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How to Implement a Gaps Analysis Framework to Guide Quality Improvement in ART Programs

AUGUST 2011

This manual was prepared University Research Co., LLC (URC) for review by the United States Agency for International Development (USAID) and authored by Ms. Fazila Shakir and Dr. Suzanne Gaudreault of URC. The Gaps Analysis Framework was developed by the USAID Health Care Improvement Project, which is managed by URC and made possible by the generous support of the American people through USAID and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

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ABBREVIATIONS

3TC	Lamivudine (antiretroviral medication)
ART	Antiretroviral therapy
ARV	Antiretrovirals
AZT	Azidothymidine (antiretroviral medication)
CD4	Cluster of differentiation 4
CDC	Centers for Disease Control and Prevention
HCI	USAID Health Care Improvement Project
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
Kg	Kilogram
Lbs	Pounds
LTFU	Lost to follow-up
MOH	Ministry of Health
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLWHA	Persons living with HIV/AIDS
QI	Quality Improvement
URC	University Research Co., LLC
USAID	United States Agency for International Development
WHO	World Health Organization

Executive Summary

A major function of the USAID Health Care Improvement Project (HCI) is to develop and validate methods for strengthening the capacity of health systems to provide and sustain high-quality HIV/AIDS services. These activities are guided by the principle that high quality HIV/AIDS programs: 1) provide essential services for all who need them, 2) retain in care and treatment everyone who accesses services, and 3) achieve optimal clinical outcomes for everyone retained in care and treatment.

Due to the great clinical complexity of HIV/AIDS and the issues associated with it, many process indicators have been generated to enable programs to monitor and evaluate the quality of HIV care and treatment programs. This multitude of indicators can make identifying priorities for improvement difficult and lead to actions that fail to address key program weaknesses. In 2009, HCI developed and began testing the Gaps Analysis Framework to guide improvement activities for antiretroviral therapy (ART) programs. The Framework offers an approach to identifying and prioritizing problems and for evaluating the long-term effects of changes made to improve the systems surrounding the delivery of ART services. The approach enables implementers to measure and better understand overall program outcomes for coverage, patient retention in care, and clinical status of patients on ART. These outcomes are defined by a small set of indicators that expose program gaps by comparing potential to actual numbers of people with HIV who: 1) receive treatment, 2) are retained in treatment, and 3) achieve a good clinical status.

At pilot sites, the Framework has been useful for guiding HIV treatment programs in choosing their quality improvement (QI) priorities and in monitoring overall program improvement. The Framework helps identify health system weaknesses and gaps which can then be addressed through QI activities. Ongoing data collection and monitoring can then guide decision-making on whether tested changes should be adopted as long-term solutions to problems related to gaps in coverage, retention, and clinical status.

The Framework employs an idealized quantitative "dashboard" for identifying gaps in ART programs. In this sense, it provides a quantitative overview of the past and present effectiveness of an ART program and exposes quality gaps to guide QI decision-making. This manual explains how to set up and work with the Framework. Also included is a description of how to develop and test changes to reduce these gaps in quality. Some or all of the data needed for this Framework may be readily available; alternatively, program implementers may need to adapt information systems so necessary data can be collected. The meaning of the gaps quantified through this Framework can vary depending on the situation, and this should be taken into account in measuring, interpreting, and addressing the three gaps. These gaps may take long periods to reduce or close. Short-term QI decisions should therefore not be based solely on the information provided by the Framework. Rather, the Framework should be used for long-term program monitoring and decision-making, while specific process and/or intermediate outcome indicators, chosen to address one or more of the outcome gaps, should be used to track data and make short-term QI decisions.

I. INTRODUCTION

The USAID Health Care Improvement Project (HCI), which is supported by the American people through the United States Agency for International Development (USAID), is working to validate methods for strengthening the capacity of health systems to provide and sustain high-quality HIV/AIDS services in a way that acknowledges the chronic nature of HIV infection. In 2009 HCI began work to develop and field test a Gaps Analysis Framework to guide Quality Improvement (QI) in ART programs. The Framework offers an approach for identifying and prioritizing problems areas to target for quality improvement activities and for evaluating the long-term effects of changes made to improve the systems surrounding the delivery of ART services.

The premise behind the Gaps Analysis Framework for ART Programs is that the goal of antiretroviral therapy (ART) programs should be to achieve the best possible:

- Coverage: All persons eligible for ART are able to receive it.
- Retention: All patients who start ART continue receiving it.
- Clinical status: Patients continuing ART achieve and maintain the best possible health status.

The approach enables implementers to measure and better understand overall program outcomes for: coverage, retention, and the clinical status of patients on ART. These outcomes are defined by a small set of indicators that expose program outcome gaps by comparing potential to actual numbers of people with HIV who: 1) receive treatment, 2) are retained in treatment, and 3) achieve a good clinical status.

To assure maximum **coverage,** patients must have access to needed HIV services, including ART. QI efforts to close the gap in ART coverage for a catchment area may require several different interventions, such as: 1) establishing or increasing HIV testing at the health care facility and/or creating/strengthening linkages with other testing sites, 2) improving the process of identifying patients who are eligible for treatment and successfully referring them to an HIV treatment facility, and 3) locating patients who have previously been identified as having HIV but who have never registered for HIV/AIDS care, and/or 4) improving efficiencies at the clinic so that everyone who needs ART can be treated.

