

The logo for the Centers for Disease Control and Prevention (CDC). It features the letters "CDC" in a large, white, serif font against a dark blue background. The background has a pattern of thin, white, diagonal lines radiating from the bottom left corner.

SAFER • HEALTHIER • PEOPLE

Program Monitoring Companion

to Antiretroviral Therapy (ART)
Adherence Interventions

2013

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The primary authors of this document were Meredith Noble Calloway, MS, and Stephen J. Tregear, D.Phil., of MANILA Consulting Group, Inc. We also wish to acknowledge the contributions of Dana Conner to writing and layout.

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Chapter 1. Introduction

1.1 Document Overview

The purpose of antiretroviral therapy (ART) for HIV is to decrease HIV-related morbidity and mortality. Successful ART requires taking nearly all doses exactly as prescribed, including frequency per day and time of day. **Medication adherence** is the act of taking medications as prescribed. Medication adherence interventions are interventions designed to increase patients' adherence to medications. **ART adherence interventions** are medication adherence interventions designed to improve adherence specifically to ART. ART adherence interventions focus on not only supporting patients to take medications as prescribed, but also on engaging patients in the intervention program and their self-care.

The aim of the ART adherence interventions described in this document is to support and enable providers to help patients routinely take ART doses as prescribed using structured programs that include attending clinic visits organized to support medication adherence. Although improving medication adherence is the objective of ART adherence interventions, the ultimate goals are to maximize the benefits of ART to improve health.

Target Audience

This document is intended for clinical (medical providers) and non-clinical HIV care providers (social workers, health educators, counselors, and/or peers), including case managers, who serve persons with HIV and are planning to implement an ART adherence intervention.

Purpose

This document is intended to support clinics or agencies planning to implement and monitor one or more of the following four ART adherence interventions:

1. HEART
2. Partnership for Health - Medication Adherence
3. Peer Support
4. SMART Couples

These four ART adherence interventions are included in the CDC's Compendium of Evidence-based HIV Behavioral Interventions. Each has been classified by CDC as an "effective intervention" supported by **good evidence**.^[1] Interventions other than the four ART adherence interventions listed above are outside the scope of this document; however, many of the program monitoring strategies presented in this document are transferrable to other ART adherence interventions.

Inside this chapter:

- ▶ Document overview, with description of the primary intended audience, document purpose, and explanation of what this document does and does not include
- ▶ Other CDC materials and capacity building resources

Information Provided

The document includes:

- **General information on program monitoring:** What it is, and how to do it.
- **Program monitoring questions that the CDC considers high priority:** These questions will be used as examples throughout this document to illustrate how HIV care providers can collect and use data to monitor your program, improve delivery of ART adherence interventions, and ultimately reduce the impact of HIV on individuals and society.
- **Tools for monitoring your program and interpreting your data:** This includes information on outcomes, individual-level and program-level data collection templates, and case studies demonstrating use of program monitoring questions.

This document **is not** a comprehensive text on ART adherence interventions or program monitoring.

Additional CDC resources for capacity building can be found in Table 1 of this chapter. Additional resources related to each of the ART interventions addressed in this document can be found in the corresponding chapters for each intervention.

1.2 Other CDC Materials and Capacity Building Assistance

This document is a companion to CDC Training Modules, available through the CDC Web site. More information on these modules is provided in Table 1. Many additional CDC-endorsed free resources are available to support you and your organization in collecting, reporting, and evaluating monitoring data, as shown in Table 1.

Table 1. Selected Resources for Capacity Building Supported or Endorsed by CDC

Resource	Description	Web site
Effective Interventions – HIV Prevention that Works Web site	Access this Web site for more information on the High Impact Prevention (HIP) interventions CDC supports for HIV prevention, general information, technology assessment guides, a training calendar, and other helpful links.	www.effectiveinterventions.org

Resource	Description	Web site
Evaluation TA (CRIS) Note: only for grantees funded by the Division of HIV/AIDS Prevention (DHAP)	The CBA Request Information System (CRIS) is a portal through which community-based organizations (CBOs) and health departments who are CDC grantees can request capacity building assistance (CBA) from CBA providers. CBA providers offer in-depth assistance with implementing and evaluating HIV prevention interventions and strategies. Types of assistance include developing organizational infrastructure to support monitoring and evaluation plan development and activities, writing SMART objectives, and adapting data collection tools specific to the evidence-based interventions and target population.	www.cdc.gov/hiv/topics/cba
Program Evaluation Web Site	A Web site including content on program evaluation frameworks, steps, standards, and supporting materials, including a self-study guide.	http://www.cdc.gov/eval/index.htm
National Network of Prevention Training Centers	Regional groups that receive CDC funding with the mission of increasing clinicians' knowledge and skills in sexual and reproductive health. They offer training, which you can learn more about on their Web site.	http://nnptc.org/

Chapter 2. Understanding Program Monitoring

This chapter provides an introduction to program monitoring, an overview of main monitoring components, including logic models, and information about how to implement a program monitoring plan for an ART adherence intervention at your clinic. This chapter addresses developing and using monitoring questions, setting objectives, and collecting and analyzing data. Case studies are used to illustrate a program monitoring plan for an ART adherence intervention at a fictitious clinic.

2.1 Program Monitoring Overview

Program monitoring is the overall process of systematically assessing your program using a structured format that is based on data collected during the program.[2] It provides a mechanism for assessing process and outcome performance and for identifying aspects of your program that are working well or that might need to be improved. The processes of program monitoring described in this section can be applied to any program.

When planned and implemented properly, the process of program monitoring can help ensure that your program optimizes the potential for good patient outcomes. Routinely reviewing key aspects of program implementation at regular time intervals using data to address monitoring questions will help you identify areas of your program that need attention, and may even prevent poor clinical outcomes by allowing you to identify and correct issues before they become problems.

The process of program monitoring is meant to be cyclical. As part of a continuous quality improvement plan, program monitoring must be repeated regularly. A common framework to reflect this cyclical process is the Plan→Do→Study→Act/Adjust model (PDSA). Identification of an area of program weakness should prompt adjustments or changes in your program, followed by reassessment. It may be necessary to repeat this process one or more times before objectives of the program are attained.

The overall program monitoring process comprises two sub-processes that focus on different aspects of the overall program: *process* monitoring, and *outcomes* monitoring.

1. **Process monitoring** is the comprehensive and continuous measurement of the delivery of the intervention, whom it serves, and how well delivery of the intervention aligns with that prescribed by the program model. In addition, process monitoring includes the measurement of the adequacy and appropriateness of resources dedicated to implementing the program (inputs), such as funding or personnel training.
2. **Outcome monitoring** is the collection and review of outcome data to determine if the effects seen in the program are those that are anticipated. Outcome monitoring cannot establish causation, or that a set of activities caused certain effects – that would be outcome

Inside this chapter:

- ▶ Program monitoring overview
- ▶ A program monitoring plan in key steps
- ▶ Case studies

evaluation. . For ART adherence interventions, outcome monitoring may include adherence to ART, viral load, HIV-related complication rates, and HIV transmission rates. Outcomes are often grouped into two main categories, *individual patient outcomes*, and *population-level outcomes*.

This document focuses on assessing individual patient outcomes, which can be aggregated to show a full picture of overall program success and potential overall benefit. Individual patient outcomes are measured for each patient and are intended to capture changes in his or her health status. Change may be detectable in some individual patient outcomes shortly after program implementation (such as ART adherence and HIV viral load). Changes in other individual patient outcomes may require more time before they can be measured (such as overall health).

For instance, assessing whether a particular patient had undetectable viral load while in your program tells you whether that patient has had successful ART adherence intervention because it suggests the patient is taking his or her medication as directed. Measuring the percentage of patients in your program who achieve undetectable viral load combines outcomes from individual patients to indicate how your program is doing overall. Individual-level and program-level outcomes may ultimately translate into improved population-level outcomes. If your patients achieve undetectable viral load and are therefore less infectious, they will have a reduced risk of transmitting HIV to other people outside your program. A longer-term population-level outcome would therefore be a reduction in the number of individuals newly infected with HIV. However, measuring population-level outcomes is generally not feasible for most clinicians or other care providers because it is expensive, requires long durations of follow-up, and outcomes may be affected by real-world influences other than the intervention.

2.2 Program Monitoring Planning for ART Adherence Interventions

Any new program should have a monitoring plan prior to implementation. A program monitoring plan typically includes a series of process and outcomes monitoring questions, a list of process and outcomes measures, and a list of criteria describing how the measures will be used to answer one's questions. Included in the criteria are a series of program objectives (or short-term goals), a list of data collection tools, a data management protocol, and an analysis plan. Below, we outline a simple, efficient, and customizable program monitoring plan.

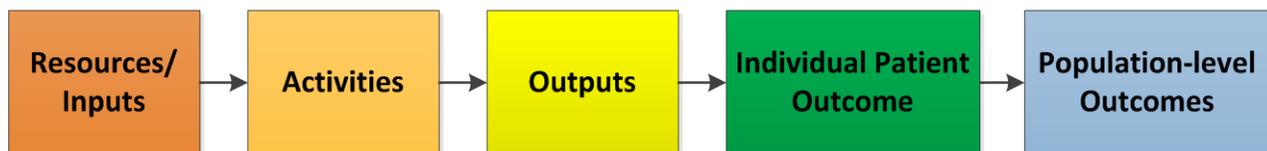
This chapter organizes program monitoring implementation into key steps, as described in the text that follows:

- Step 1: Defining your program logic model
- Step 2: Developing monitoring questions
- Step 3: Setting program objectives
- Step 4: Selecting and defining data elements to answer questions and assess progress
- Step 5: Collecting and routinely utilizing data
- Step 6: Making corrective action, if necessary
- Step 7: Communicating findings

Step 1: Defining Your Program Logic Model

Understanding your program, how it operates, and defining what you hope to accomplish by implementing it is the first step in program monitoring. A **logic model** facilitates results-oriented program planning and implementation by providing a visual schematic of your program. It outlines the logical relationships between the resources invested and the activities conducted in your program, to the outputs, outcomes, and the intended, long-term impact of the program. It lays out the reasoning that links investments in the program with the intended results of the program, as shown in the general schematic below in Figure 1.

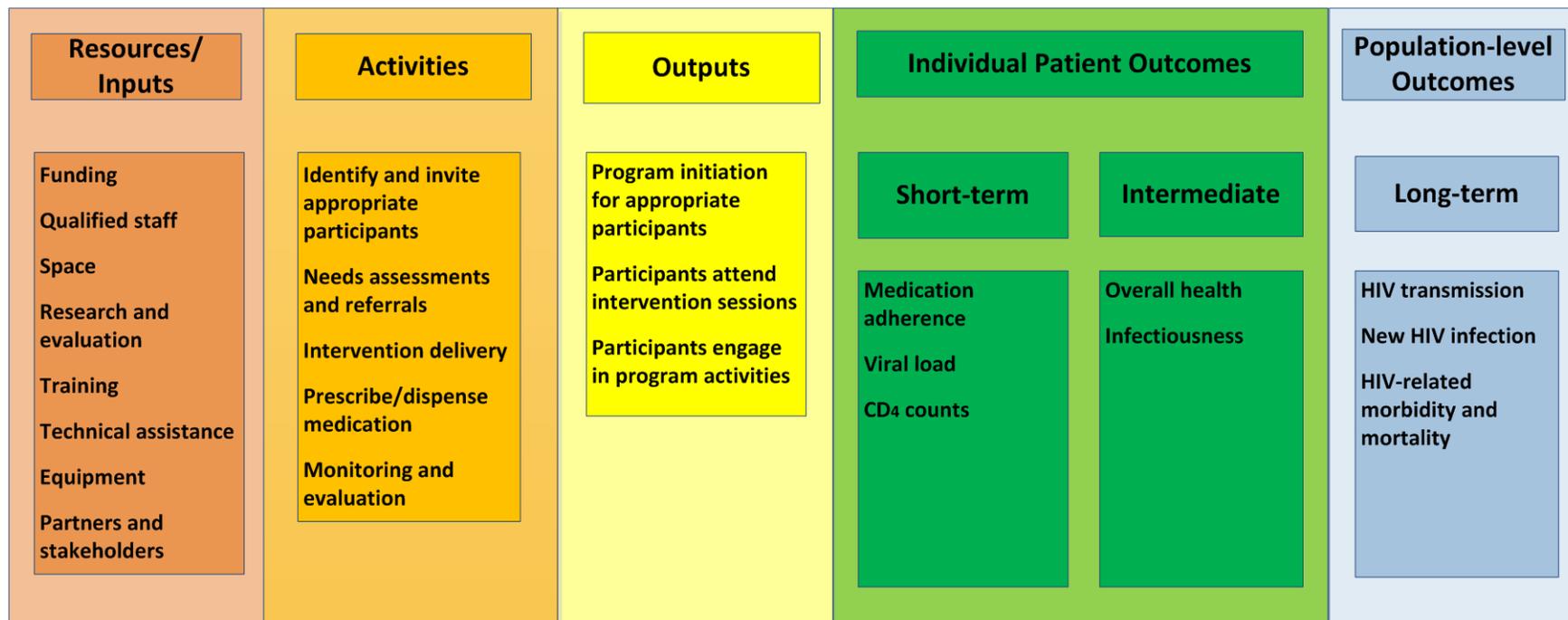
Figure 1. Conceptual Logic Model



Greater detail is used to construct a full logic model. Details include the specific resources required to run the program and the particular activities that define the program. The logic model also lists relevant measurable factors that comprise program implementation and specific measures that can be assessed to monitor the program. In this document, logic models are used to outline key program components and determine how to monitor whether your program is accomplishing its intended goals. Figure 2 is a general logic model for ART adherence interventions; logic models specific to HEART, Partnership for Health - Medication Adherence, Peer Support, and Smart Couple are provided in subsequent chapters.

A logic model can be elaborated into a flow chart at any point in the model, which is often useful to, for example, describe the flow of specific activities in relation to anticipated outputs and outcomes or to indicate at what point in activity data are collected.

Figure 2. Logic Model for ART Adherence Intervention Programs



Step 2: Developing Program Monitoring Questions

Program monitoring questions ask whether your program includes the components identified in the program logic model. These questions may be used to routinely oversee the delivery of the program as part of a continuous quality improvement plan, and to assess areas for program delivery improvement if you observe poor clinical outcomes.

Examples of program monitoring questions for ART adherence interventions include:

- Are clinicians or care providers qualified to deliver this intervention (e.g., do they have appropriate skills, experience, academic credentials, and licensure)?
- Were clinicians or care providers appropriately trained to deliver this intervention using the CDC e-learning course?
- Was the intervention appropriate for the patients identified and invited to participate in the program?
- Did all patients attend all required intervention sessions?
- Were key aspects of the program consistently delivered? You may wish to itemize the aspects and address them individually.
- Were other needs of patients that could interfere with successful medication adherence addressed (such as substance abuse treatment, housing, transportation)?
- Was ART adherence assessed after program initiation and at appropriate intervals?
- Was undetectable viral load achieved in the expected percentage of patients?

