI
17. Incidence/prevalence of HIV

Operations, Evaluation, Interventions, and Other Research Topics

The following questions are illustrative and relate to clinical care activities. However, they also address clinical care evaluation within the context of a comprehensive care and support program.

Knowledge, Attitudes, and Behaviors

1. What is the impact of ARVs on prevention behaviors?
2. Have clinical care programs changed community attitudes around stigma?
3. What is the impact of ARV availability on family and community attitudes toward people with AIDS? Does availability of ARVs change mothers' breastfeeding decisions (mixed or exclusive)?
4. Has there been a change in behavior among people who know their serostatus?
5. What type of care, support, and treatment interventions will reduce stigma and discrimination in the community and among healthcare providers?

Cost

6. What is the cost per client to provide clinical care services?
7. Are the models of clinical care service delivery the most cost-beneficial and most cost-effective to the setting?
8. How much does it cost to introduce or start up a comprehensive program (by cost category, program intervention, activity, and field level)?
9. How much does it cost to expand or scale-up the project?
10. Are local partners increasingly taking over the funding of the program, thus moving toward financial sustainability?
11. How can clinical care services become financially sustainable?

Service Provision

12. Does integration of VCT into existing STI, TB, and PMTCT services or introduction of STI, TB, and PMTCT services into VCT service provision increase VCT service utilization?
13. What are the clients' willingness and ability to pay for clinical care services?
14. What are the determinants of adherence to ART and OI regimens? What factors contribute to adherence?
15. How equitable is the provision of treatment, and what criteria are being used to select recipients for services?
16. What is the most feasible way to implement a surveillance system for drug resistance?
17. What is needed to improve the motivation and confidence of healthcare workers?
18. What are the minimum requirements (e.g., infrastructure, laboratory, training, and/or drugs) needed to maintain quality of care?
19. How can quality of service be ensured?
20. What is effect of involving PLHA on coverage, use, and success of treatment programs?
21. What processes help ensure the meaningful involvement of communities in designing and implementing clinical care programs?
22. What are community preferences for accessing treatment in terms of sources and types of care?
23. Which entry points (or combinations of entry points) for HIV care are most efficient, acceptable, effective, and feasible (e.g., MTCT, VCT, STI, TB, general outpatient, or HIV clinics)?
24. What is the balance between integrated and vertical clinical care services in relation to quality, sustainability, ownership, and acceptance?

What to Monitor for Clinical Care Programs

- Overall project implementation and management
- Guidelines and procedures (for treating opportunistic infections and tuberculosis, ARV drug treatment regimens, clinical procedures, laboratory procedures, systems for maintaining client records, and quality control)
- Infrastructure and supplies (clinical/counseling space, commodities management, and procurement)
- Human resources (staff training and management)
- Quality of services
- Patient health status and outcomes
- Referral systems

Monitoring Questions

You have __ minutes for this exercise, so keep your eye on the time. Each section should take about __ minutes. Do not try to make an exhaustive list, rather play with ideas on each section for about __ minutes and then move on to the next section. Use the topic assigned by the facilitator.

1. Brainstorm together and make a list on a flipchart page:
What information do you think is needed to monitor this?

You should also refer to the Handout: Monitoring and Evaluation Questions

Circle in **red** any questions you see regarding monitoring that component of your clinical care services on a monthly basis.

Circle in **blue** the information needed on a quarterly or semi-annual basis.

Circle in **green** the information needed on an annual or end-of-project basis.

2. Discuss the following with your group:

- *Who needs the information?*
- *Why is this information important?*
- *What is the value to the service providers in answering these questions?*
- *How would the information be used?*

Example Goal and Objectives

Goal:

Provide comprehensive clinical care and treatment services, and improve the quality of life* of individuals living with HIV in District X.

Objectives:

1. Strengthen existing services and improve the capacity of clinics to provide ART and OI services
2. Provide quality clinical and community-based services for HIV/AIDS prevention, care, treatment, and support
3. Develop a community-centered model for the provision of comprehensive prevention, care, treatment, and support services in resource-constrained settings

*Defined as individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, and concerns (WHO, 2002).