Improving **retention** requires minimizing the number of patients who are lost to follow-up and increasing their regular clinic attendance. In designing interventions to improve retention, it is necessary to explore the reasons why patients missed clinic appointments. By asking patients for their views on barriers to keeping appointments, health care workers can work with patients to design interventions which facilitate clinic attendance.

In order for patients to achieve their best possible **clinical status,** improvements in the provision of evidence-based clinical care and in the support of patient self-management are often needed. To enhance the clinical status of patients, health care workers should explore and design interventions which address issues contributing to poor clinical outcomes. These issues may involve specific deficiencies in the health care system; inadequate diagnosis and treatment of AIDS-related illnesses; or problems involving antiretroviral (ARV) medications, such as poor adherence and side-effects.

The purpose of this manual is to: describe the Framework and how it is used; provide instructions for its implementation; and present a general approach to the application of QI methods to close the gaps revealed by the framework. An appendix is included, which describes successful changes and change ideas that have been implemented by HCI-supported QI teams to close ART program gaps.

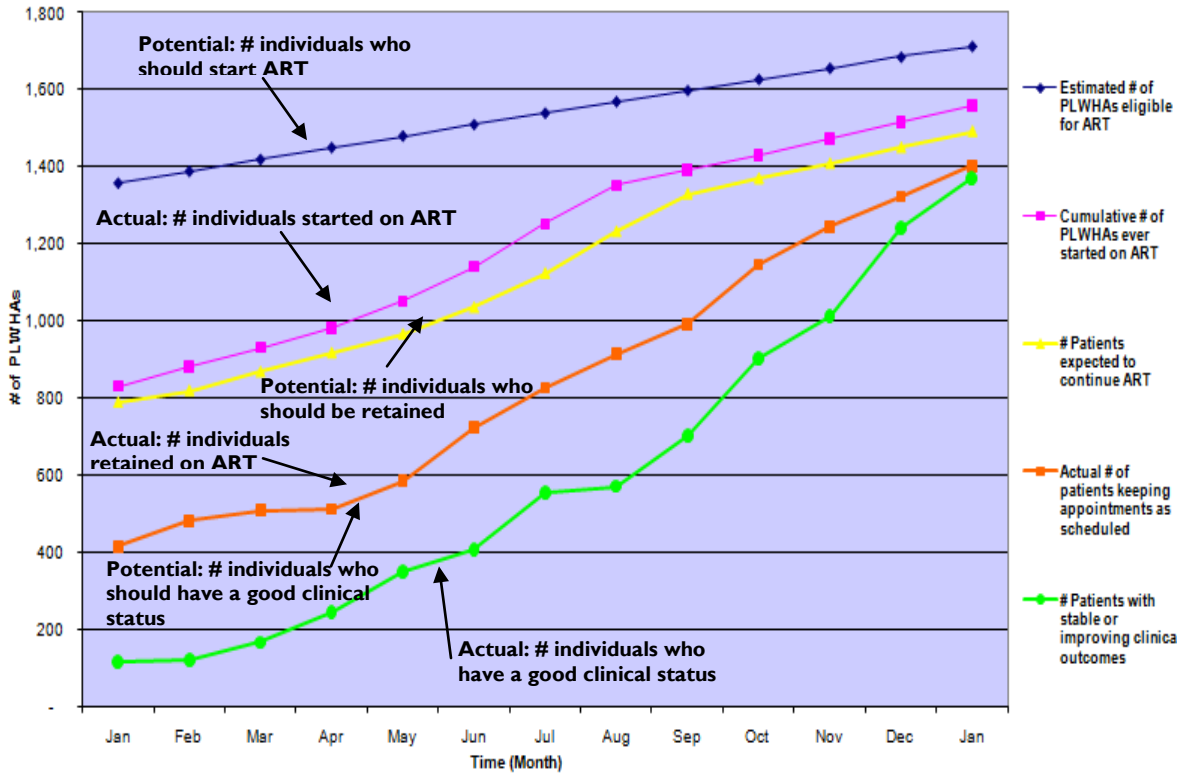
II. WHAT IS MEANT BY "GAPS"

In business and economics, "gap analysis" is a tool used to measure actual performance against potential performance. Gap analysis can similarly be used in health care to measure actual performance, determined by measuring an indicator, against potential performance, determined by calculating the best possible measure of that indicator. The "gaps" in the Gaps Analysis Framework to Guide Quality Improvement in ART Programs are the differences between actual and potential:

1. **Coverage**: actual coverage of ART-eligible people by ART and potential coverage of ART-eligible people by ART
2. **Retention**: actual numbers of people who started ART and are still on ART and potential numbers of people who started ART and are still taking antiretrovirals (ARVs), and
3. **Clinical Status**: actual numbers of people on ART who are doing well clinically and potential numbers of people on ART who are doing well clinically

In gap analysis, the "actual" total for one indicator is often the "potential" total for another indicator. In this case, the "actual # retained on ART," is the "potential # with a good clinical status", as seen in Figure 1.

Figure 1. Defining gaps: Comparing actual totals to potential totals



III. DATA COLLECTION

Health care workers interested in improving ART services at their facility need a data system that provides continuous information on the gaps in quality of their program. This data system can be used to identify areas needing improvement and to provide feedback on the success or failure of changes introduced to the facility to improve the quality of services. Prior to setting up the Gaps Analysis data system however, a baseline assessment can be useful for guiding improvement activities and providing insight into existing data sources and systems. The baseline assessment is usually more time-consuming and difficult to complete than routine ongoing data collection because the necessary data are either completely missing or not easily extracted from existing data sources. Once a baseline assessment has been completed, a system can be established for ongoing collection of the data needed for the Gaps Analysis Framework. The baseline data collection does not need to be repeated each month. In this section of the manual, guidance is provided for completing a baseline assessment and for setting up a system to monitor the gaps in quality on an ongoing basis.