Because program monitoring questions ask about the factors that define the program, they should be geared to the intervention you are assessing. You can use the logic model you developed in Step 1 to inform this. Suggested program monitoring questions specific to HEART, Partnership for Health - Medication Adherence, Peer Support, and SMART Couples are provided in corresponding chapters for each of these interventions.

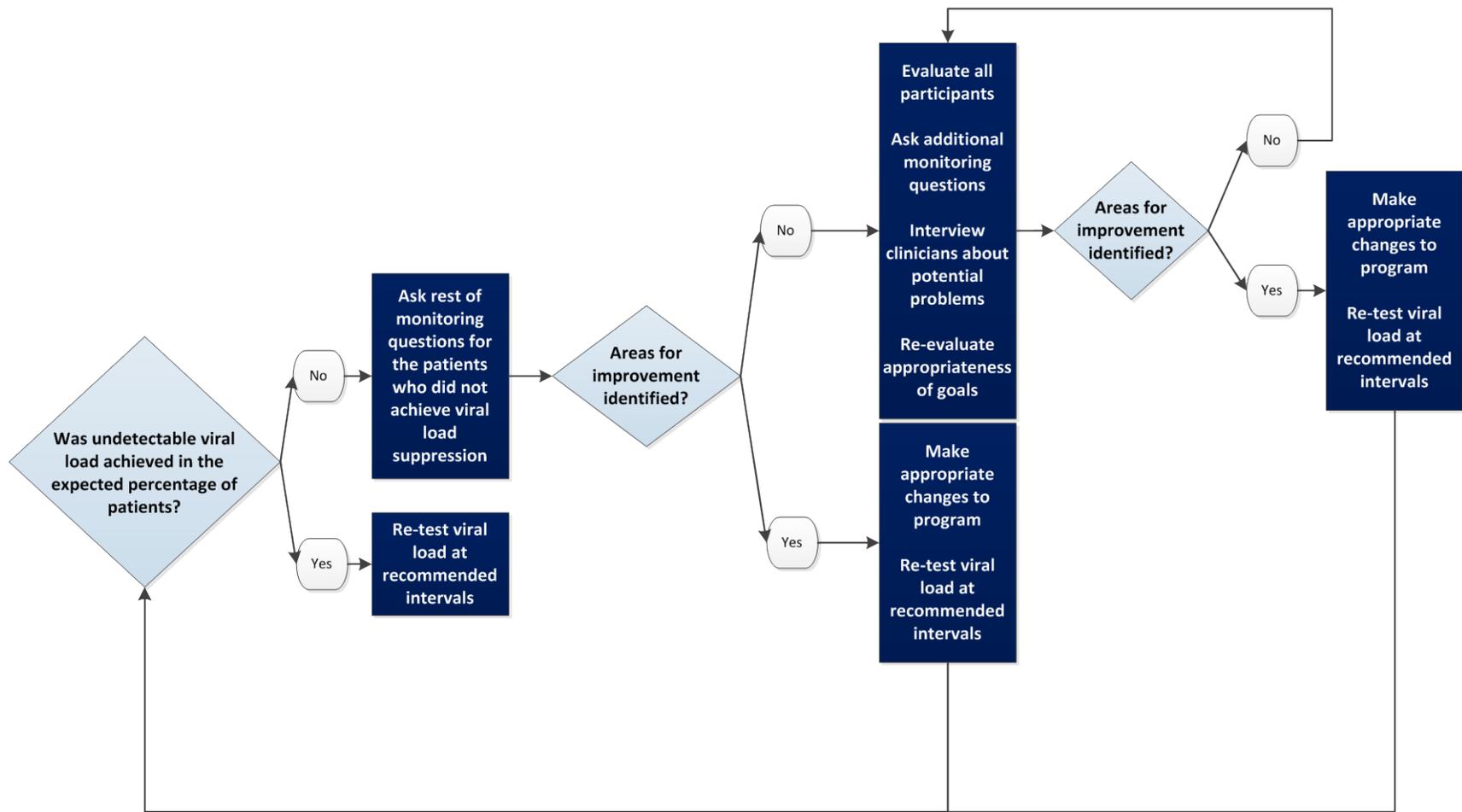
There are many questions you can ask, but limiting your list of questions to those most important will reduce your workload. You may even consider monitoring your program using just one question. For example:

- Was undetectable viral load achieved in the expected percentage of patients?

Undetectable viral load in an individual patient suggests the ART adherence intervention is working well for that person. To determine the effectiveness of your program, you can assess what percentage of patients in your program achieved undetectable viral load at the follow-up time point of interest (e.g., 3 months after beginning ART). If your clinic is not meeting its objective for this, you may wish to ask additional monitoring questions (which may require collection of more data), such as those listed in the chapters on the different ART adherence interventions, to help identify areas for program improvement. For efficiency, you might initially focus on assessing delivery of

care to patients who did not achieve undetectable viral load. If the problem is not identified through limited assessment, fuller assessment using more data, all patients, or additional methods such as clinician interview may be necessary. Once potential areas for improvement are identified and delivery care changes are made, viral load can be reassessed to determine whether the actions taken were sufficient to improve clinical outcomes. This process is illustrated in Figure 3.[3] For information on recommended intervals on outcome reassessment, refer to the National Institutes of Health guidelines (<http://www.aidsinfo.nih.gov/guidelines>).

Figure 3. Program Monitoring Plan



Step 3: Setting Program Objectives

Once you have your list of program monitoring questions, you should next set program objectives. Program objectives are the results you wish to achieve by implementing the ART adherence intervention. Objectives enable you to interpret data that answer your monitoring questions. The information you collect from individual patients can collectively show whether your program is meeting your objectives. Examples specific to ART adherence interventions are whether patients attended all required program sessions, or whether the expected proportion of patients achieved undetectable viral load.

Program objectives must be determined with respect to your clinic, as realistic objectives for attainment vary. **SMART Objectives** is a framework that can help you develop objectives. While this framework can be used to develop objectives for any intervention or program, the examples below illustrate developing objectives for ART adherence interventions. Developing program objectives using SMART Objectives requires consideration of the following factors, from which the SMART acronym is drawn:

- **S**pecific: Identify the program inputs, activities, and outcomes to be assessed, delineated in the logic model. Each factor should be evaluated individually. Your assessment should be specific to a particular intervention program and appropriate patient population.
- **M**easurable: Identify outcomes that can be recorded and counted, and for which program data and objectives can be compared. Measure outcomes in such a way that the answers can be compiled across individuals within the same program (e.g., yes/no answers can be easily tabulated). Some health outcomes in the logic models are important but cannot be easily measured, such as HIV transmission or overall health status. You may decide these are not worth attempting to measure. Other outcomes, such as viral load, are very feasible to measure. Some outcomes, such as ART adherence, can be measured in more than one way, such as patient self-report, clinical observation, pill counts, use of automated dispenser, or a combination of the above. You will want to consider the method of ART adherence monitoring most appropriate to your clinic. For more information on how to measure ART adherence, see Chapter 3.
- **A**ttainable/Achievable: Set objectives that are realistically attainable in the context of your resources and your clinic attendants' needs. See the text following this outline for more information.
- **R**elevant: Ensure that each objective is relevant to the purpose of implementing an ART adherence intervention. Following the logic model and the above SMART Objectives steps should help you focus on relevance.

- **Time bound:** The duration of time needed to achieve an objective may vary by program schedule and by outcome. For some outcomes, such as ART adherence, you might expect to see improvement within days of intervention. Biological change, such as achieving undetectable viral load, may take more time. You may also wish to define how frequently you will reassess outcomes.

Try to set program objectives that support measurement of individual patient outcomes, indicate improvement in patient health, and are realistic and attainable. For questions about fundamental aspects of program delivery, such as employing properly trained clinicians and enrolling patients for whom the ART adherence intervention is appropriate, an objective of 100% attainment may be reasonable. Setting program objectives for clinical outcomes, such as proportion of patients with undetectable viral load, requires more consideration. There are no universally accepted benchmarks for what defines undetectable viral load, or what proportion of patients should attain it before your program can be considered successful. To address monitoring questions on clinical outcomes, you will need to determine a **target** for what defines clinical success (e.g., for undetectable viral load, the copies of HIV in a milliliter of blood), and a program objective of what proportion of patients must achieve the target for the program to be considered successful overall. You can identify targets in clinical literature, clinical practice guidelines, and white papers from HIV/AIDS organizations. More information on targets for ART adherence outcomes is provided in Chapter 3.

If your clinic faces substantial barriers to successfully implementing an ART adherence intervention, you may wish to use an incremental approach in which you set initial program objectives lower than your ultimate objectives. Some factors you may consider include:[4]

- **Resources:** If you have an insufficient number of care providers to administer the program, such as insufficient clinic staff, it is less likely that all activities for all patients can be performed.
- **Patient Characteristics:** Clinical studies suggest factors associated with non-adherence include younger age, nonwhite race, ethnicity, lower income, lower literacy, and unstable housing. Also, individuals with personal histories of non-adherence are at greater risk of non-adherence in the future.
- **Treatment Regimen:** Regimens that are complicated or entail taking more pills or have more side effects have been associated with poorer adherence.

Step 4: Selecting and Defining Data Elements to Answer Questions and Assess Progress

Developing a program monitoring plan prior to implementing the ART adherence intervention enables you to decide what data to collect. **What data you need to collect depends on the monitoring questions you plan to use.** Once you identify the monitoring questions you want to answer, then you define the data elements needed to answer those questions. For example, if you are interested in knowing if undetectable viral load was achieved in the expected percentage of patients, you will need know the number of all patients in the program during a specified time frame and the number of patients that achieved undetectable viral load. The data elements in this

case include: patient ID, dates of participation in the program, and viral load before and after the intervention. If your question is whether all patients attended the required program sessions, then the required data elements will consist of patient ID and session number.

Step 5: Collecting and Routinely Using Data

Recording needed data on forms designed to help you monitor and evaluate your program will reduce data collection time, minimize missing and invalid data, and expedite analysis

Data Collection Tools

Patient Visit Data Collection Form

Program monitoring questions can be rephrased to ask about the outcome of interest in individual patients. The monitoring questions in this document were developed to be yes/no questions whenever possible to make record keeping during patient visits easier. A data collection form for a clinician to use during a patient visit might be as simple as answering “yes” or “no” to each of the individual-level monitoring questions. Using such a form during a patient visit could also serve as a reminder to help the clinician ensure key aspects of the intervention are consistently delivered.

If all individual-level monitoring data are collected during initial and follow-up patient visits, no additional data sources are needed. If data are not collected during patient visits, this information should be recoverable from patient records and laboratory test results. It is important to remember that retrospectively collecting data can be more time-consuming and subject to error, especially if needed data are missing.

Table 2 is a sample data collection form for a patient visit. It uses individual-level monitoring questions. It is based on the generic ART adherence monitoring questions (listed on page 8) that could be integrated into paper records or adapted to electronic recording systems. Forms designed for use with HEART, Partnership for Health - Medication Adherence, Peer Support, and Smart Couple are provided in subsequent chapters.

Table 2. Sample Patient Visit Data Collection Template with Generic ART Adherence Monitoring Questions

Generic ART Adherence Intervention Patient Visit Data Collection Form	
Patient identification:	
Patient visit date:	
Administering clinician:	
Monitoring Questions – Individual Level	Finding
Were clinicians or care providers appropriately trained to deliver this intervention using the CDC e-learning course?	
Was the intervention appropriate for the patient?	
Were key aspects of the program delivered?	
Were other needs that could interfere with successful medication adherence addressed (such as substance abuse treatment, housing, transportation)?	
Was ART adherence assessed? Interval since intervention initiation: Interval since last assessment:	
Was viral load undetectable? Interval since intervention initiation: Interval since last assessment: Viral load:	
Clinician notes, including program modifications or implementation problems:	

Program Monitoring Worksheet

Individual-level data collected during patient visits can be compiled into program monitoring data. Aggregating data simply requires tabulating the number of “yes” responses on the corresponding individual patient data collection form questions and dividing by the total number of patients.

Table 3 is a sample program monitoring worksheet using generic ART adherence intervention monitoring questions. Forms designed for use with HEART, Partnership for Health - Medication Adherence, Peer Support, and Smart Couple are provided in subsequent chapters. Filling in each column is a simple way to keep track of results and compare them to objectives.

Table 3. Sample Program Monitoring Worksheet with Generic ART Adherence Intervention Program Level Monitoring Questions

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Were clinicians or care providers appropriately trained to deliver this intervention using the CDC e-learning course?		Number of clinicians and care providers who completed the CDC e-learning course Total number of clinicians and care providers				
Was the intervention appropriate for the patients identified and invited to participate in the program?		Number of patients who participated in the program that were appropriate candidates based on program description Total number of patients enrolled				
Were key aspects of the program consistently delivered?		Program activities were carried out				
Were other needs of patients that could interfere with successful program participation addressed (such as substance abuse treatment, housing, transportation)?		Non-program barriers to treatment success were considered and addressed				
Was ART adherence assessed?		Number of patients for whom ART adherence was assessed at relevant visit Total number of patients enrolled				

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients?		Number of patients with undetectable viral load Total number of patients enrolled				

Routine data collection and use of the results is an important component in program monitoring and it's more than just determining if targets were met. The real benefit of program monitoring comes from the conversations you have with staff and other stakeholders about these results, and the actions you take to build on successes and address weaknesses in implementation.

If monitoring data indicate that targets have been met or exceeded, you may gain understanding of your implementation strengths and how to further build upon them. When data show that you have deviated from what you planned to do, you may gain insight about how intervention implementation can get back on track. Sometimes, intervention adjustments occur spontaneously in the field but go unrecognized without a systematic process to collect and use monitoring data. This is yet another way in which monitoring may help you improve the interventions.

Step 6: Taking Corrective Actions, if Necessary

Completing Step 4 will provide you with clear information on how your individual patients are doing, and on how the program is doing overall. If your program objectives have not been met, consider further assessment to identify the underlying problem(s) and corrective action to address it. As previously described in this chapter, this may entail strategies such as:

- Asking additional monitoring questions to gain more information about the underlying problem(s)
- For efficiency, initially focusing on patients for whom objectives were not achieved and then expanding assessment to more or all patients if further information is required

As shown in Figure 3 of Chapter 2, taking corrective action is not a final step in program monitoring; it is another step in a program monitoring cycle. Continuous program monitoring is needed as part of an ongoing quality improvement process to ensure that corrective action was appropriate and successful. For illustrative accounts of how a fictitious clinic used program monitoring results to inform corrective action, see the case studies at the end of Chapter 2.