Client Initial Assessment Form

CLIENT RECORD _____ Hospital _____ ID # _____

Client Name

Date of First Visit

Postal Address _____

Exact Location (description with landmarks): _____

Phone no. (patient or contact person): _____ Contact person at residence: _____

Referred by (circle one):

diagnostic HIV testing walk-in VCT site PMTCT program old patients other

Gender (circle one): M F **Age:** _____

Marital Status (circle one): Single Married Widowed Divorced Cohabiting

children at home: **For women, # pregnancies:** **# live children:**

Comment:

Vital Signs: Height____ Weight____ (measured at clinic) Temperature____ Pulse____ Blood pressure____

Drug Allergies: _____

Current Medications:

Name_____ Dosage _____ # _____ pills ____ times a day

Name_____ Dosage _____ # _____ pills ____ times a day

Name_____ Dosage _____ # _____ pills ____ times a day

Name_____ Dosage _____ # _____ pills ____ times a day

Past ARV exposure Yes No (If yes, list drugs, dates. If discontinued, provide reason.)

Drug_____ Dosage_____ # times a day Duration (taken from what date to what date) _____

Drug_____ Dosage_____ # times a day Duration (taken from what date to what date) _____

Drug_____ Dosage_____ # times a day Duration (taken from what date to what date) _____

Nevirapine for PMTCT:

Yes/No If yes, date(s) of treatment _____ Baby treated? Yes/No If yes, date of treatment _____

History and Physical Exam Findings

Presenting problem (in patient's words)

History of chief complaint(s) (onset, duration, progression, treatment, and response)

SYMPTOM HISTORY AS SCREEN FOR OPPORTUNISTIC INFECTIONS

Condition (HIV-related and other)	Yes	No	If yes, comments
Weight loss			<i>Over what period?</i>
Chronic (>1 month) diarrhea			<i>(Definition: Passing >3 stools/day x 1 month)</i>
Chronic cough			Describe: Production? Duration?
Tuberculosis in past year			Treatment and duration: Other:
Sexually transmitted infections			
Oral thrush			
Visual changes (floaters)			Describe:
Persistent headache			Describe:
Difficulty swallowing?			Describe:

PAST MEDICAL HISTORY

	Yes	No	Comments
Herpes zoster in past five years			
HIV-related conditions in the past. Ask about OI-related symptoms to detect: <ul style="list-style-type: none"> • cryptococcal meningitis • esophageal candidiasis • lymphoma • Kaposi's syndrome 	List:		
Other chronic conditions	Yes	No	
Hypertension			
Asthma			
Heart disease			
Sickle cell disease			
Diabetes			
Other			

PSYCHOSOCIAL HISTORY

children in home _____ For women: # pregnancies _____ # live children _____ Comment:

Circle where applicable: Education: Nil Primary JSS MSLC SEC Tertiary

Occupation: _____ (circle one) Perm Casual Part-time Seasonal Unemployed

Religion (circle one) Muslim Christian Traditional None Other

Habits:

Smoking: Yes/No If yes, type _____ # /day or week _____ duration _____

Alcohol: Yes/No If yes,

Type _____ Amount/day or amount/week _____ Duration: _____

Type _____ Amount/day or amount/week _____ Duration: _____

Type _____ Amount/day or amount/week _____ Duration: _____

HIV diagnosis and client and family response: Disclosed/Not Disclosed Supportive/Not

Supportive

Sources of emotional support:

Other:

Physical Exam

General description of patient presentation:			
Physical Findings			Comment/Description
General Appearance			
Pale	Yes	No	
Febrile	Yes	No	
Dehydrated	Yes	No	
Jaundiced	Yes	No	
Peripheral edema	Yes	No	
Other findings			
Lymphatic System			
Lymphadenopathy	Yes	No	Describe location, consistency, size of enlarged nodes
Skin			
Rash (e.g., pruritic papular eruption)	Yes	No	
Abscesses	Yes	No	
Kaposi's lesions	Yes	No	
Herpetic lesions (e.g., zoster)	Yes	No	
Seborrheic dermatitis	Yes	No	
Fungal infection	Yes	No	
Other findings			Describe abnormal findings
Oral			
Oral hairy leukoplakia	Yes	No	
Oral thrush	Yes	No	
Other findings			Describe findings
Respiratory			
Rate:			
Labored breathing (dyspneic)	Normal	Ab-normal	Describe abnormal findings
Wheezing	Yes	No	
Intercostal recession/ Subcostal recession/ flaring of the alae nasae	Yes	No	
Auscultation findings (Describe)	Normal	Ab-normal	
Cardiac			
Heart rate and rhythm	Rate:	Rhythm :	
Auscultation findings: normal, murmurs, etc.	Normal	Ab-normal	Describe abnormal findings
Genitalia			
Vaginal/urethral discharge	Yes	No	Yellowish/Whitish/Greenish/Brownish/Purulent/Other (Specify)
Genital ulcer, other lesion	Yes	No	Describe lesion(s)
Inguinal node enlargement	Yes	No	
Other findings			Describe abnormal findings