A. Baseline Data Collection

To determine the size of the gaps at baseline, an initial assessment must be completed at the facility level. The results of this assessment will define the starting point for QI activities and guide the prioritization of problems to be addressed. The assessment must answer the questions:

1. How many people has the program placed on ART over a given time period?
2. How many of those placed on ART have been retained on ART over the same time period? and
3. How many of those retained on ART have been improving clinically over the same time period?

Generally, facilities should collect retrospective data over a minimum period of six months prior to the date of the assessment. If, for example, data collection occurs in August, the data should be collected from February through July of the same year, to cover the six months prior to the month of the data collection. For the purposes of this manual, hypothetical data have been included for a six month baseline period (January through June). However, based on context and data availability, health care workers can decide to collect baseline data covering a shorter or longer number of months prior to the date of the assessment. Once baseline data have been collected, a system must be established to collect and track these data on a routine basis (see section III.B. Ongoing Data Collection).

Both the baseline and ongoing data collection systems should capture the following data points:

1) Estimated number of ART-eligible individuals (both adults and children) in the catchment area ;
2) Cumulative total of people who have ever started ART or received ART at the facility;
3) Number of people expected to continue ART (current patient load);
4) Number of people on ART who are actually keeping appointments (or picking up ARVs) as scheduled; and
5) Number of people remaining on ART who have a stable or improving clinical status.

The gap between the numbers of persons 1) estimated to be eligible for ART and 2) ever started on ART is the *coverage gap.* The gap between number of persons 3) expected to continue ART and 4) keeping appointments (or picking up ARVs) as scheduled is the *retention gap*. The gap between 4) number of patients keeping appointments (or picking up ARVs) as scheduled and 5) the number of patients with a stable or improving clinical status is the *clinical status gap*.

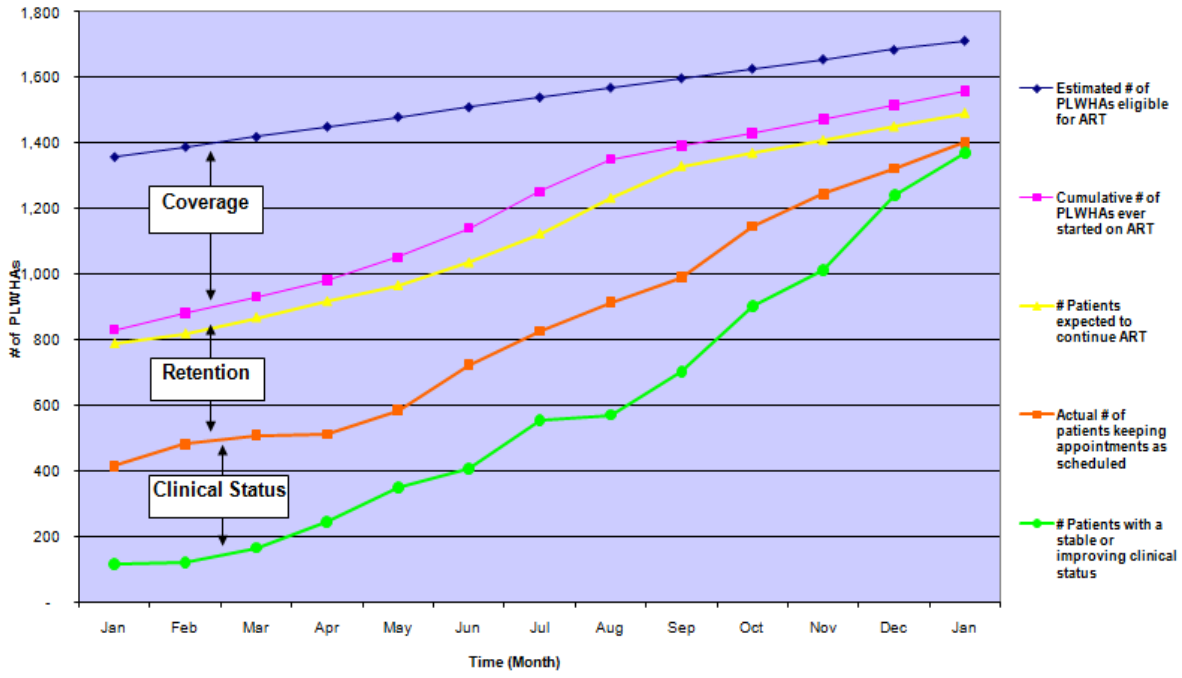
In total, there are five data points to be collected for implementation of this Framework. Data can either be entered into an Excel spreadsheet to create a graph similar to the one depicted in Figure 1 or can also be graphed manually if computer access is not available. The lines move horizontally over time and vertically as more people become covered, retained, and clinically healthier. Figure 2 depicts hypothetical data for the Framework: The lines are the data points and the space between them represents the gaps in program quality.

When applying this Framework, health care workers will develop a graph similar to Figure 1, although they may decide to measure at first only one or two gaps rather than all three, based on data availability or advance knowledge of a program area needing the most improvement.