Step 7: Communicating Findings

Following the above steps entails compiling relevant information in a clear, concise, and well-organized format. Your program monitoring data and assessment can therefore aid you in sharing information about aspects of your program of interest to stakeholders, those individuals with an interest in your program's outcomes. Identify your stakeholders and consider what they need to know about your program. Stakeholders vary by organization, but may include ART adherence intervention staff, other clinic staff, funders, and board members.

Program monitoring worksheets such as those in this document provide a starting point to communications. You may even wish to share these worksheets, since they are simple to understand and can be distributed as stand-alone documents. You can share steps taken in response to findings achieved through use of the monitoring worksheet, as illustrated in case studies throughout this document.

For clinical staff, sharing program data may include reinforcement of competent program delivery and identification of areas for program delivery improvement when interacting with individual patients. For stakeholders who oversee or fund your program, key areas of interest may include overall program challenges and successes, and identification of areas that require additional resources for improvement to be effected. Your findings can also be useful for communicating with audiences outside of your organization. You may wish to use this information to prepare presentations, posters, or publications.

2.3 Case Studies in Program Monitoring Planning for ART Adherence Interventions

This section of Chapter 2 provides fictitious examples of recording and using program monitoring information for four of the generic ART adherence intervention program monitoring questions. These cases present sample objectives, data collection, and determination of whether the program objective was satisfied for four monitoring questions.

Table 4 shows a sample program monitoring worksheet, followed by examples of interpreting the results. The examples demonstrate how assessing the results of your program monitoring plan can inform which areas of your program are strong and should be maintained, and which areas require more resources or a change in approach. These case studies are for illustrative purposes only and do not suggest specific objectives or assessment methods for your clinic. Case studies for HEART, Partnership for Health - Medication Adherence, Peer Support, and Smart Couple are provided in subsequent chapters.

Table 4. Case Study for Program Monitoring with Generic ART Adherence Intervention Monitoring Questions

Monitoring Question	Sample Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
<p>Was undetectable viral load achieved in the expected percentage of patients?</p> <p>Case Study 1</p>	At least 50% of patients should have undetectable viral load 3 to 6 months following the intervention	<p>Number of patients with undetectable viral load</p> <p>Total number of patients enrolled</p> <p>Duration(s) of follow-up assessed: 3 months</p>	35	100	35%	No
<p>Was ART adherence assessed?</p> <p>Case Study 2</p>	ART adherence should be assessed in at least 90% of patient visits	<p>Number of patients for whom ART adherence was assessed</p> <p>Total number of patients enrolled</p>	75	100	75%	No
<p>Was the clinician or care provider appropriately trained to deliver this intervention using the CDC e-learning course?</p> <p>Case Study 3</p>	100% of patients should have an appropriately trained care provider	<p>Number of clinicians and care providers who satisfactorily completed the CDC e-learning course for this intervention</p> <p>Total number of clinicians and care providers</p>	100	100	100%	Yes
<p>Was the intervention appropriate for the patients identified and invited to participate in the program?</p> <p>Case Study 4</p>	100% of enrolled patients should be appropriate candidates for the ART adherence intervention	<p>Number of patients who participated in the program who were appropriate candidates based on program description</p> <p>Total number of patients enrolled</p>	75	100	75%	No

Case Study #1: Undetectable Viral Load

Monitoring Question:
Was undetectable viral load achieved in the expected percentage of patients?

Objective:
At least 50% of patients should have undetectable viral load.

Results:
Only about a third of program patients had undetectable viral load at follow-up visits at the designated time point(s).

Assessment

Every 3 months, Fictitious Clinic evaluates what proportion of patients in their program had undetectable viral load. In their most recent assessment, they found only 35% of patients did.

Action

As the objective was not met, Fictitious Clinic decided to employ additional program monitoring questions to identify areas for program delivery improvement. Based on clinician and care provider discussions, the program manager determined that ART adherence, patient selection, and intervention administrator training were potential areas of program weakness that should also be assessed. They extracted these data from the individual patient visit forms and carried out the next three case studies.

Case Study #2: ART Adherence

Monitoring Question:
Was ART adherence assessed?

Objective:
ART adherence should be assessed in at least 90% of patient visits.

Results:
ART adherence was assessed in 75% of patient visits.

Assessment

In response to the unmet undetectable viral load objective, Fictitious Clinic assessed ART adherence, as high ART adherence is highly predictive of viral load. They found that ART adherence was only being assessed in 75% of patient visits, so the opportunity for early intervention was lost.

Action

Fictitious Clinic recognized that inadequate assessment of adherence likely accounted for the unmet viral load objective and decided further program monitoring was necessary to determine what the root cause of the poor delivery of this key program aspect was. Based on general program monitoring observations, they identified inadequate clinician training as a potential reason why the program might not be meeting objectives.

Case Study #3: Clinician or Care Provider Training

Monitoring Question:

Was the clinician or care provider appropriately trained to deliver this ART adherence intervention?

Objective:

100% of patients should have an appropriately trained care provider.

Results:

100% of patients had a care provider who completed the CDC e-learning course and administered their intervention.

Assessment

Fictitious Clinic was confident that staff qualifications were satisfactory, but assessed whether clinicians and care providers at their clinic were appropriately trained to administer the ART adherence intervention using the CDC e-learning course.

Action

Assessment showed that all clinicians and care providers were appropriately trained to administer the intervention. However, Fictitious Clinic decided to plan refresher training on the intervention for all care providers because these individuals are responsible for most aspects of program delivery.

Case Study #4: Enrollment of Patients for whom the Intervention is Appropriate

Monitoring Question:

Was the intervention appropriate for the patients identified and invited to participate in the program?

Objective:

100% of enrolled patients should be appropriate candidates for the ART adherence intervention.

Results:

75% of patients were appropriate candidates for the selected ART adherence intervention.

Assessment

The program Fictitious Clinic implemented was intended for patients who were new to ART. They found only 75% of patients participating in the program were appropriate for this particular ART adherence intervention. Fictitious Clinic investigated further and found that ART-experienced patients with poor adherence were being enrolled for this intervention.

Action

Fictitious Clinic focused this intervention program on ART-naïve patients and enrolled ART-experienced participants in programs more appropriate for their needs. They also recognized that further staff training on appropriate assignment of patients to different interventions was needed, and added this to their criteria for assessing whether clinicians were appropriately trained.

Chapter 3. Measuring Adherence to Antiretroviral Therapy in Clinical Practice

The main objective of implementing an ART adherence intervention is to improve adherence to antiretroviral medication, with the ultimate goals of reducing HIV-related morbidity and mortality. This chapter describes different ways to measure adherence to antiretroviral therapy in clinical practice. Chapter 2 provided an overview of program monitoring. This chapter provides more information to assist you in selecting and measuring individual patient outcomes as part of your program monitoring plan.

This chapter includes:

- ▶ Overview of measuring ART adherence
- ▶ Assessing and measuring viral load, medication adherence, and CD₄ counts

3.1 Overview of Methods of Measuring ART Adherence

As illustrated in the logic model in Chapter 2, there are multiple outcomes that you can assess to monitor your program. Individual patient outcomes focus on short-term clinical outcomes (e.g., ART adherence, viral load, and CD₄ counts) and are generally feasible to measure in the context of clinical practice. Intermediate-term general patient health status and population-level outcomes are not as feasible to measure. Therefore, this chapter focuses on short-term individual patient outcomes.

You may wish to use a combination of direct and indirect outcomes to assess ART adherence.

Direct outcomes measure exactly what you want to know about. Asking patients whether they took all of their ART doses as prescribed is a direct measure of ART adherence. You may also consider using **indirect** outcomes, which are proxy measures for what you want to know. For example, having an undetectable viral load suggests that a patient is taking nearly all of his or her ART doses as prescribed, but it is not a direct measurement of their adherence. You may decide to save resources by not directly assessing ART adherence in individuals with undetectable viral load. Indirect measures may also be useful when the outcome you are interested in cannot be realistically measured within clinical practice. For instance, measuring viral load directly tells you how severe the burden of virus is in a patient, and it also suggests indirectly whether ART adherence is adequate, and if the likelihood of HIV-related morbidity and mortality or HIV transmission is reduced.

3.2 Viral Load

ART decreases the ability of the virus to reproduce itself within the patient and to reduce how much virus there is in the patient, thereby improving his or her health and infectiousness.[5] A viral load test measures the number of copies of HIV RNA per mL in patient blood plasma, and is performed by a blood test. Research suggests that transmission rarely occurs when viral load is undetectable.[6] Target viral loads in ART adherence intervention clinical studies vary. The study assessing HEART by Koenig and colleagues (2008) had a target viral load suppression of either at least a 1-log drop in viral load *or* undetectable viral load.[7] The study assessing Partnership for

Health - Medication Adherence by Milam and colleagues (2005) had a target reduction of undetectable viral load, which they defined as fewer than 500 copies of HIV RNA per mL.[8] Other studies on HIV treatment use different definitions.

3.3 ART Adherence Measures

ART adherence generally refers to taking prescribed ART doses at prescribed times. There is consensus in the literature that it is necessary for at least 90 to 95 percent of ART doses to be taken as prescribed in order to suppress viral load effectively, thereby reducing transmission risk, minimizing mutation risk, and protecting the immune system.[5]

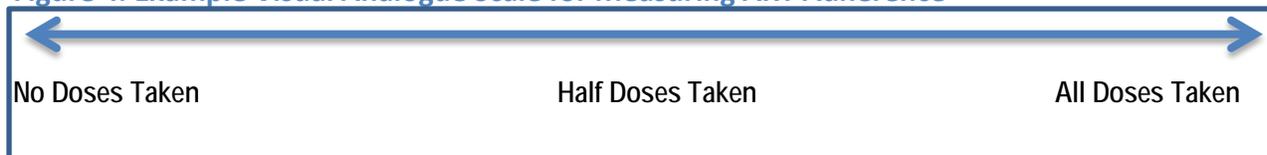
Because there is no single best approach to assessing adherence,[4] consider the various measures described in this chapter in the context of what would work well at your clinic. Many of these methods are simple and inexpensive. However, most are indirect measures, and even if patients report they took all of their doses exactly as prescribed, it is possible they did not. More than one method may be used to measure adherence if appropriate for your clinic.

Self-reported Adherence

Self-reported adherence measures whether patients say they are taking ART doses as prescribed. This is a subjective measure and may be influenced by factors such as mistakes in patient recall or overestimation; however, self-reported measures are inexpensive and easy to record. Studies have associated self-reported adherence with viral load.[9]

There are several different ways to measure self-reported adherence. To choose one, consider your resources available, patient literacy, and how you keep records. Data can be collected during clinical evaluation, on a form, or through a computer interface. Consider asking structured questions to measure self-reported adherence, such as whether at least 95 percent of doses were taken during the past week. Asking about recent dosing may improve patient recall, but you will need to reassess frequently to get a complete picture of adherence. You could also ask patients to keep a written record, such as a pill diary. Some researchers have found that using a Visual Analogue Scale (VAS) is a useful tool for data collection.[4] Rather than asking patients to report a percent of pills taken, they can indicate adherence by pointing to or circling adherence on a VAS (such as Figure 4).

Figure 4. Example Visual Analogue Scale for Measuring ART Adherence



Target levels of self-reported ART adherence include 95 percent of prescribed doses in the Partnership for Health - Medication Adherence study,[8] and 100% of prescribed doses in the Peer Support study.[10]

Pharmacy Refill Checks

Requesting ART refills or prescriptions for refills at expected intervals (e.g., 30 days since last refill if a 30-day supply is dispensed) suggests patients are adhering to their prescription plan. If your

clinic dispenses the prescription, this should be easy to measure. Pharmacy refill checks may be useful for long-term adherence. However, having to obtain this information from independent sources may make it too time-consuming to be feasible. Pharmacy refill checks are an indirect measure and only suggest patients are taking their pills as prescribed.

Pill Counts

A clinician or care provider could count pills in the patient's prescription at each visit to determine whether the expected number remains. This depends on the patient remembering to bring the ART to every appointment, and requires time from the provider. Alternatively, clinicians can make unannounced visits to patients to count their pills. This does not require the patient to remember to bring pills to visits and reduces the possibility of subversion of counts, but is resource intensive and generally not accepted by patients or clinicians. Further, pill counts have been inconsistently associated with clinical outcomes.[9]

Electronic Caps

Special caps that record when the bottle is opened have been used in clinical studies to objectively assess when the patient takes pills. These caps are called Medication Event Monitoring Systems (MEMS), and they record each date and time the bottle is opened, which is presumed to indicate that the patient has taken a dose. These caps may be less conducive for use in clinical practice because they are costly and preclude the use of organizational pill cases; however, some clinicians have found patients accept MEMS. The clinical study on HEART employed these cases. In this study, the target was for patients to take 90 percent of prescribed doses.[7]

Biological Assays

Measuring concentrations of the prescribed drugs in patients' blood plasma or urine has not been strongly associated with clinical outcomes and may be affected by which drugs are taken and individual patient metabolisms.[9] Also, they may only provide information about the most recent dose taken.[11]

Direct Observation

In direct observation, a clinician observes a patient take pills. Outside special settings such as inpatient clinics or correctional facilities, this is unlikely to be feasible because it requires every patient to report to the clinic for every dose, and requires a clinician to take time to observe them take it.

3.4 CD₄ T-cell Counts

CD₄ T-cell count, often simply referred to as CD₄ count, is a measure of immune function. Higher values represent better immune function. In the context of assessing an ART adherence intervention, CD₄ increases suggest immunologic response to ART,[11] which indirectly suggests better patient health through resistance to HIV-related complications such as opportunistic infections. ART adherence and CD₄ counts have been associated in clinical studies.[4] The Peer Support study by Simoni and colleagues assessed whether CD₄ counts were higher or lower than 350 cells per cubic millimeter.[10]

Chapter 4. HEART

This chapter provides information about HEART, including a program description and logic model. It also provides information for clinics implementing HEART, including program monitoring questions, setting objectives to interpret your clinic's results, data needs and collection methods, and sample patient visit forms and program monitoring worksheets. It also includes case studies to demonstrate use of the program monitoring worksheet and interpretation of its findings.

4.1 Program Description

Helping Enhance Adherence to Antiretroviral Therapy (HEART) is a systematic approach to developing and maximizing an individualized adherence plan (IAP) for patients who are beginning ART for the first time or for those who are not responding to their current regimen and are changing to a new regimen. HEART is intended to help patients start ART successfully by considering their schedules, addressing potential barriers to adherence and developing strategies to address them, and by providing social support.