Breasts						
Lumps, masses	Yes	No				
Discharge	Yes	No				
Gastrointestinal						
Hepatomegaly	Yes	No				
Splenomegaly	Yes	No				
Tenderness	Yes	No	Describe findings, including site			
Other findings						
Neurological						
Orientation to time, place person	Normal	Ab-normal	Describe abnormal findings			
Speech	Normal	Ab-normal				
Neck stiffness	Yes	No				
Kernig's, Brudzinski's sign	Yes	No				
Blindness one/both eyes	Yes	No				
Hemiplegia/paresis (R/L, both)	Yes	No				
Numbness of extremities	Yes	No				
Other findings			Describe findings			
ARV and OI Assessment (Eligibility Criteria are listed below. If all responses are yes, then patient starts ART.)						
Response to past treatment, if applicable:						
WHO clinical stage (circle)	I	II	III	IV		
Performance scale	1	2	3	4		
ARV Assessment Criteria	Yes	No	<i>To Be Completed Over 1-2 Visits</i>			
CD4 below 250	Yes	No				
WHO Stage III or IV	Yes	No				
Resident of Many or Yilo Krobo	Yes	No				
Disclosure to selected other person	Yes	No				
Pre-treatment visit to home	Yes	No				
Complete at least one pre-treatment adherence counseling session	Yes	No				
Normal LFT, RFT	Yes	No				
OI Prophylaxis Assessment (Stage II, III, IV): If yes to any of the below conditions, treatment before prophylaxis may be indicated. Investigate further before starting prophylaxis.						
Cotrimoxazole screen	Yes	No	Yes	No		
Cough			Jaundice			
Allergy			Pregnant			

Recommendation OI Prophylaxis: Yes/No

Diagnosis _____

Differential diagnosis: _____

PLAN

Admission: Yes/No **Laboratory** _____

X-ray _____

Treatment: 1st Line Regimen—Separate Drugs

Drug	Dose	Important Notes	Selection	Reason
Zidovudine	30mg bid	Causes anemia	Yes/No	
Stavudine	30mg bid if less than 60kg, 40mg bid if >60kg	Can cause peripheral neuropathy	Yes/No	
Lamivudine	150mg bid		Yes/No	
Nevirapine	200mg daily for 14 days, then 200mg bid	Hepatitis, Stevens Johnson Syndrome	Yes/No	
Efavirenz	600mg at night	Contraindication: Pgcy.causes bad dreams	Yes/No	

Treatment: 1st Line Regimen—Combination Drugs

Drug	Dose	Important notes	Selection	Reason
Combivir (Zidovudine 300mg+Lamivudine 150mg)	One tablet morning and evening	Need to add Nevirapine or Efavirenz. Combivir not to be given alone	Yes/No	
Triomune (Stavudine+Lamivudine +Nevirapine)	One tablet daily for 14 days. If no problem one tablet bid.	Need to add Stavudine and Lamivudine every evening for the first 14 days Specific notes on Stavudine, Nevirapine applicable	Yes/No	

Final 1st line ARV selection:

Other drugs_____

ADHERENCE PLAN

Next appointment_____

Referred to_____ for _____

Special comments:

CLIENT RECORD**FOLLOW-UP VISITS**

_____ Hospital
 _____ ID #
 _____ Client Name

Gender (circle): M F Age: ____

Vital Signs:

Weight ____ (measured at clinic) Temperature ____ Pulse ____ Blood Pressure ____

Scheduled Visit? Y / N If yes, did patient come on the date of appointment?
 Y / N

Unscheduled/Sickness visit? Y / N

Patient on: ARV ____ CTX Prophylaxis ____ No ARVs or CTX prophylaxis ____

Patient complaints:

Other Questions			Additional Comments
Cough	Yes	No	
Dyspnea on exertion	Yes	No	
Hemoptysis	Yes	No	
Fever	Yes	No	
Jaundice	Yes	No	
Skin rash	Yes	No	

Adherence for CTX and ARVs			
	Excellent (all days)	Good (5-6 days/week)	Poor (< 5 days/weeks)
CTX (self-reporting)			
CTX (pill count)			
ARVs (self-reporting)			
ARVs (pill count)			
Pharmacy Records (check appointment card)			
ARV refills on time?	Yes	No	
CTX refills on time?	Yes	No	

ARV side-effects (for patients on ARVs): (List. Include onset and what has been used to alleviate symptoms and response to these measures.)