To reduce the gaps, facilities should aim to: 1) start treatment in all patients who are eligible for ART, 2) continue treatment for all patients who have started on ART, and 3) improve (or stabilize if already good) the clinical status for all patients receiving ART. QI methods are applied to identify and implement changes to achieve these objectives. When changes are effective, the gaps decrease and the lines merge, indicating that the quality of the ART program is improving over time.

After completing the baseline retrospective data collection, the next step is to set up a system for prospectively collecting data on the five data points mentioned above which will enable a facility to monitor progress in closing the gaps. Once baseline data collection has been completed and a system has been set up to routinely collect these data, facilities can continuously monitor their gaps. As the gaps shrink (or, despite efforts continue to grow or remain stable), health care workers see whether their efforts to minimize the gaps are successful. This knowledge can be used to guide decision-making in implementing QI activities. The data collection process may need to be adapted to the local context on the basis of: 1) how the care delivery system is designed and 2) the feasibility of collecting these particular data on a routine basis.

Figure 2. Hypothetical graph showing quality gaps for coverage, retention and clinical status



Note: "PLWHA" stands for people living with HIV/AIDS.

Baseline data collection requires a review of patient medical files, pharmacy records, appointment books, ART registries, and any other records. Data gathered can either be entered into a spreadsheet for graphing or can be collected and graphed manually. Certain data points might be missing from the baseline assessment due to poor documentation practices. A lack of needed data would indicate that data collection and documentation systems need to be established and/or strengthened so that data may be prospectively tracked.

Sections IIIA through IIIF describe step-by-step how to collect and interpret baseline data on each of the five data points used in the Framework. Once health care workers have identified the records that will provide necessary data and have completed baseline data collection, they can refer to Sections IV and V for guidance on closing the gaps in quality and for setting up systems to prospectively collect these data.

1. Estimating ART Need

The *ART Gap Calculator* is available for free download from http://www.hciproject.org/node/2190. This tool gives an estimate of the number of people eligible for ART at baseline and predicts future numbers of people needing ART. Once the Calculator has been downloaded, internet access is not required for estimating ART need. Depending on the setting and availability of data, ART need estimation can occur at the facility level or at the local, district, or regional levels.

In choosing the specific population for which an estimate of "# of ART-eligible people" is most accurate in a given context, several factors should be taken into consideration. For example, if a health facility has a "well-defined" catchment area (i.e., having little overlap of patients from other catchment areas), "# of ART-eligible people" could be calculated at the facility level. However, if there is much overlap in catchment areas, it might be more useful to estimate "# of ART-eligible people" for the population of a local subdivision (municipality, district, region, etc.).

After determining the appropriate population for which to estimate ART need, the next steps are to gather the following epidemiological data and enter them into the Calculator:

- Total population of the catchment area, facility, or district;
- The year ART was first available to the population;
- Percentage of adults 15 years of age or older in the population; and
- HIV prevalence among adults 15 years or older in the population.

The percentage of adults in the population and the adult HIV prevalence should be as specific to the local population as possible. Generally, prevalence rates at the regional or district level are sufficiently accurate for estimating ART need for local catchment areas. However, if regional/district data are not available, national data can be used. However, estimates will not be as accurate as when local data are used.

Using these statistics, health care workers or local health officials can determine how many total patients (adults and children) should currently be on ART and how many patients will need ART during the 10-year period starting from the first year ART was offered.

While the calculation provides yearly estimates of # of people eligible for ART, the Coverage Calculator can be used to break these estimates down by month in order to estimate approximately how many patients should be starting ART each month.

These estimates (past, present, and future need for ART) are useful in quantifying the coverage gap. The baseline estimate for "# of ART-eligible people" can be compared with the number of patients *ever started ART* at the facility (or district, region, etc.) to determine the size of the gap in coverage. Two ways to make this comparison are: examining the width between these two lines, or calculating the percentage of those estimated to be ART-eligible who ever started ART (described in detail in Section IIIF). Depending on the size of the coverage gap, facilities, districts, regions, etc. can decide whether QI activities should be directed toward improving coverage.

The baseline estimate of coverage allows health workers and officials to determine how many patients should have started treatment for the purpose of determining the need to prioritize coverage as an area for improvement. The Coverage Calculator gives a rough estimate of how many patients should be starting ART in the future. This estimate can be used to continuously evaluate whether coverage targets are being reached and whether introduced changes are reducing the coverage gap. It also allows planning for the increasing number of patients who will need ART in the future.

When implementing this Framework, it was not always feasible to estimate the ART need at certain facilities (due to lack of data availability, lack of computer access, etc.). In such circumstances, health care providers can either decide to focus on gaps in retention and clinical status only or simply focus on increasing the number of patients who ever started ART(by increasing HIV testing at the facility, enrollment of those testing HIV-positive, and/or assessment of patients for ART eligibility). Based on the context, decisions on the best way to measure and improve coverage can be made.

2. Determining the Number of Patients Who Ever Started ART

The cumulative number of patients who ever received ART must be calculated at baseline and re-calculated monthly as new patients begin ART and as patients already on ART transfer into the facility. The baseline 'cumulative total ever started' prior to January (see Table 1 below) includes all patients who have ever received ART at the facility since the start of the program. This value should include all patients who: 1) were on ART (either having started during the month or having entered the facility's patient population after starting on ART somewhere else), 2) have transferred out of the facility's patient population but received ART at the facility at some point since the start of the program, 3) have died but who did received ART at the facility at some point since the start of the ART program, or 4) have been lost to follow-up (LTFU) after starting ART.