HEART's goals are to improve patients' health and reduce patient infectiousness, with the long-term aims of preventing HIV transmission and new HIV cases while decreasing HIV-related morbidity and mortality. This program was assessed in a randomized controlled trial (RCT) by Koenig and colleagues,[7] who reported that at 6 months follow-up, statistically significantly more patients enrolled in HEART met objectives for ART adherence and had undetectable viral load than those enrolled in conventional care (i.e., the comparison group).

HEART uses a multi-component strategy that includes the patient, a patient-identified support partner, and a health care provider (i.e., physician, nurse, case manager, or health educator at clinics or community-based organizations). The patient's role is to actively engage in his or her own care by identifying likely barriers to adherence, creating ideas for how to address those barriers, doing his or her best to follow the IAP that is developed, and recognizing which aspects of the plan are and are not working. The provider's role is to conduct a comprehensive needs assessment, offer support, and collaborate with the patient to schedule ART dosing, identify and address potential adherence barriers, monitor adherence, and adjust adherence strategies as needed.

The support partner is a person who the patient identifies as having a close relationship with the patient and who agrees to provide ongoing support to the patient in following his or her ART adherence plan. The support partner first meets with the patient and provider to help identify dosing cues, potential barriers to adherence, and solutions for overcoming these barriers. The support partner then provides the patient ongoing help and support outside the clinic setting. Some ways that support partners can help patients are to provide encouragement and emotional

Inside this chapter for HEART:

- ▶ Program description
- ▶ Program monitoring questions
- ▶ Setting program objectives
- ▶ Case studies

support, check in with patient daily to see whether he or she took prescribed doses, help the patient remember and keep medical appointments, help the patient identify emerging circumstances that may cause missed doses, and, when doses are missed, develop strategies to avoid missing doses in the future. The provider should ensure that the support partner understands his or her roles and expectations. Also, the provider should mediate if the support partner becomes overinvolved or if the patient reports having problems with the support partner.

The collaborative, problem-solving method, along with a series of **semi-structured interviews** for **developing a medication adherence plan** (referred to as SIDMAP) takes place both before and after the start of ART. It includes:

- Educating the patient and support partner
- Tailoring treatment regimens to fit patients' needs
- Identifying adherence barriers
- Developing ideas and methods for patients to overcome identified barriers

The pre-ART phase consists of two in-person visits during the 2 weeks before the patient starts ART. In Session 1, the provider conducts a comprehensive social services needs assessment, maps the patient's daily schedule to identify opportune dosing times, and invites the patient to choose a support partner and bring them to the next visit. In Session 2, the patient, provider, and support partner together identify potential adherence barriers, collaboratively generate strategies to overcome these barriers, and create the initial IAP. The provider facilitates these discussions guided by the SIDMAP tool, allowing the patient to take the lead in identifying barriers and solutions and encouraging input from the support partner.

The post-ART phase consists of three visits at weeks 2, 4, and 8 to assess ART adherence and modify the IAP, if necessary. Using the SIDMAP tool, the patient and provider together review the patient's current circumstances, missed doses, and ongoing barriers; evaluate whether strategies to address barriers are working and generate new strategies if necessary; and review and update the IAP. The support partner attends some but not all of these sessions.

Between the sessions, the care provider also conducts follow-up phone calls to:

- Detect adherence problems early
- Review patients' missed doses
- Devise new adherence strategies if necessary
- Monitor support partner's role
- Celebrate adherence success and provide support

A patient may continue HEART beyond five sessions until the patient, provider, and support partner feel confident in the patient's ability to maintain adherence. A booster session at 6 months may be offered to assess adherence and reinforce long-term adherence.

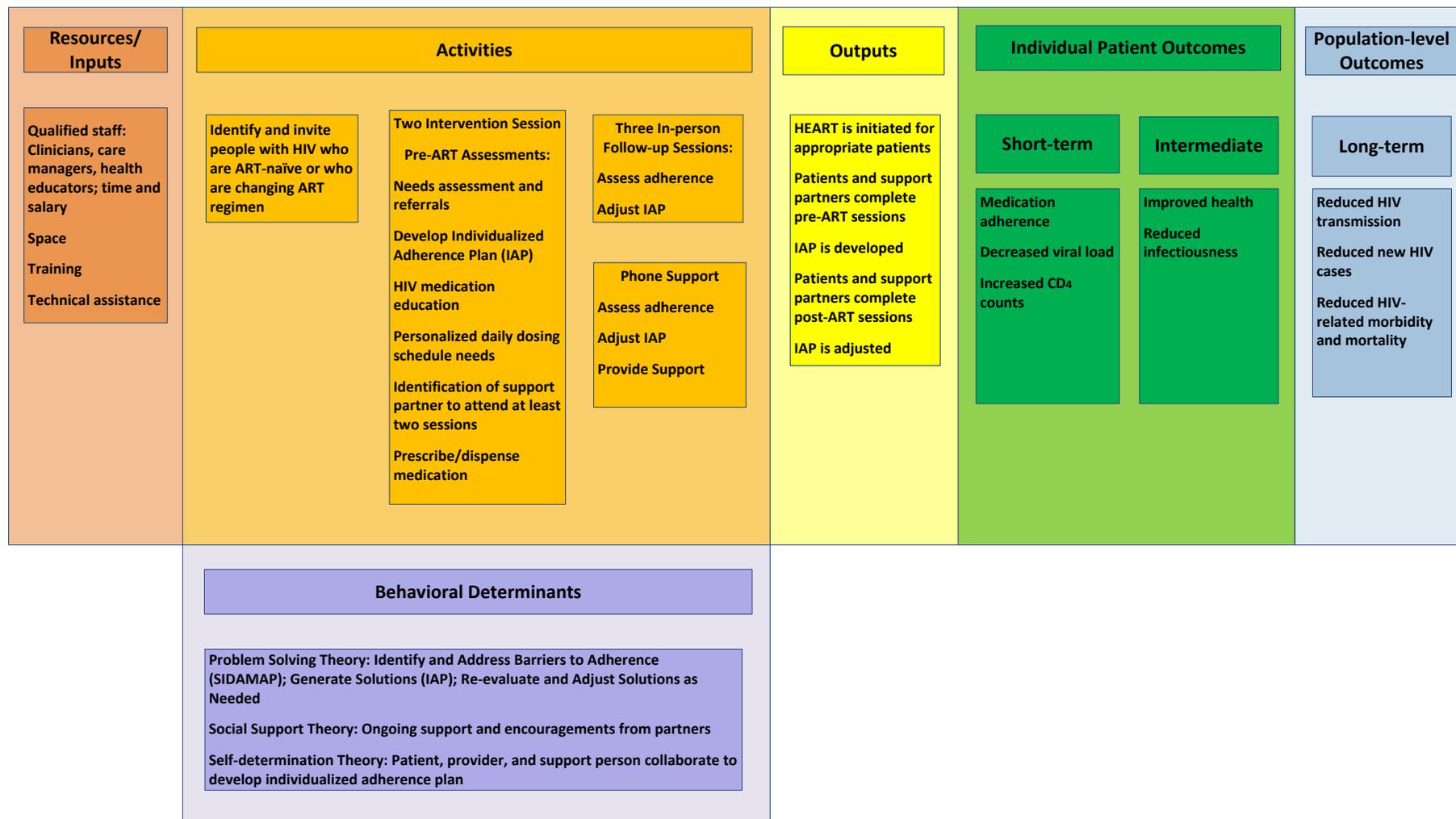
Table 5 highlights key components of the two phases of ART and the between-visit phone calls.

Table 5. Key Components of HEART

Phase I	Phase II	
Pre- ART visits	Post-ART-start visits	Phone calls between visits
<ul style="list-style-type: none"> ■ Identify patients who would benefit from HEART ■ Have patient identify support partner and discuss support partner role ■ Conduct needs assessment ■ Provide HIV medication education ■ Identify adherence barriers and brainstorm strategies ■ Map doses to daily schedule ■ Develop initial IAP ■ Test patient's viral load and CD₄ count ■ Prescribe/dispense HIV medication ■ Provide referrals as needed 	<ul style="list-style-type: none"> ■ Review adherence to date/analyze missed doses ■ Identify ongoing or additional barriers and generate new/revised strategies as needed ■ Revise IAP accordingly ■ Check whether and how support partner has been helpful ■ Continue monitoring patient's viral load and CD₄ count 	<ul style="list-style-type: none"> ■ Review missed doses ■ Monitor support partner role ■ Revise IAP as needed ■ Provide support and answer questions

Figure 5 is a logic model for HEART that shows the relationship between program implementation and outcomes. It lists its required resources, activities, and outputs, and the outcomes it is intended to achieve. The model lists specific measures that can be assessed to monitor the program and evaluate its outcomes.

Figure 5. Logic Model for HEART



4.2 Program Monitoring Questions for HEART

The effectiveness of HEART in improving ART adherence may be evaluated using a single question:

- Was undetectable viral load achieved in the expected percentage of patients?

If the proportion of patients achieving undetectable viral load meets or exceeds your objective, ART adherence is satisfactory. You may not need to evaluate your program further. If it is not satisfactory, you may wish to use the additional program monitoring questions for HEART listed below. If your clinic routinely collects information needed to address each of these questions during individual patients visits (such as using the form in Table 6) as part of your program monitoring plan, you will have the information you need to address all of the program monitoring questions. Items you answer “no” to identify potential areas for improvement. Refer to Chapter 2 for more information on using monitoring questions in the context of program monitoring.

- Were the HEART providers appropriately trained using the CDC e-learning course?
- Did all patients have support partners?
- Did all support partners attend at least one of two pre-ART sessions?
- Did all support partners attend two or more post-ART sessions?
- Did all patients have an IAP developed?
- Was ART adherence assessed in all patients after ART was initiated?
- Did all patients with ART adherence challenges have their IAP adjusted?
- Were patients’ other needs addressed (e.g., substance abuse treatment, housing, transportation)?
- Did all patients attend all required intervention sessions?

4.3 Setting Program Objectives for HEART

Program objectives are the results you wish to achieve, such as the expected percentage of patients attaining undetectable viral load, or whether patients attended all required intervention sessions. Objectives enable you to interpret answers to the program monitoring questions and determine whether your clinic is meeting its short-term goals.

Consider using the SMART Objectives framework in Chapter 2 to form objectives that are specific, measureable, attainable/achievable, relevant, and time bound. Set objectives that are large enough to indicate health improvement, but not so high that they are unattainable. For program monitoring questions about the delivery of key aspects of HEART (e.g., did all patients have an IAP developed?), it may be reasonable to set an objective of 100 percent attainment because this activity should be completed for all patients. However, there are no universally accepted benchmarks for clinical outcomes, and realistic objectives for clinical outcomes vary by clinic. For more information about key clinical outcomes and measuring ART adherence, refer to Chapter 3.

4.4 Data Collection Tools for HEART

This section includes a sample individual patient visit data collection form and program monitoring worksheet for HEART, and fictitious case studies on their use. The HEART patient visit data collection form (Table 6) is intended to enable you to collect data as you administer your program, and to support and expedite data compilation and assessment using the program monitoring

worksheet (Table 7).

Table 6. HEART Patient Visit Data Collection Template

HEART Patient Visit Data Collection Form	
Patient identification:	
Patient visit date:	
Circle one: Pre-ART Visit 1 – Pre-ART Visit 2 – Post-ART Visit 1 – Post-ART Visit 2 – Post-ART Visit 3	
Administering clinician:	
Monitoring Questions – Individual Level	Findings
Was viral load suppressed? Interval since intervention initiation: Interval since last assessment: Viral load:	
Does this patient have a support partner?	
Did the support partner attend today?	
Does the patient have an IAP?	
Was ART adherence assessed? (post-ART sessions only) Interval since intervention initiation: Interval since last assessment:	
If this patient had adherence challenges, was the IAP revised? (post-ART sessions only)	
Were patient's other needs addressed (e.g., substance abuse treatment, housing, transportation)?	
Clinician notes, including program modifications or implementation problems:	

Table 7. HEART Program Monitoring Worksheet

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients?		Number of patients with undetectable viral load Total number of patients Duration(s) of follow-up assessed: 3 months				
Were the HEART providers appropriately trained using the CDC e-learning course?		Whether all care providers completed the e-learning course				
Did all program patients have support partners?		Number of program patients with support partners Total number of patients				
Did all support partners attended at least one of two pre-ART sessions?		Number of support partners who attended at least one pre-ART session Total number of patients				
Did all support partners attended two or more post-ART sessions?		Number of support partners who attended at least two post-ART sessions Total number of patients				
Did all patients have an IAP developed?		Number of patients who had an IAP developed Total number of patients				
Was ART adherence assessed in all patients after ART was initiated?		Number of patients for whom ART was assessed at designated follow-up visits Total number of patients Duration(s) of follow-up assessed:				

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Did all patients with ART adherence challenges have their IAP adjusted?		Number of patients who did not meet objectives for ART adherence had IAP adjusted Total number of patients who did not meet objectives for ART				
Were patients' other needs addressed (e.g., substance abuse treatment, housing, transportation)?		Number of patients for whom clinicians provided assessments of factors that could affect ART adherence Total number of patients				
Did all patients attend all required intervention sessions?		Number of patients who attended all required sessions Total number of patients				

4.5 Case Studies in HEART

This section provides fictitious examples of program monitoring information collection and assessment for HEART. These cases present sample objectives, data collection, and determination of whether the program objective was satisfied for four monitoring questions. Table 8 shows a sample program monitoring worksheet, and examples of interpretation of the results follow. The examples demonstrate that assessing the results of your program monitoring plan can inform you about which areas of your program are strong and should be maintained, and which areas require more resource or a change in approach. Sample objectives and assessment intervals are based on the HEART program, and the viral load objective is based on clinical outcomes in the RCT by Koenig and colleagues. These case studies are for illustrative purposes only and do not suggest what are appropriate objectives or assessment methods for your clinic.

Table 8. Case Study for Program Monitoring of HEART

Monitoring Question	Sample Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients? Case Study 1	At least 40% should have undetectable viral load at 3 to 6 months following the intervention	Number of patients with undetectable viral load Total number of patients enrolled Duration(s) of follow-up assessed: 3 months	35	100	35%	No
Did all patients have an IAP developed? Case Study 2	100% of patients should have an IAP developed during their two pre-ART visits	Number of patients with IAP Total number of patients enrolled	100	100	100%	Yes
Was ART adherence assessed in all patients after ART was initiated? Case Study 3	100% of patients should have ART adherence assessed at all three in-person post-ART visits	Number of patients for whom self-reported ART adherence was assessed Total number of patients who initiated ART	100	100	100%	Yes
Did all patients with ART adherence challenges have their IAP adjusted? Case Study 4	100% of patients who took fewer than 90% of their doses or who said they were challenged by adherence should have an IAP review with their care provider.	Number of patients with ART adherence challenges who had their IAP adjusted Total number of patients with ART adherence challenges	80	100	80%	No

HEART Case Study #1: Undetectable Viral Load

Monitoring Question:

Was viral load undetectable?