Physical Exam

General description of patient presentation:			
Physical Findings			Comment/Description
General Appearance			
Pale	Yes	No	
Febrile	Yes	No	
Dehydrated	Yes	No	
Jaundiced	Yes	No	
Peripheral edema	Yes	No	
Other findings			
Lymphatic System			
Lymphadenopathy	Yes	No	Describe location, consistency, size of enlarged nodes
Skin			
Rash (e.g., pruritic papular eruption)	Yes	No	
Abscesses	Yes	No	
Kaposi's lesions	Yes	No	
Herpetic lesions (e.g., zoster)	Yes	No	
Seborrheic dermatitis	Yes	No	
Fungal infection	Yes	No	
Other findings			Describe abnormal findings
Oral			
Oral hairy leukoplakia	Yes	No	
Oral thrush	Yes	No	
Other findings			Describe findings
Respiratory			
Rate:			
Labored breathing (dyspneic)	Normal	Ab-normal	Describe abnormal findings
Wheezing	Yes	No	
Intercostal recession/ Subcostal recession/ flaring of the alae nasae	Yes	No	
Auscultation findings (Describe)	Normal	Ab-normal	
Cardiac			
Heart rate and rhythm	Rate:	Rhythm :	
Auscultation findings: normal, murmurs, etc.	Normal	Ab-normal	Describe abnormal findings
Genitalia			
Vaginal/urethral discharge	Yes	No	Yellowish/Whitish/Greenish/Brownish/Purulent/Other (Specify)
Genital ulcer, other lesion	Yes	No	Describe lesion(s)
Inguinal node enlargement	Yes	No	
Other findings			Describe abnormal findings

Breasts					
Lumps, masses	Yes	No			
Discharge	Yes	No			
Gastrointestinal					
Hepatomegaly	Yes	No			
Splenomegaly	Yes	No			
Tenderness	Yes	No	Describe findings, including site		
Other findings					
Neurological					
Orientation to time, place, person	Normal	Ab-normal	Describe abnormal findings		
Speech	Normal	Ab-normal			
Neck stiffness	Yes	No			
Kernig's, Brudzinski's sign	Yes	No			
Blindness one/both eyes	Yes	No			
Hemiplegia/paresis (R/L, both)	Yes	No			
Numbness of extremities	Yes	No			
Other findings			Describe findings		
ARV and OI Assessment (Eligibility Criteria are listed below. If all responses are yes, then patient starts ART.)					
Response to past treatment, if applicable :					
WHO clinical stage (circle)	I	II	III	IV	
Performance scale	1	2	3	4	
ARV Assessment Criteria	Yes	No	<i>To Be Completed Over 1-2 Visits</i>		
CD4 below 250	Yes	No			
WHO Stage III or IV	Yes	No			
Resident of Many or Yilo Krobo	Yes	No			
Disclosure to selected other person	Yes	No			
Pre-treatment visit to home	Yes	No			
Complete at least one pre-treatment adherence counseling session	Yes	No			
Normal LFT, RFT	Yes	No			
OI Prophylaxis					
Is the patient on OI prophylaxis?	Yes	No	If no, do OI prophylaxis assessment.		
OI Prophylaxis Assessment (Stage II, III, IV): If yes to any of the below conditions, treatment before prophylaxis may be indicated. Investigate further before starting prophylaxis.					
Cotrimoxazole screen	Yes	No	Yes	No	
Cough			Jaundice		
Allergy			Pregnant		

Recommendation OI Prophylaxis: Yes/No

Diagnosis _____

Differential diagnosis _____

PLAN

Admission: Yes/No **Laboratory** _____

X-ray _____

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Other drugs _____

ARV Status:

a) Start ARV b) Continue ARVs c) Discontinue ARVs d) ARVs at later date

ADHERENCE PLAN _____

Next appointment _____

Referred to _____ for _____

Special comments:



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