Data for patients ever started on treatment might be obtained from:

- Medical records;
- Pharmacy records;
- Appointment books;
- ART registry;
- Death registries;
- Transfer records;
- Electronic databases of patients on ART; and
- Official reports to the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund, etc.

Table 1 presents a hypothetical example of what these data will look like once gathered.

Table 1: Example of baseline data, calculating patients who ever started ART

	Pre-Jan	**Baseline Period (January – June)**					
		Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Number estimated to need ART in the catchment area	**---**	180	195	210	225	240	255
Cumulative total of patients, at the beginning of the month, who ever started ART (includes currently on ART, deaths, transfer-ins on ART, transferred out on ART, LTFU on ART)	---	100	105	115	120	128	135
Patients who newly started ART during the month	---	**+3**	4	4	6	4	5
Patients who transferred into the facility already having started ART during the month	---	**+2**	6	1	2	3	2
New Cumulative total who ever started on ART	*100*	***=105***	*115*	*120*	*128*	*135*	*142*

Notes: "Cumulative" means that each month's number is added to the previous month's number: For example, this table indicates in the second row that at the beginning of February, 5 more people who had ever started ART were in the population compared to the beginning of January.

For each month of the baseline period from January through June, patients starting ART and those who transfer-in to the facility already on ART should be added to the 'cumulative total ever started' for purposes of calculating the coverage and retention gaps.

The gap in coverage is represented by the difference between numbers of patients who ever started ART and the estimated number of people who need it. The cumulative total of patients who ever started ART will also be used in estimating how many patients are expected to continue ART. For these reasons, it is important to include *all patients' currently on treatment as well as those who previously initiated or received ART at the facility,* even if they are not currently on ART at that particular site.

If the gap in coverage is estimated at the district level, all calculations pertaining to coverage must be at the district level. The calculation of the number of patients who ever started ART would therefore include all patients who ever started ART *in the district.* In counting patients who transferred in, include only those who have *transferred into the district,* disregarding any transfers between facilities within the district. The same rules apply when the gap in coverage is estimated at the regional level or any other country-specific division. However, to calculate the gap in retention, the cumulative total of patients who ever started ART must still be calculated at the facility level.

3. Calculating the Number of Patients Expected to Continue ART

The next step is to determine how many of the patients ever started ART are expected to continue treatment. This number is calculated and used to drive QI activities at the facility level but can be aggregated by facilities to give a district or regional estimate for retention. First, calculate the cumulative number of patients who have died after initiating treatment at the facility and the cumulative number of patients who have transferred out for period between the start of the ART program and January (see Table 2 below). Deaths include all known deaths (either from AIDS or non-AIDS-related) that occurred at the facility or outside the facility.

The cumulative number of patients who died and transferred out should be calculated up to the start of the baseline assessment. Additional transfers and deaths occurring each month for the baseline period should be added to the cumulative total for each subsequent month, as shown in Table 2.

Table 2: Example of baseline data, tabulating cumulative deaths and transfers

	Pre-Jan	Baseline Period (January – June)					
		Jan	Feb	Mar	Apr	May	Jun
Number estimated to need ART in the catchment area	---	180	195	210	225	240	255
Cumulative total who ever started ART	100	105	115	120	128	135	142
Cumulative total who died	6	7	7	9	10	12	12
Cumulative total who transferred out	10	11	12	14	15	17	17

Once these data are collected, the next step is to calculate the number of patients expected to continue ART, or the "current patient load." This value includes patients who have started ART and who are expected to currently return to the clinic for ongoing care and treatment. This value should be calculated by subtracting the number of people who died and transferred out from the cumulative number of patients who ever started ART for each month. Table 3 is a hypothetical example of this calculation; the numbers in the last row are calculated by subtracting the number of those who died or transferred out (from data rows three and four) from the number who ever started.

Table 3: Example of baseline data, calculating expected ART patient load

	Pre-Jan*	Baseline Period (January – June)					
		Jan	Feb	Mar	Apr	May	Jun
Number estimated to need ART in the catchment area	--	180	195	210	225	240	255
Cumulative total who ever started ART	100	105	115	120	128	135	142
Cumulative total on ART who died	6	**7**	7	9	10	12	12
Cumulative total on ART who transferred out	10	**11**	12	14	15	17	17
Number of patients expected to continue ART	*—*	***87***	*96*	*97*	*103*	*106*	*113*

** Pre-January data (meaning data from the start of the ART program until December 31) are being collected specifically to aid in the calculation of the different cumulative values (cumulative ever started on ART, cumulative deaths of patients on ART, and cumulative patients on ART who transferred out). For that reason, the 'Number of patients expected to continue ART' is not being calculated for pre-January.*

When prospectively collecting data after the baseline period, cumulative totals of those who either die on ART or who transfer out to other facilities should be maintained to ensure that the current patient load remains as accurate as possible.

4. Determining the Number of Patients Retained on ART or Keeping ART Appointments as Scheduled

The next step is to determine the number of patients who routinely attend scheduled clinic appointments and pick up ARVs. To collect this information, refer to available documentation of clinic visits. For example:

- Medical records,
- Pharmacy records (doses dispensed, drug pick-up registry, etc.),
- Appointment books,
- ART registry and/or
- Electronic databases of patients on ART.

If the true number of patients retained in an ART program is difficult to calculate due to insufficient documentation and recordkeeping, baseline data should be calculated using the information that is available. If poor documentation is a problem, baseline numbers might be lower than the actual numbers and documentation of clinic visit attendance and missed appointments should be addressed.