Objective:

At least 40% should have undetectable viral load at 3 months.

Results:

Only about a third of program patients had undetectable viral load three months after starting HEART.

Assessment

Fictitious Clinic evaluated what proportion of program enrollees had undetectable viral load 3 months after starting HEART. They found only 35% of patients did.

Action

As the objective was not met, Fictitious Clinic decided to employ additional program monitoring questions to identify areas for program delivery improvement. Based on clinician and care provider discussions, the program manager decided to evaluate whether ART adherence was being assessed and whether the IAPs that are of central importance to HEART were being developed for all patients and modified as necessary. The program manager believed these factors might be contributing to the poor clinic performance in viral load. She extracted these data from the individual patient visit forms and carried out program assessment as summarized in the next three case studies.

HEART Case Study #2: IAP Development

Monitoring Question:

Did all patients have an IAP developed?

Objective:

All patients should have an IAP developed.

Results:

All patients had an IAP developed.

Assessment

As IAP development is the main output that defines HEART, Fictitious Clinic wanted to ensure that all patients enrolled in HEART had an IAP developed during their pre-ART initiation in-person visit. They assessed their records and found that all did.

Action

Fictitious Clinic was assured that all patients did have an IAP, but wondered whether IAPs were being modified if patients faced challenges with adherence.

HEART Case Study #3: ART Adherence Assessment

Monitoring Question:
Was ART adherence assessed in all patients after ART was initiated?

Objective:
100% of patients should have ART adherence assessed at all three in-person post-ART visits.

Results:
ART adherence was assessed in 100% of post-ART visits.

Assessment

In response to the unsatisfied viral load objective, Fictitious Clinic assessed ART adherence, as high ART adherence is the behavior the intervention is intended to effect. Undetectable viral load is less likely if ART adherence is poor. They set their objective at 100% assessment because the main intent of implementing HEART is to improve ART adherence, so measuring it regularly is important. They did find that ART adherence was being assessed at all in-person post-ART visits.

Action

Fictitious Clinic was pleased they met their ART adherence objective, and communicated this finding to all care providers in HEART to encourage maintenance. They also assessed whether clinicians were using information gathered using this monitoring question to revise IAPs as needed, as described in Case Study 4.

HEART Case Study #4: IAP Adjustment

Monitoring Question:
Did all patients with ART adherence challenges have their IAP adjusted?

Objective:
100% of patients who took less than 90% of their doses or who said they were challenged by adherence should have an IAP review and adjustment with their care provider.

Results:
80% of HEART patients who reported challenges with ART adherence had an IAP review at an in-person visit.

Assessment

Fictitious clinic had found that viral load objectives were not met and wondered if it might be because clinicians were not adjusting IAPs when ART adherence challenges were identified. Because adjusting IAP is a critical factor in implementing HEART, they expected that 100% of patients with ART adherence challenges would have their IAP modified; however, only 80% did.

Action

The program manager at Fictitious Clinic identified failure to modify IAPs as a likely contributing cause to poor clinical outcomes at her clinic. She met with all clinicians administering HEART to re-educate them about HEART and emphasize the importance of revising IAPs in response to adherence challenges. She reminded them that filling out the individual patient visit data collection form prompted adjusting the IAP if needed. She scheduled reassessment of whether Fictitious Clinic was attaining objectives for the following month.

Chapter 5: Partnership for Health - Medication Adherence – Medication Adherence

This chapter provides information about Partnership for Health - Medication Adherence-Medication Adherence, including a program description and logic model. It also provides information for clinics implementing Partnership for Health - Medication Adherence, including program monitoring questions, setting objectives to interpret your clinic's results, data needs and collection methods, and sample patient visit forms and program monitoring worksheets. It also includes case studies to demonstrate use of the program monitoring worksheet and interpretation of its findings.

Inside this chapter for Partnership for Health - Medication Adherence:

- ▶ Program description
- ▶ Program monitoring questions
- ▶ Setting program objectives
- ▶ Case studies

5.1 Program Description

Partnership for Health - Medication Adherence is an individual-level, provider-administered ART adherence intervention for HIV-positive individuals who have not taken ART before. This intervention emphasizes the importance of the patient-provider relationship to promote patients' healthy behaviors. The intervention includes 3 to 5 minute counseling sessions during clinic visits to increase patients' knowledge and self-efficacy, and to promote behaviors associated with adherence to ART. Partnership for Health - Medication Adherence also uses printed materials during counseling sessions such as posters in the waiting and examination areas and brochures and flyers.

Partnership for Health - Medication Adherence was assessed in a RCT at six clinics: four comparison clinics that did not deliver ART adherence intervention, and two clinics that provided Partnership for Health - Medication Adherence.[8] The study took place in California between 1999 and 2000 and assessed outcomes of 437 HIV-positive patients on ART, of whom 149 participated in the Partnership for Health - Medication Adherence intervention. After 10 months, the intervention was found to be effective in helping ART-adherent patients maintain their adherence. However, it did not help non-adherent patients improve their adherence.

The purpose of Partnership for Health - Medication Adherence is to establish a partnership between the patient and primary care provider to improve understanding of the patient's health care needs and life circumstances. As with other chronic illnesses, adherence to treatment may change over time, and patients may need support at different periods during their treatment. Adherence counseling is a non-linear, seven-step counseling session with follow-up sessions lasting 3 to 5 minutes. The intervention provides a way to:

- Establish trust and mutual respect
- Inform the patient about their treatment
- Discuss concerns and barriers to adherence
- Problem-solve solutions to overcome barriers
- Establish behavioral cues to support adherence

- Motivate patients to establish adherence objectives
- Provide referrals for additional support to patients in need

Establishing a trusting and supportive relationship with the patient is key to the program. Assurance of confidentiality, a non-judgmental attitude, mutual respect, and clear communication are the foundation upon which the partnership is built. Effective communication is the provider’s principal tool in this strategy. Some effective counseling skills include:

- Active listening
- Reflection of listening
- Use of open- and close-ended questions
- Paraphrasing
- Redirecting

Additionally, materials designed to help providers follow the protocol and maintain the integrity of the strategy include:

- Brochures to introduce the patient to the partnership concept and messages about ART adherence
- Posters in the waiting room to convey the partnership theme, and posters in the examination rooms that include adherence messages
- Messages from the primary care provider during the medical examination to solidify the partnership, present adherence messages, and emphasize strategies and adherence objectives
- One-page information flyers given to patients upon subsequent visits to support provider messages and address commonly asked questions about ART and adherence. All materials were presented in English and Spanish and were designed to help providers adhere to the protocol and maintain the integrity of the strategy

Table 9 highlights steps of initial and follow-up ART counseling in Partnership for Health - Medication Adherence.

Table 9. Counseling Steps for Partnership for Health - Medication Adherence

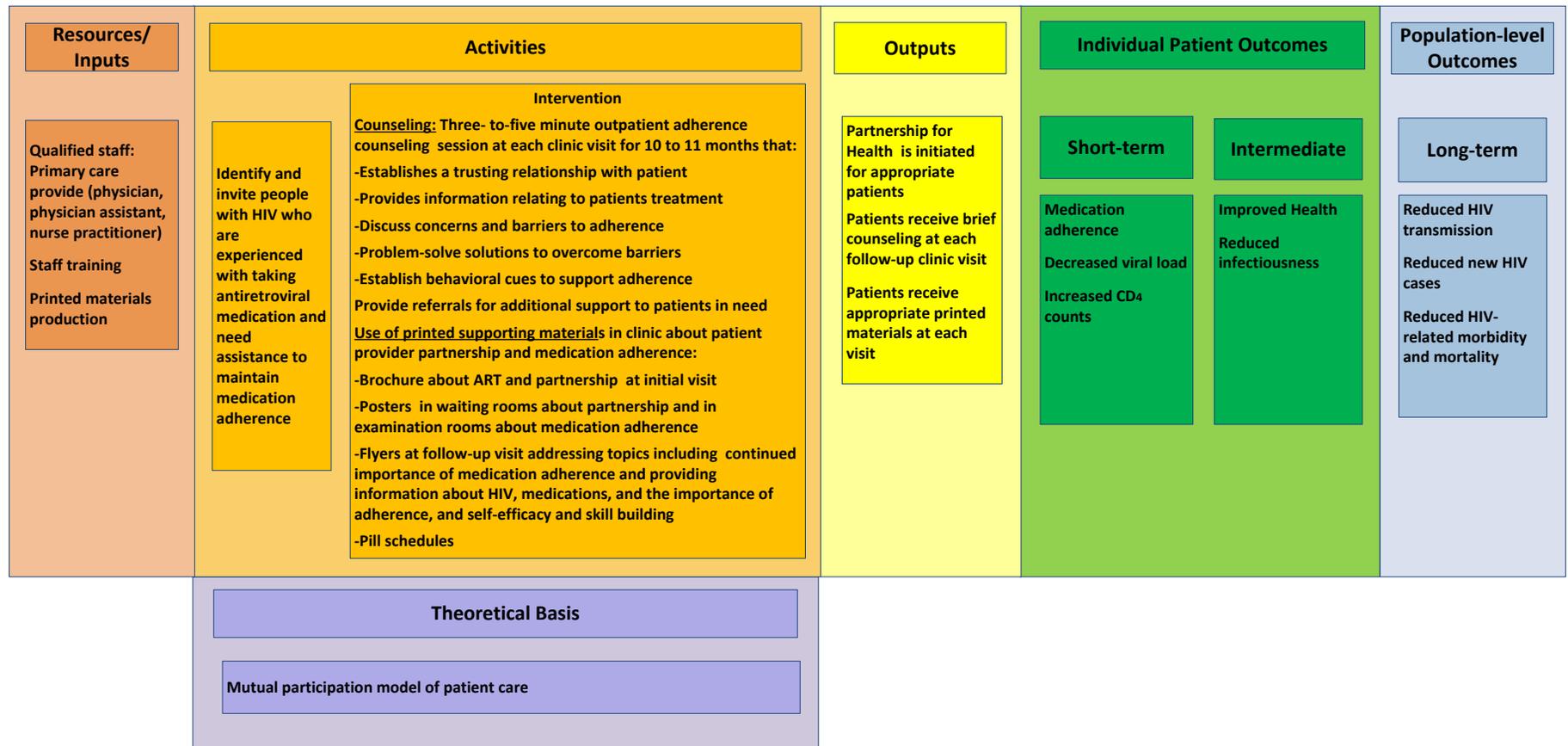
Step	Purpose	Activities
Initial Session		
1	Establish trust and communication with the patient.	<ul style="list-style-type: none"> ▪ Establish trust ▪ Assure confidentiality ▪ Effectively communicate information
2	Introduce the Partnership for Health - Medication Adherence program to the patient and include any combination of the key points.	<ul style="list-style-type: none"> ▪ Emphasize the importance of adherence to treatment and consequences of non-adherence ▪ Discuss the patient’s expectations of treatment ▪ Discuss the patient’s current health status (e.g., current or past opportunistic infections, lab results)

Step	Purpose	Activities
3	Review the treatment regimen with the patient and discuss any questions he or she may have about the medications.	<p>Possible discussion points include:</p> <ul style="list-style-type: none"> ■ Information about the medication(s) ■ Reviewing dosing instructions (i.e., when to take and instructions on food and fluid intake) ■ Reviewing plans for storing medications
4	Ask specific questions about the patient's adherence and identify concerns or barriers.	<p>Examples of possible adherence-related questions include:</p> <ul style="list-style-type: none"> ■ "How has it been going taking your medicines?" ■ "What seems to get in the way of your taking your medicines?" ■ "Have you missed any in the last week?" ■ "When are you most successful at taking your meds according to the regimen?"
5	Problem-solve barriers, identify strategies, and set a behavioral goal to improve the patient's adherence.	<p>Problem solving might include the following:</p> <ul style="list-style-type: none"> ■ Use the Adherence Strategies Brochure to identify a strategy to overcome barrier(s). ■ When time permits, the primary health care provider should develop the strategy with his or her patient. ■ Motivate the patient to set a behavioral goal that will support their adherence to ART. ■ Make a direct referral for the patient to see the adherence counselor and/or pharmacist for the purpose of providing additional support and counseling.
6	Before ending the discussion, reinforce three important adherence messages with the patient.	<ol style="list-style-type: none"> 1. "Every dose, every day. Use the strategy that we discussed to remind yourself when and how to take your medicines." 2. "Don't stop taking your medicines or change your medicines without first discussing this with me." 3. "Call me right away if you experience any side effects or problems with your medicines."
7	Document any behavioral objectives in the patient's chart and brochure and plan a follow-up visit.	Emphasize the importance of the patient assuming an active role in his or her health care and that you will be following up during subsequent visits about their response to ART and what they are doing to maintain adherence.
Follow-Up Sessions		
1	First follow-up	Upon a follow-up visit, give the patient an informational brochure that reinforces the prevention message and answer questions your patient may have about treatment.

Step	Purpose	Activities
2	Probe for the effectiveness of the strategy chosen during the last visit.	<p>Explore the effectiveness of the strategy identified during the previous visit by using questions or statements like these:</p> <ul style="list-style-type: none"> ■ “How has it been going taking your medications since we created the pill schedule?” ■ “How well has the strategy we discussed last time worked out for you?” ■ “Are you experiencing any side effects?” ■ “What questions do you have about your medications or how to take them?” ■ “Tell me which medications are you taking, when you take them, and how.”
3	Make adjustments to the strategy or suggest a different strategy.	<p>If there is a need to make adjustments to or select a different strategy:</p> <ul style="list-style-type: none"> ■ Identify barriers that continue to pose a problem for the patient's adherence and problem-solve solutions. ■ Suggest making adjustments to the strategy or identifying a different strategy. ■ Make appropriate referrals for the patient to additional resources and his or her adherence counselor.
4	Before ending the discussion, reinforce three important adherence messages with your patient.	<p>Before ending the discussion, reinforce three key messages introduced in the first adherence discussion:</p> <ol style="list-style-type: none"> 1. “Every dose, every day. Use the strategy that we discussed to remind yourself when and how to take your medicines.” 2. “Don't stop taking your medicines or change your medicines without first discussing this with me.” 3. “Call me right away if you experience any side effects or problems with your medicines.”
5	Document any behavioral objectives in the patient's chart and brochure and plan a follow-up visit.	<p>Again, as at the end of the initial visit, emphasize the importance of the patient assuming an active role in his or her health care and that you will be following up during subsequent visits about their response to ART and what they are doing to maintain adherence.</p>

Figure 6 is a logic model for Partnership for Health - Medication Adherence that shows the relationship between Partnership for Health - Medication Adherence program implementation and outcomes. The model lists its required resources, activities, and outputs, and the outcomes it is intended to achieve. It also lists specific measures that can be assessed to monitor the program and evaluate its outcomes.