Continuing with the previous example, 142 patients had started ART by June. To determine clinic attendance, all patient medical records should be reviewed, excluding the records of the six who died and the ten who transferred out prior to January. This exclusion results in a remainder of 126 (142 – 6 – 10 = 126) patient records that must be reviewed. For these 126 patients, how many attended clinic appointments for ART *as scheduled* for the six months of retrospective baseline data collection. Not all patients will have started ART yet during each month of the retrospective baseline period. Therefore, these patients should not be included in the totals for keeping appointments (even if they came to the clinic for pre-ART visits). "Patients keeping appointments (or picking up ARVs) as scheduled" is defined as: the number of patients who should be continuing ART and who receive a continuous supply of ARVs (uninterrupted treatment). As long as patients have an uninterrupted supply of ARVs, the frequency of visits can be left to the discretion of the clinician.

Table 4: Example of baseline data, calculating patients retained on ART or keeping ART appointments as scheduled

	Pre-Jan	Baseline Period (January – June)					
		Jan	Feb	Mar	Apr	May	Jun
Number estimated to need ART in the catchment area	--	180	195	210	225	240	255
Cumulative total ever started ART	100	105	115	120	128	135	142
Cumulative total on ART who died	6	7	7	9	10	12	12
Cumulative number total on ART who transferred out	10	11	12	14	15	17	17
Expected ART patient load	---	87	96	97	103	106	113
Number of patients keeping appointments	*–*	*62*	*68*	*58*	*75*	*62*	*75*

Medical records generally have the most complete information on clinic attendance before QI activities start, but this data source could be overly time-consuming to review, depending on the number of patients on ART. If the patient load is manageable (e.g., less than 300), medical charts can be reviewed for all patients expected to be on ART for the baseline period, and the findings can be used to document how many patients attended clinic visits as scheduled during each month. All medical records would need to be included in this review, with the exception of those who died or transferred out prior to the start of the baseline. For reviewed records, *documentation of the clinic visit* for each month of the baseline would be counted toward "patients keeping clinic appointments as scheduled." Often the medical records also include the date of the next appointment, which can be used to determine whether the patient returned on or around the scheduled appointment date. Again, since medical record documentation can be inconsistent or incomplete, the baseline value might be lower than the true number of patients keeping appointments. However, the process of collecting these data should highlight the importance of documenting clinic visits.

Pharmacy records are another source for these data. The number of patients picking up ARVs along with the number of months of treatment dispensed can serve as a proxy for "patients keeping appointments as scheduled" (if this information is tracked by the pharmacist). If the patient load is very high or if this information has not been documented, pharmacists often keep track of the number of doses of ARVs dispensed by month which can also be used as a proxy for attendance.

EXAMPLE: *100 patients are on the drug regimen Combivir + Efavirenz at a clinic. Combivir is a pill that combines AZT and 3TC and has to be taken twice daily for adults.*

Calculation

Monthly dose of Combivir dispensed for a patient on Combivir: 2 pills per day x 30 days = 60 pills

Monthly doses dispensed for 100 patients on Combivir

- 60 pills per month x 100 patients = 6000 doses dispensed each month for 100 patients

  If, of these 6000 doses of Combivir, only 4800 were dispensed, an estimated 80 of the 100 patients on this drug regimen came to pick up their medication.
- 4800 doses dispensed / expected 6000 □ 80% of patients picked up
- 80% x 100 patients = 80 patients keeping appointments or picking up medication as scheduled for the month

Steps to calculate clinic attendance based on ART doses dispensed:

1) Review all drug regimens of patients and select the **one** most commonly prescribed drug across the patient population
2) Calculate the number of pills of this medication that should be dispensed each month
3) Compare this result to the actual number of pills dispensed to determine how many patients picked up their ART medication, and
4) For patients who were not on the selected drug (in this example Combivir), select the next most commonly prescribed medication and conduct a similar calculation

This method of determining retention has limits. It works best for estimating "patients keeping appointments as scheduled' at health care facilities with a large patient population (over 500 patients) and for an adult population. Since ART drug dosages for pediatric HIV cases can vary and change often, as the child's weight increases, the calculation might be difficult to do for children. It also fails to take into account patients who pick up ART medication for more than one month, patients who receive medication for less than one month, and patients switching drug regimens.

Appointment books, ART registries, and electronic databases that track patients' attendance at the clinic are other sources of information on patients keeping appointments as scheduled.

If these data are difficult to collect for all patients, selecting a sample of patients to review is another option for the baseline data collection. In this situation, the percentage keeping appointments in the sample of patients would be applied to the entire patient load to approximate clinic attendance.

Calculation

For example, in a sample of 50 patients where 35 patients attended their ART appointment as scheduled for the month of January 2009:

- 35 / 50 = 70% clinic attendance in January 2009
- Approximately 70% of patients attended their clinic appointment in January 2009
- 70% attendance x 87 expected patients 61 patients keeping appointments

Sampling of records is not recommended for small patient populations due to validity weaknesses. If sampling is performed, however, care must be taken to select medical records randomly in order to ensure that the sample represents the entire patient population.

5. Identifying Patients with Good Clinical Status

After collecting information on patients' keeping appointments, the next and final step of the baseline assessment is to collect data on their clinical status. This requires a medical chart review. For each month of the baseline (e.g., January through June), identify how many of the patients who kept their appointments can be classified as having a good clinical status. "Good clinical status" can be defined as stable or improving clinical status based on virologic, immunologic, or clinical indicators. Generally speaking, the health status and responsiveness to ART should be determined according to national HIV care and treatment guidelines. If such guidelines are not available, the following indicators are suggested to determine whether patients on ART have a stable or improving clinical status.

- ***Virologic indicators:*** By measuring HIV suppression, viral load testing offers the most direct information regarding the effectiveness of ART. For patients who have received viral load testing, an undetectable viral load would indicate a healthy clinical outcome, unless clinical factors suggest otherwise. Because viral loads can change quickly, health care workers should rely on viral loads measured only within the previous four months. It is also important to remember that viral loads can require many weeks to reach undetectable levels in patients newly starting ART.

- ***Immunologic Indicators*:** Immunologic tests can serve as a marker for treatment success. Patients with a CD4 count ≥350 cells/mm³ and stable or increasing over time are considered to have a good clinical status, unless other clinical signs and symptoms suggest otherwise. However, significant decreases in CD4 counts (even if CD4 remains ≥350) may signal ARV failure and a poor clinical status, and these patients should be followed closely. Most HIV guidelines suggest repeating a CD4 count at least every six months, which is not always feasible. Health care workers should rely only on CD4 counts measured within this time frame to assess ART success.
- ***Clinical Indicators:*** Patients' physical health should always be monitored routinely to assess their clinical status. If necessary, the results of such monitoring can be used when lab tests are unavailable to monitor the clinical status gap. For the purposes of the Framework, a patient should meet all the following criteria to be judged as having a good clinical outcome:
  - *Weight:* Patients on ART should have a stable or increasing weight. Review patients' weight changes in their medical charts: Anyone who lost more than 2 kg (4.4 lbs) between clinic visits should not be considered as having a healthy clinical outcome.
  - *Clinical Status (WHO [World Health Organization] or CDC [Centers for Disease Control and Prevention] HIV Staging):* Patients who advance from one clinical stage to a more severe stage or present with any new opportunistic infections should not be considered as having a healthy clinical outcome.
  - *Functional Status (Karnofsky or other functional status score):* Patients on ART should be working (or have the capacity to work) or at least be ambulatory.

By reviewing data on these indicators, health care workers can evaluate and identify patients on ART who have a healthy clinical status. Determining clinical status using clinical indicators requires a *comparison of a patient's current clinical status to that of the patient during the previous clinic visit.* Patients who were clinical Stage ≥2 at baseline should improve on ART and stabilize once doing well.

As part of the baseline assessment, *medical charts of ART patients who keep appointments as scheduled should be reviewed to calculate the number having a good clinical status*. Continuing with the previous example of the 62 patients who kept appointments as scheduled in the month of January, immunologic, virologic, and/or clinical factors are reviewed for each of these patient. If the patient is not improving or stable relative to the previous visit, he/she should be categorized as not having an improving or good and stable clinical status. In this example, 48 of the 62 patients were considered as having a documented stable or improving clinical status following the medical record review.

If a patient's clinical status during a clinic visit cannot be retrospectively evaluated due to poor documentation, that patient should not simply be categorized as having a stable or improving clinical status. Areas of documentation needing improvement that are discovered in collecting baseline data should be noted and addressed. Table 5 displays hypothetical data on the clinical status indicator.

Table 5: Example of baseline calculation of patients with stable or improving clinical status

	Pre-Jan	**Baseline Period (January – June)**					
		Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Number estimated to need ART in the catchment area	--	180	195	210	225	240	255
Cumulative total who ever started on ART	100	105	115	120	128	135	142
Cumulative total on ART who died	6	7	7	9	10	12	12
Cumulative total on ART who transferred out	10	11	12	14	15	17	17
Expected ART patient load	---	87	96	97	103	106	113
Number keeping appointments as scheduled	---	62	68	58	75	62	75
Number with stable or improving clinical status	---	***48***	***45***	***35***	***42***	***39***	***51***

6. Plotting and Interpreting Baseline Data

Once the baseline data collection has been completed, the data are plotted graphically; see Figure 3 and Table 6 for an example of summary baseline data plotted graphically. Plotted data provide a visual impression of the size of the gaps for the baseline period. Tracking these data into the future can also show how the size of the gaps changes over time. Once the data are plotted, with time on the x-axis and number of patients on the y-axis, the next step is to quantify the gaps.