Figure 6. Logic Model for Partnership for Health - Medication Adherence



5.2 Program Monitoring Questions for Partnership for Health - Medication Adherence

The efficacy of Partnership for Health - Medication Adherence in improving ART adherence may be evaluated using a single question:

- Was undetectable viral load achieved in the expected percentage of patients?

If the proportion of patients achieving undetectable viral load meets or exceeds your objective, ART adherence is assumed to be satisfactory. You may not need to evaluate your program further, but you may choose to increase your objective. If it is not satisfactory, you may wish to use the additional program monitoring questions for Partnership for Health - Medication Adherence listed below. If your clinic routinely collects information needed to address each of these questions during individual patients visits (such as using the form in Table 6) as part of your program monitoring plan, you will have the information you need to address all of the program monitoring questions. Items you answer “no” to identify potential areas for improvement. Refer to Chapter 2 for more information on using monitoring questions in the context of program monitoring.

- Were the Partnership for Health - Medication Adherence providers appropriately trained using the CDC e-learning course?
- Was the initial seven-step session administered to all program patients?
- Were 3- to 5-minute follow-up sessions delivered at all clinical care visits for all program patients?
- Were brochures about ART adherence disseminated?
- Were posters about partnership placed in every examination room, and posters about ART adherence posted in every examination room?
- Were information flyers designed for each follow-up session given to every program patient at the appropriate follow up visit?
- Was ART adherence assessed in all patients after ART was initiated?
- Were patients’ other needs addressed (e.g., substance abuse treatment, housing, transportation)?
- Did all patients attend all required intervention sessions?

5.3 Setting Program Objectives for Partnership for Health - Medication Adherence

Program objectives are the results you wish to achieve, such as the expected percentage of patients attaining undetectable viral load, or whether patients attended all required intervention sessions. Objectives enable you to interpret answers to the program monitoring questions and determine whether your clinic is meeting its short-term goals.

Consider using the SMART Objectives framework in Chapter 2 to form objectives that are specific, measureable, attainable/achievable, relevant, and time bound. Set objectives that are high enough

to indicate health improvement, but not so high that they are unattainable. For program monitoring questions about the delivery of key aspects of Partnership for Health - Medication Adherence (e.g., were brochures about ART adherence disseminated?), it may be reasonable to set an objective of 100% attainment because this activity should be completed for all patients. However, there are no universally accepted benchmarks for clinical outcomes, and realistic objectives for clinical outcomes vary by clinic. For more information about key clinical outcomes and measuring ART adherence, refer to Chapter 3.

5.4 Data Collection Tools for Partnership for Health - Medication Adherence

This section includes a sample patient visit data collection form and program monitoring worksheet for Partnership for Health - Medication Adherence, and fictitious case studies on their use. The Partnership for Health - Medication Adherence patient visit data collection form (Table 10) is intended to enable you to collect data as you administer your program, and to support and expedite data compilation and assessment using the program monitoring worksheet (Table 11).

Table 10. Partnership for Health - Medication Adherence Patient Visit Data Collection Template

Partnership for Health - Medication Adherence Patient Visit Data Collection Form	
Patient identification:	
Patient visit date:	
Visit type (circle one): Initial – Follow-up	
Administering clinician:	
Monitoring Questions – Individual Level	Findings
Was viral load suppressed? Interval since intervention initiation: Interval since last assessment: Viral load:	
Was the initial seven-step session administered to this patient?	
If this was a clinical care follow-up session, was a 3- to 5-minute follow-up session delivered?	
Were brochures about ART adherence given to this patient?	
Are there posters about partnership placed in every examination room, and posters about ART adherence posted in every examination room?	
Was the appropriate information flyer designed for this follow-up session given to this patient today?	
Was ART adherence assessed? Interval since intervention initiation: Interval since last assessment:	
Were this patient's other needs addressed (e.g., substance abuse treatment, housing, transportation)?	
Has this patient missed any sessions to date?	
Clinician notes, including program modifications or implementation problems:	

Table 11. Partnership for Health - Medication Adherence Program Monitoring Worksheet

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients?		Number of patients with undetectable viral load Total number of patients Duration(s) of follow-up assessed: 3 months				
Were the Partnership for Health - Medication Adherence providers appropriately trained using the CDC e-learning course?		Whether all care providers completed the e-learning course				
Was the initial seven-step session administered to all program patients?		Number of patients for whom the initial seven-step session was administered Total number of patients				
Were 3- to 5-minute follow-up sessions delivered at all clinical care visits for all program patients?		Number of patients for whom the brief follow-up sessions were delivered at each subsequent visit Total number of patients				
Were brochures about ART adherence disseminated?		Number of patient visits at which a brochure was given to patients Total number of patient visits				
Were posters about partnership placed in every examination room, and posters about ART adherence posted in every examination room?		Whether posters were posted, and in the appropriate locations				

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Were information flyers designed for each follow-up session given to every program patient at the appropriate follow-up visit?		Number of patient visits at which information flyers relevant to the follow-up visit were given to patients Total number of patient visits				
Was ART adherence assessed in all patients after ART was initiated?		Number of patients for whom the clinician assessed whether ART was being taken as prescribed Total number of patients				
Were patients' other needs addressed (e.g., substance abuse treatment, housing, transportation)?		Number of patients for whom clinicians provided assessments of factors that could affect ART adherence Total number of patients				
Did all patients attend all required intervention sessions?		Number of patients who attended all required sessions Total number of patients				

5.5 Case Studies in Partnership for Health - Medication Adherence

This section provides fictitious examples of program monitoring information for Partnership for Health - Medication Adherence. These cases present sample objectives, data collection, and determination of whether the program objective was satisfied for four monitoring questions. Table 12 shows a sample program monitoring worksheet, and examples of interpretation of the results follow. The examples are intended to demonstrate that assessing the results of your program monitoring plan can inform which areas of your program are strong and should be maintained, and which areas require more resource or a change in approach. These case studies are for illustrative purposes only and do not suggest what are appropriate objectives or assessment methods for your clinic.

Table 12. Case Study for Program Monitoring of Partnership for Health - Medication Adherence

Monitoring Question	Sample Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
<p>Was undetectable viral load achieved in the expected percentage of patients?</p> <p>Case Study 1</p>	At least 75% should have undetectable viral load at 3 to 6 months following the intervention	<p>Number of patients with undetectable viral load</p> <p>Total number of patients enrolled</p> <p>Duration(s) of follow-up assessed: 3 months</p>	60	100	60%	No
<p>Was the initial seven-step session administered to all program patients?</p> <p>Case Study 2</p>	100% of patients should have the initial seven-step session	<p>Number of patients who had initial seven-step session</p> <p>Total number of patients enrolled</p>	100	100	100%	Yes
<p>Were 3- to 5-minute follow-up sessions delivered at all clinical care visits for all program patients?</p> <p>Case Study 3</p>	100% of patients should have Partnership for Health - Medication Adherence follow-up sessions at each clinic visit	<p>Number of patients who had a brief follow-up at each clinic visit</p> <p>Total number of clinic visits</p>	80	100	80%	No

Monitoring Question	Sample Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
<p>Were information flyers designed for each follow-up session given to every program patient at the appropriate follow-up visit?</p> <p>Case Study 4</p>	<p>100% of patients should receive appropriate information flyers at each visit</p>	<p>Number of clinic visits at which the appropriate flyer was given to the program patient</p> <p>Total number of clinic visits</p>	<p>78</p>	<p>100</p>	<p>78%</p>	<p>No</p>

Partnership for Health - Medication Adherence Case Study #1: Undetectable Viral Load

Monitoring Question:
Was undetectable viral load achieved in the expected percentage of patients?

Objective:
At least 75% should have an undetectable viral load at 3 months.

Results:
60% had undetectable viral load.

Assessment

Fictitious Clinic evaluated what proportion of program enrollees had undetectable viral load 3 months after enrolling in Partnership for Health - Medication Adherence. They found only 60% of patients did, which did not reach their objective.

Action

As the objective was not met, Fictitious Clinic decided to employ additional program monitoring questions to identify areas for program delivery improvement. Fictitious Clinic identified initial and clinic follow-up sessions, with distribution of informational flyers as appropriate, as key aspects of their Partnership for Health - Medication Adherence program. They assessed these aspects of their program.

Partnership for Health - Medication Adherence Case Study #2: Initial Visit

Monitoring Question:
Was the initial seven-step session administered to all program patients?

Objective:
100% of patients should have the initial seven-step session.

Results:
100% of patients had the initial seven-step session.

Assessment

Fictitious Clinic found that all patients who were enrolled into their Partnership for Health - Medication Adherence program did receive the initial seven-step session.

Action

Clinicians were notified that this objective had been met and were encouraged to continue to deliver the initial session as planned. Further program assessment using additional questions was performed to identify potential causes of suboptimal clinical outcomes.

Partnership for Health - Medication Adherence Case Study #3: Follow-up Visits

Monitoring Question:

Were 3- to 5-minute follow-up sessions delivered at all clinical care visits for all program patients?

Objective:

100% of patients should have Partnership for Health - Medication Adherence follow-up sessions at each clinic visit.

Results:

The 3- to 5-minute follow-up session was delivered in only 80% of all clinic follow-up sessions for patients in the Partnership for Health - Medication Adherence program.

Assessment

Fictitious Clinic management staff wondered if the 3- to 5-minute ART adherence interventions were being delivered at all visits for patients in their Partnership for Health - Medication Adherence program. They tabulated the data and found that these follow-up interventions were only being delivered in 80% of the clinic visits.

Action

Management staff recognized that this key aspect of program delivery had to be addressed. As follow-up sessions were not always delivered as planned, they also wondered whether printed materials about ART were being distributed, and decided to assess this aspect of program delivery as shown in Case Study #4, below.

Partnership for Health - Medication Adherence Case Study #4: Informational Flyer Distribution

Monitoring Question:

Were information flyers designed for each follow-up session given to every program patient at the appropriate follow-up visit?

Objective:

100% of patients should receive appropriate information flyers at each visit.

Results:

Flyers were given in only 78% of follow-up visits for patients in Partnership for Health - Medication Adherence.

Assessment

Although Fictitious Clinic set the objective of appropriate informational flyers being given to patients at each follow-up visit, they were only distributed at 78% of follow-up visits. Fictitious Clinic investigated further and found usually these were the same visits in which the 3- to 5-minute ART adherence interventions were not administered.

Action

Management staff convened a mandatory meeting with all program delivery staff to re-train them on the importance of follow-up sessions and informational flyer distributions as part of the Partnership for Health - Medication Adherence program using CDC e-learning courses. Management recommended that staff use the individual patient collection data form as a reminder to make sure they deliver these program components at all applicable clinic follow-up visits.

Chapter 6: Peer Support

This chapter provides information about Peer Support, including a program description and logic model. It also provides information for clinics implementing Peer Support, including program monitoring questions, setting objectives to interpret your clinic's results, data needs and collection methods, and sample patient visit forms and program monitoring worksheets. It also includes case studies to demonstrate use of the program monitoring worksheet and interpretation of its findings.

6.1 Program Description

Peer Support is an individual- and group-level strategy to maintain ART adherence among HIV-positive individuals. In this intervention, people with HIV, who are adherent to their ART regimen are trained and supervised by program staff to support other HIV-positive patients who are initiating or changing their ART regimen, and ART-experienced patients struggling to maintain adherence. These peers provide ART-related social support through biweekly or monthly group meetings and weekly individual telephone calls, both of which provide a comprehensive support infrastructure to promote and support consistent ART adherence in program patients.

Peer Support was evaluated in 57 patients (called consumers in this program) in a randomized control trial for 3 months at a public HIV specialty clinic in Seattle, as described by Simoni and colleagues in 2009.[10] Peer Support patients were twice as likely to report 100 percent ART adherence immediately after the intervention than those who did not receive Peer Support. This effect did not persist after Peer Support was discontinued at 6 or 9 months follow-up, and there were no statistically significant changes in viral load or CD₄ count.

Table 13 describes and highlights the roles of the key players of the Peer Support Program: Peers, consumers, and program staff members. Further description is provided in the text that follows.

Inside this chapter for Peer Support:

- ▶ Program description
- ▶ Program monitoring questions
- ▶ Setting program objectives
- ▶ Case studies

Table 13. Key Players in Peer Support Intervention

Peers	Consumers	Program Staff Members
<ul style="list-style-type: none"> ■ Individuals with HIV who have maintained high levels of adherence to ART regimen. ■ Act as a support partner and group leader for a small cohort of HIV-positive program patients. ■ Help patients identify, discuss, and work to overcome adherence barriers. 	<ul style="list-style-type: none"> ■ HIV-positive individuals who are new to ART, changing ART regimen, or are ART-experienced but need additional support. ■ Receives ART adherence support from peer through phone conversations and from other peers and patients during group meetings. 	<ul style="list-style-type: none"> ■ Paid full-time employees ■ Physician, nurse, case manager, or other clinician with expertise in ART adherence ■ Responsible for identifying, training, supporting, and supervising Peers, and for overseeing strategy implementation.

Peers provide three types of support: affirmational, emotional, and informational. They also provide adherence tips tailored to consumers’ needs and appropriate referrals for medical inquiries. They do not provide medical advice. Supervision of peers by the program manager is critical to this strategy’s success. The program manager should meet with peers at least monthly to address any concerns in providing support to consumers and to monitor the fidelity of the program. One-on-one supervision is vital to help provide support and feedback to individual peers; group supervision may be another useful way to build rapport among peers.

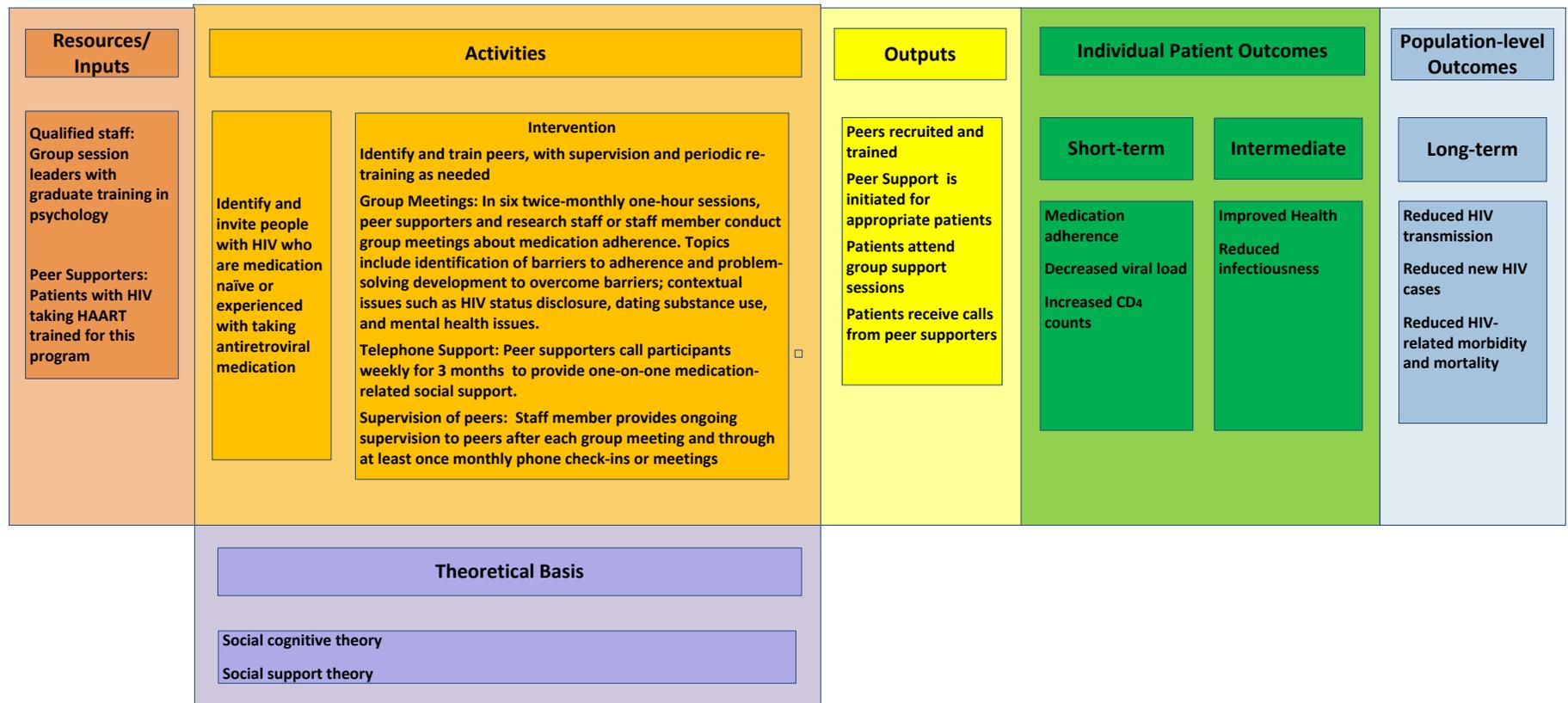
Table 14 highlights the activities and intended benefits of individual meetings and group meetings.

Table 14. Group and Individual Meeting Activities and Goals

Individual Weekly Calls	Group Biweekly or Monthly Meetings
<ul style="list-style-type: none"> ■ Facilitate the development of a trusting peer-patient relationship. ■ Provide an opportunity for patients to discuss barriers and facilitators to ART adherence. ■ Establish personal support for patients. ■ Encourage discussion with patients with confidentiality concerns and those who have trouble attending or speaking in group meetings. 	<ul style="list-style-type: none"> ■ Meeting frequency depends on available resources and the ability of patients to attend. ■ Led by peers and supervised by a staff member. ■ Staff member provides food for patients and introduces the meeting. Following these initial remarks, the staff member allows the peer to facilitate the discussion with patients. ■ Provide patients an opportunity to interact face-to-face with their assigned peers, hear from other peers and patients, and share experiences with the group. ■ Diminishes stigma and patients’ sense of isolation, and fosters norms that support adherence.

Figure 7 is a logic model for Peer Support that shows the relationship between Peer Support program implementation and outcomes. It lists its required resources, activities, and outputs, and the outcomes it is intended to achieve. The model lists specific measures that can be assessed to monitor the program and evaluate its outcomes.

Figure 7. Logic Model for Peer Support



6.2 Program Monitoring Questions for Peer Support

The effectiveness of Peer Support in improving ART adherence may be evaluated using a single question:

- Was undetectable viral load achieved in the expected percentage of patients?

If the proportion of patients achieving undetectable viral load meets or exceeds your objective, ART adherence is satisfactory. You may not need to evaluate your program further. If it is not satisfactory, you may wish to use the additional program monitoring questions for Peer Support listed below. If your clinic routinely collects information needed to address each of these questions during individual patients visits (such as using the form in Table 6 on page 32) as part of your program monitoring plan, you will have the information you need to address all of the program monitoring questions. Items you answer “no” to identify potential areas for improvement. Refer to Chapter 2 for more information on using monitoring questions in the context of program monitoring.

- Were the Peer Support program staff members appropriately trained using the CDC e-learning course?
- Were peers selected for good adherence and appropriately trained?
- Did the program manager meet with each peer at least once per month?
- Were biweekly meetings offered consistently?
- Did peers phone individual consumers weekly?
- Was ART adherence assessed in all patients after ART was initiated?
- Were patients’ other needs addressed (e.g., substance abuse treatment, housing, transportation)?
- Did all patients attend all required intervention sessions?

6.3 Setting Program Objectives for Peer Support

Program objectives are the results you wish to achieve by implementing the ART adherence intervention, such as the expected percentage of patients attaining undetectable viral load, or whether all patients attended all required intervention sessions. Objectives enable you to interpret answers to the program monitoring questions and determine whether your clinic is meeting its short-term goals.

Consider using the SMART Objectives framework in Chapter 2 to form objectives that are specific, measureable, attainable/achievable, relevant, and time bound. Aim to set objectives that are large enough to indicate health improvements, but not so high that they are unattainable. For program monitoring questions about the delivery of key aspects of Peer Support (e.g., were peers selected for good adherence and appropriately trained?), it may be reasonable to set an objective of 100% attainment because this is a key aspect of program delivery. However, there are no universally accepted benchmarks for clinical outcomes, and realistic objectives for clinical outcomes vary by clinic. For more information about key clinical outcomes and measuring ART adherence, refer to

6.4 Data Collection Tools for Peer Support

This section includes a sample individual patient visit data collection form and program monitoring worksheet for Peer Support, and fictitious case studies on their use. The Peer Support patient visit data collection form (Table 15) is intended to enable you to collect data as you administer your program, and to support and expedite data compilation and assessment using the program monitoring worksheet (Table 16).

Table 15. Peer Support Patient Visit Data Collection Template

Peer Support Patient Visit Data Collection Form	
Patient identification:	
Patient visit date:	
Administering clinician:	
Monitoring Questions – Individual Level	Findings
Was viral load suppressed? Interval since intervention initiation: Interval since last assessment: Viral load:	
Were peers selected for good adherence and appropriately trained?	
Did the program manager meet with each peer at least once per month?	
Were biweekly meetings offered consistently?	
Did peers phone individual consumers weekly?	
Was ART adherence assessed? Interval since intervention initiation: Interval since last assessment:	
Were this patient's other needs addressed (e.g., substance abuse treatment, housing, transportation)?	
Has this patient missed any sessions to date?	
Clinician notes, including program modifications or implementation problems:	

Table 16. Peer Support Program Monitoring Worksheet

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients?		Number of patients with undetectable viral load Total number of patients Duration(s) of follow-up assessed: 3 months				
Were the Peer Support program staff members appropriately trained using the CDC e-learning course?		Whether all staff completed the e-learning course				
Were peers selected for good adherence and appropriately trained?		Number of peers for whom ART adherence is acceptable and appropriate training was completed Total number of peers				
Did the program manager meet with each peer at least once per month?		Number of peers who met with the program manager in a given month (or over multiple months, if you wish to calculate an average) Total number of peers				
Were biweekly meetings offered consistently?		Verification that biweekly meetings occurred				
Did peers phone individual consumers weekly?		Number of individual consumers called by peer reviewers Total number of individual consumers				
Was ART adherence assessed in all patients after ART was initiated?		Number of patients for whom the clinician assessed whether ART was being taken as prescribed Total number of patients				

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Were patients' other needs addressed (e.g., substance abuse treatment, housing, transportation)?		Number of patients for whom clinicians provided assessments of factors that could affect ART adherence Total number of patients				
Did all patients attend all required intervention sessions?		Number of patients who attended all required sessions Total number of patients				

6.5 Case Studies in Peer Support

This section provides fictitious examples of recording program monitoring information for Peer Support. These cases present sample objectives, data collection, and determination of whether the program objective was satisfied for four monitoring questions. Table 17 shows a sample program monitoring worksheet, and examples of interpretation of the results follow. The examples are intended to demonstrate that assessing the results of your program monitoring plan can inform which areas of your program are strong and should be maintained, and which areas require more resources or a change in approach. These case studies are for illustrative purposes only and do not suggest what are appropriate objectives or assessment methods for your clinic.

Table 17. Case Study for Program Monitoring of Peer Support

Monitoring Question	Sample Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients? Case Study 1	At least 40% should have undetectable viral load at 3 to 6 months following the intervention	Number of patients with undetectable viral load Total number of patients enrolled Duration(s) of follow-up assessed: 3 months	42	100	42%	Yes
Were the Peer Support program staff members appropriately trained using the CDC e-learning course? Case Study 2	100% of Peer Support program staff members should be appropriately trained using the CDC e-learning course	Number of Peer Support program staff members who completed the CDC e-learning course Total number of Peer Support program staff members	100	100	100%	Yes
Were peers selected for good adherence and appropriately trained? Case Study 3	100% of peers should have good ART adherence should have been appropriately trained	Number of peers with good ART adherence and appropriate training Total number of peers	100	100	100%	Yes
Did the program manager meet with each peer at least once per month? Case Study 4	The program manager should meet with at least 90% of the peers each month	Number of peers with whom the program manager met in a month Total number of peers	75	100	75%	No

Peer Support Case Study #1: Undetectable Viral Load

Monitoring Question:

Was undetectable viral load achieved in the expected percentage of patients?

Objective:

At least 40% should have undetectable viral load at 3 months.

Results:

42% of program patients achieved undetectable viral load.

Assessment

Fictitious Clinic was pleased that they had met their objective for proportion of patients with undetectable viral load at 3 months follow-up.

Action

Fictitious Clinic decided to raise the objective to 50% of patients with undetectable viral load for the 6-month follow-up, and implemented additional program monitoring questions to make sure their program was well-implemented to support achieving the new objective.

Peer Support Case Study #2: Program Staff Training

Monitoring Question:

Were the Peer Support program staff members appropriately trained using the CDC e-learning course?

Objective:

100% of Peer Support program staff members should have been appropriately trained using the CDC e-learning course.

Results:

100% of program staff were appropriately trained.

Assessment

Fictitious Clinic had rapidly implemented Peer Support, and the program manager wondered whether all program staff members had completed the CDC e-learning course. They found that all had.

Action

Fictitious Clinic was assured that appropriate training had occurred, but to support meeting their new objective, decided to give a brief review session to program staff based upon the CDC e-learning course.

Peer Support Case Study #3: Peer Selection and Training

Monitoring Question:

Were peers selected for good adherence and appropriately trained?

Objective:

100% of peers should have good ART adherence and should have been appropriately trained.

Results:

100% of peers had good ART adherence and were appropriately trained.

Assessment

Fictitious Clinic reviewed the individual patient visit data collection forms to verify that program staff members noted that peers supporting each patient had good ART adherence and had undergone appropriate training. They found that all had.

Action

Fictitious Clinic notified program staff members that this objective had been met, and recommended that program staff members verify ongoing ART adherence during monthly peer-program manager follow-up sessions.

Peer Support Case Study #4: Monthly Peer Meetings

Monitoring Question:

Did the program manager meet with each peer at least once per month?

Objective:

The program manager should meet with at least 90% of the peers each month.

Results:

The program manager met with only 75% of peers per month on average over the 3-month period.

Assessment

Fictitious Clinic asked whether the program manager met with at least 90% of the peers on average. Although 100% meeting monthly would be ideal, they set the objective at 90% to realistically allow for scheduling conflicts. They found that the program manager had actually only met with 75% of peers on average each month.

Action

The program manager was surprised to hear that the proportion of peers met with per month was so low, and renewed efforts to ensure as many peers as possible were met with. When scheduling in-person meetings was prohibitive, the program manager scheduled telephone or internet-based meetings. The program manager believes these meetings are important for ensuring good support delivery by peers and is hopeful that working to achieve this objective will help improve overall care delivery and clinical outcomes.

Chapter 7: SMART Couples

This chapter provides information about SMART Couples, including a program description and logic model. It also provides information for clinics implementing SMART Couples, including program monitoring questions, setting objectives to interpret your clinic's results, data needs and collection methods, and sample patient visit forms and program monitoring worksheets. It also includes case studies to demonstrate use of the program monitoring worksheet and interpretation of its findings.

7.1 Program Description

SMART Couples—Sharing Medical Adherence Responsibility

Together—comprises four 45- to 60-minute sessions for serodiscordant couples in which the HIV-positive partner has poor ART adherence or is switching to a new ART regimen because of drug resistance. The sessions are scheduled weekly, with a 2-week break period between Session 3 and Session 4. The time needed to deliver the program may vary according to the involvement level of the couples participating. Sessions are administered by a health educator or a HIV medical provider, such as a nurse, nurse practitioner, social worker, or counselor. The sessions have structured itineraries that emphasize cognitive-behavioral strategies to improve the HIV-positive partner's ART adherence by fostering active support from the HIV-negative partner. In addition, sexual transmission prevention strategies are addressed. The program was designed to be implemented in a clinical setting or through an AIDS service organization or community-based organization that collaborates with a clinical site.

The efficacy of SMART Couples was assessed in a RCT that took place between 2000 and 2004 at two HIV clinics in New York City.[12] The results showed higher mean ART adherence during the intervention and at 2 weeks post-intervention among study completers, but not the overall enrolled sample, compared to the usual care control group. Differences in adherence at longer durations of post-intervention follow-up were generally not statistically significant.

The objectives of SMART Couples are to:

- Improve adherence to ART
- Increase social support for adherence to ART and transmission risk reduction
- Address couple's sexual transmission concerns
- Address couple's issues of sex and intimacy

Table 18 describes and highlights the roles of the key players of the SMART Couples intervention: the intervention provider and the serodiscordant couple.

Inside this chapter for SMART Couples:

- ▶ Program description
- ▶ Program monitoring questions
- ▶ Setting program objectives
- ▶ Case studies

Table 18. Key Players in SMART Couples Intervention

Provider	Serodiscordant Couples	
<ul style="list-style-type: none"> ■ Nurses, nurse practitioners, social workers, counselors, or health educators. ■ Facilitate dialogue to help couples increase their knowledge of the importance of HIV medication adherence, develop communication and problem-solving skills to address adherence barriers, and to make a commitment to improving adherence together. 	<ul style="list-style-type: none"> ■ Couples are heterosexual or same-sex couples in a committed relationship for at least 6 months. ■ Couples are committed to participating in four sessions, which may last up to an hour ■ Couples with an unstable relationship status may not be appropriate patients in this strategy. This strategy should not be viewed as couple’s therapy. 	
	HIV-Positive Partners	HIV-Negative Partners
	<ul style="list-style-type: none"> ■ Must be in medical care and have been on antiretroviral medication for at least 1 month. ■ Have poor medication adherence or is switching to a new treatment regimen because of treatment failure. ■ Engage with partner and provider to identify barriers to medication adherence and strategize solutions to challenges. 	<ul style="list-style-type: none"> ■ Support partner’s commitment to medication adherence improvement. ■ Help partner identify and address adherence challenges.

No more than 4 weeks should pass between sessions. At the start of each session, the provider reviews laboratory results or the patient’s self-reported ART adherence. Following review, each session consists of discussion, instruction, and structured exercises that focus on the following concepts:

- Knowledge and understanding about ART and treatment
- Commitment to adherence
- Problem-solving skills to identify and overcome adherence barriers
- Building commitment, motivation, and self-efficacy for optimal adherence

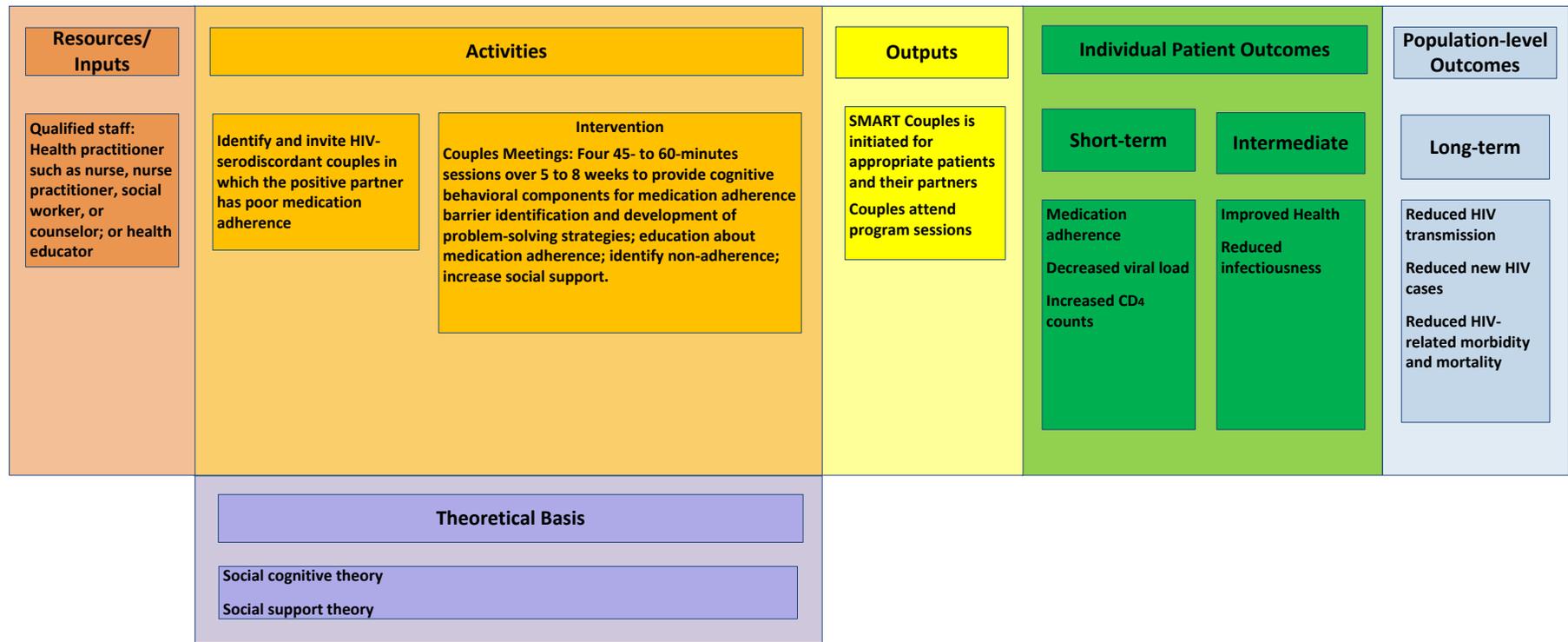
Table 19 provides an overview of the activities conducted in each session and the concepts each session addresses.

Table 19. SMART Couples Activities and Concepts

Session	Description	Activities	Concepts Addressed
1	Introducing ART and the Role of the Partner	<ul style="list-style-type: none"> ■ Establish rules and build rapport with couple. ■ Introduce couple to various components of ART adherence. ■ Educate about the importance of ART adherence in relation to health outcomes and drug resistance. ■ Review information about medication regimen, medical appointment schedules, and prescription plan. ■ Discuss the partner role and how he/she will help promote and motivate commitment to adherence, as well as provide couple-level support for adherence. 	<ul style="list-style-type: none"> ■ Knowledge and understanding about medication and treatment ■ Commitment to adherence
2	Identifying and Addressing Adherence Barriers	<ul style="list-style-type: none"> ■ Identify barriers and facilitators to adherence. ■ Review and model steps for problem-solving. ■ Have couple choose a barrier and practice applying the problem-solving process. ■ Perform an activity designed to enhance communication around health care concerns. ■ Discuss reminder devices. 	<ul style="list-style-type: none"> ■ Problem-solving skills to identify and overcome adherence barriers
3	Coping with Stressful Situations	<ul style="list-style-type: none"> ■ Work with the couple to choose another barrier and practice the problem solving application again. ■ Discuss how couple deals with sexual risk and medication side effects. ■ Teach how to enhance coping skills. ■ Identify barriers to adherence and apply problem-solving process to a specific barrier. 	<ul style="list-style-type: none"> ■ Problem-solving skills to identify and overcome adherence barriers
4	Making a Commitment to Adherence	<ul style="list-style-type: none"> ■ Identify triggers and early warning signs for difficult times ahead. ■ Review adherence strategies that worked and link them to self-efficacy. ■ Review ongoing barriers adherence and steps to problem solving. ■ Build couple's commitment to caring for each other and self-efficacy to maintain adherence behaviors moving forward. 	<ul style="list-style-type: none"> ■ Building commitment, motivation, and self-efficacy for optimal adherence

Figure 8 is a logic model for SMART Couples that shows the relationship between SMART Couples program implementation and outcomes. It lists its required resources, activities, and outputs, and the outcomes it is intended to achieve. The model lists specific measures that can be assessed to monitor the program and evaluate its outcomes.

Figure 8. Logic Model for SMART Couples



7.2 Program Monitoring Questions for SMART Couples

The effectiveness of SMART Couples in improving ART adherence may be evaluated using a single question:

- Was undetectable viral load achieved in the expected percentage of patients?

If the proportion of patients achieving undetectable viral load meets or exceeds your objective, ART adherence is satisfactory. You may not need to evaluate your program further. If it is not satisfactory, you may wish to use the additional program monitoring questions for HEART listed below. If your clinic routinely collects information needed to address each of these questions during individual patients visits (such as using the form in Table 6) as part of your program monitoring plan, you will have the information you need to address all of the program monitoring questions. Items you answer “no” to identify potential areas for improvement. Refer to Chapter 2 for more information on using monitoring questions in the context of program monitoring.

- Were the SMART Couples program staff members appropriately trained using the CDC e-learning course?
- Are the couples free from relationship issues that need to be addressed before SMART Couples can be effectively administered?
- Did both partners in the couple attend all four sessions?
- Was ART adherence assessed in all patients after ART was initiated?
- Were patients’ other needs addressed (e.g., substance abuse treatment, housing, transportation)?

7.3 Setting Program Objectives for SMART Couples

Program objectives are the results you wish to achieve by implementing the ART adherence intervention, such as the expected percentage of patients attaining undetectable viral load, or whether patients attended all required intervention sessions. Objectives enable you to interpret answers to the program monitoring questions and determine whether your clinic is meeting its short-term goals.

Consider using the SMART Objectives framework in Chapter 2 to form objectives that are specific, measureable, attainable/achievable, relevant, and time bound. Aim to set objectives that are high enough to indicate health improvement, but not so high that they are unattainable. For program monitoring questions about the delivery of key aspects of SMART Couples (e.g., are the patient couples free from relationship issues that need to be addressed before SMART Couples can be effectively administered?), it may be reasonable to set an objective of 100 percent attainment because this is a fundamental enrollment criterion. However, there are no universally accepted benchmarks for clinical outcomes, and realistic objectives for clinical outcomes vary by clinic. For more information about key clinical outcomes and measuring ART adherence, refer to Chapter 3.

7.4 Data Collection Tools for SMART Couples

This section includes a sample individual patient visit data collection form and program monitoring

worksheet for SMART Couples, and fictitious case studies on their use. The SMART Couples patient visit data collection form (Table 20) is intended to enable you to collect data as you administer your program, and to support and expedite data compilation and assessment using the program monitoring worksheet (Table 21).

Table 20. SMART Couples Patient Visit Data Collection Template

SMART Couples In-Person Patient Visit Data Collection Form	
Patient identification:	
Patient visit date:	
Session (circle one): Session 1 – Session 2 – Session 3 – Session 4	
Administering clinician:	
Monitoring Questions – Individual Level	Finding
Was viral load suppressed? Interval since intervention initiation: Interval since last assessment: Viral load:	
Is this couple free from relationship issues that need to be addressed before SMART Couples can be effectively administered?	
Are both partners present at this session?	
Was ART adherence assessed? Interval since intervention initiation: Interval since last assessment:	
Were the patient's other needs addressed (e.g., substance abuse treatment, housing, transportation)?	
Clinician notes, including program modifications or implementation problems:	

Table 21. SMART Couples Program Monitoring Worksheet

Monitoring Question	Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients?		Number of patients with undetectable viral load Total number of patients Duration(s) of follow-up assessed: 3 months				
Were the SMART Couples program staff members appropriately trained using the CDC e-learning course?		Whether all clinicians completed the CDC e-learning course				
Are the patient couples free from relationship issues that need to be addressed before SMART Couples can be effectively administered?		Number of couples free from relationship issues that could interfere with care delivery Total number of couples				
Did both partners in the couple attend all four sessions?		Number of couples that attended all four sessions Total number of couples				
Was ART adherence assessed in all patients after ART was initiated?		Number of patients for whom the clinician assessed whether ART was being taken as prescribed Total number of patients				
Were patients' other needs addressed (e.g., substance abuse treatment, housing, transportation)?		Number of patients for whom clinicians provided assessments of factors that could affect ART adherence Total number of patients				

7.5 Case Studies in SMART Couples

This section provides fictitious examples of recording and using program monitoring information for SMART Couples. These cases present sample objectives, data collection, and determination of whether the program objective was satisfied for four monitoring questions. Table 22 shows a sample program monitoring worksheet, and examples of interpretation of the results follow. The examples are intended to demonstrate that assessing the results of your program monitoring plan can inform which areas of your program are strong and should be maintained, and which areas require more resource or a change in approach. These case studies are for illustrative purposes only and do not suggest what are appropriate objectives or assessment methods for your clinic.

Table 22. Case Study for Program Monitoring of SMART Couples

Monitoring Question	Sample Objective	What to Measure	Number of Individuals with "Yes" Response	Total Number of Program Patients	Attainment Percentage	Program Objective Met or Exceeded?
Was undetectable viral load achieved in the expected percentage of patients? Case Study 1	At least 40% of patients should have undetectable viral load at 3 to 6 months following the intervention	Number of patients with undetectable viral load Total number of patients enrolled Duration(s) of follow-up assessed: 3 months	35	100	35%	No
Are the patient couples free from relationship issues that need to be addressed before SMART Couples can be effectively administered? Case Study 2	100% of couples should be free from relationship issues that would interfere with the program	Number of couples free from relationship issues that could interfere with care delivery Total number of couples	75	100	75%	No
Did both partners in the couple attend all four sessions? Case Study 3	100% of couples should attend all sessions	Number of couples that attended all four sessions Total number of couples	60	100	60%	No

SMART Couples Case Study #1: Undetectable Viral Load

Monitoring Question:
Was undetectable viral load achieved in the expected percentage of patients?

Objective:
At least 40% of patients should have undetectable viral load at 3 months.

Results:
35% had undetectable viral load at 3 months.

Assessment
Fictitious Clinic found that 35% of seropositive patients had undetectable viral load, shy of their objective of 40%.

Action
The program manager conferred with staff and suspected that inappropriate selection of couples and inadequate session attendance by couples might be contributing to the poor clinical outcome. The program manager began a brief program monitoring assessment using data collected on individual patient data collection forms about these two factors.

SMART Couples Case Study #2: Couples' Relationship Issues

Monitoring Question:
Are the patient couples free from relationship issues that need to be addressed before SMART Couples can be effectively administered?

Objective:
100% of couples should be free from relationship issues that would interfere with the program.

Results:
75% of couples were free from relationship issues that would interfere with the program.

Assessment
The program manager recognized the importance of appropriate patient enrollment for SMART couples, since couples with unresolved relationship issues would be unlikely to benefit. He checked the individual patient collection forms and found that for a quarter of the couples, the program staff member providing the SMART Couples sessions believed a relationship issue was interfering with care delivery.

Action
The program manager contacted each of the staff members who noted potential relationship problems with the couples and advised them to arrange appropriate counseling and support to address the issues and then reinitiate SMART Couples for them. He also reminded all staff members to proactively address relationship issues that could potentially interfere with ART adherence or participation in SMART Couples.

SMART Couples Case Study #3: Session Attendance

Monitoring Question:

Did both partners in the couple attend all four sessions?

Objective:

100% of couples should attend all four sessions.

Results:

60% couples attended all four sessions.

Assessment

SMART Couples is structured as a four-session program; each session provides unique and important information. The program manager at Fictitious Clinic believed strongly that the program would be most successful if all sessions were delivered, but found only 60% of couples enrolled in SMART Couples attended all four sessions.

Action

The program manager concluded that poor attendance was a likely cause of the weak clinical outcomes, and that determining why session attendance was so low was critical to improving program delivery. He decided to launch a full program monitoring assessment using data collected on the individual patient visit data collection forms. He convened all program staff to discuss the program monitoring findings and potential solutions and to determine a plan of action.

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