Figure 3: Identifying gaps in ART programs

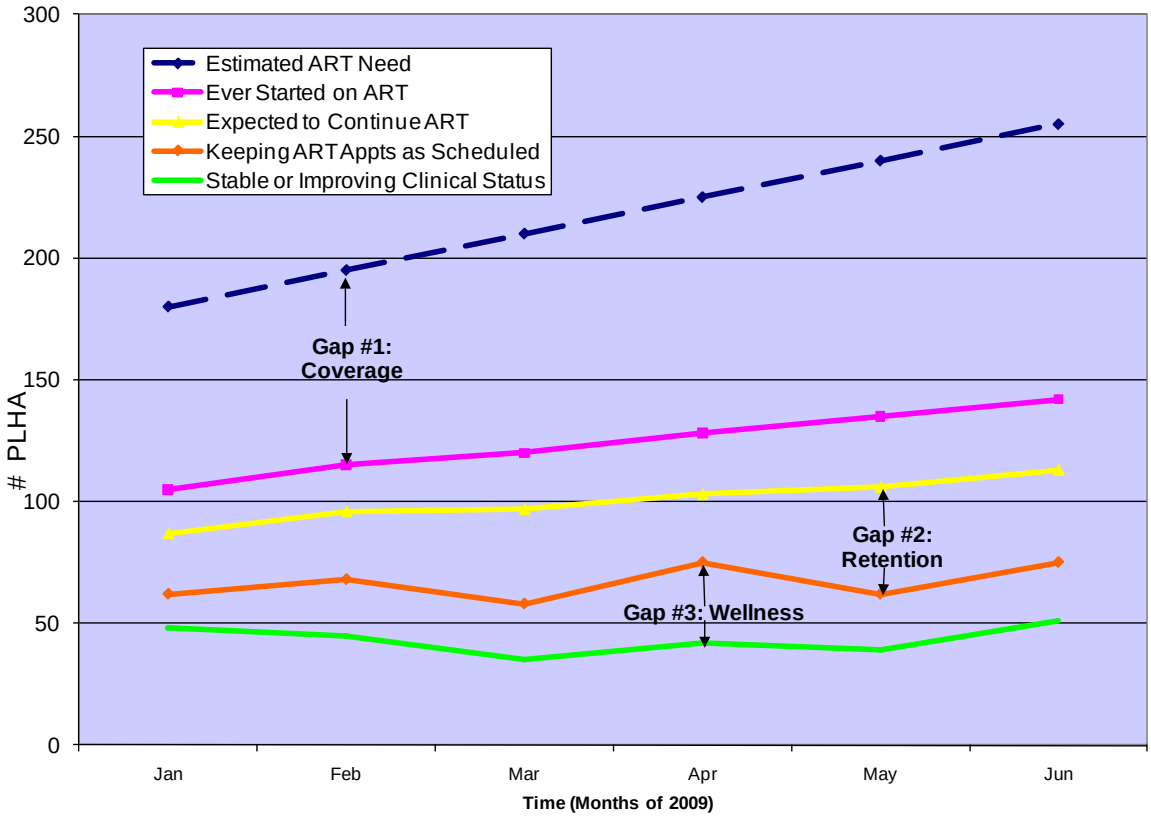


Table 6: Example of baseline data to assess ART program quality

	Jan	Feb	Mar	Apr	May	Jun
Number estimated to need ART in the catchment area	180	195	210	225	240	255
Cumulative total who ever started on ART	105	115	120	128	135	142
Expected ART patient load	87	96	97	103	106	113
Number keeping appointments as scheduled	62	68	58	75	62	75
Number with stable or improving clinical status	48	45	35	42	39	51

Figure 3 depicts the gaps in quality for coverage, retention, and clinical status for the data shown in Table 6. To gain a purely quantitative understanding of the data, each gap can be quantified as percentages, using the "actual" measure of an indicator as the numerator and the "potential" measure of the same indicator as the denominator. For example, to quantify percentages in coverage, retention, and good clinical status, the following calculations are used:

$$\% \text{ Coverage} = \frac{\text{Cumulative total who ever started ART}}{\text{Number estimated to need ART in the catchment area}} \times 100\%$$

$$\% \text{ Retained} = \frac{\text{Number keeping appointments}}{\text{Expected ART patient load}} \times 100\%$$

$$\% \text{ Good clinical status} = \frac{\text{Patients with stable or improving clinical status}}{\text{Patients keeping appointments as scheduled}} \times 100\%$$

Table 7 shows the gap percentages to the same numeric data shown in Table 6.

Table 7: Example of baseline data, with gap percentages

	Baseline Period (January – June)					
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Number estimated to need ART in the catchment area	180	195	210	225	240	255
Cumulative total who ever started ART	105	115	120	128	135	142
% Coverage	58%	59%	57%	57%	56%	56%
Expected ART patient load	87	96	97	103	106	113
Number keeping appointments as scheduled	62	68	58	75	62	75
% Retention	71%	71%	60%	73%	58%	66%
Number keeping appointments as scheduled	62	68	58	75	62	75
Patients with good and stable or improving clinical status	48	45	35	42	39	51
% Good clinical status	77%	65%	60%	56%	63%	68%

Reviewing these data and taking into consideration the clinical context will enable facilities to identify areas of HIV care needing improvement. In this hypothetical example, the QI team might decide to focus on improving coverage first, since this gap is the largest, and the majority of coverage for the baseline period falls below 60%. However, since all areas need improvement, the team might decide to introduce changes to the ART delivery system that would address multiple gaps.

By prospectively collecting data on the ART Framework as QI activities progress, QI teams can track and quantify how changes affect program quality.

B. Ongoing Data Collection

In order to evaluate quality of care on a routine basis and determine if changes made through QI activities are improving quality of services, a system must be established to prospectively record and gather data. Retrospective baseline data collection should only be performed initially and need *not* be repeated each month. The requirements for ongoing data collection to apply the ART Framework are much less intensive than for baseline data collection.

The ART Gap Calculator or any available local tools or statistics can be used to estimate the number of ART eligible individuals during ongoing data collection. The remaining minimum data to be collected for the continuous implementation of this framework are:

- # of patients newly starting ART and transferring into the facility already on ART,
- # of patients on ART transferred out to another facility,
- # of known deaths of patients on ART,
- # of patients expected to continue ART (calculated),
- # of patients who keep ART appointments as scheduled, and
- # of patients with improving or good and stable clinical status.

Once baseline data collection has been completed, simple systems to facilitate routine prospective collection of the data listed above should be developed. Examples of techniques developed in the field to collect or to facilitate collection of these data are:

- Reviewing the ART register to count how many patients newly started ART or transferred in each month already on ART, then adding this number to the cumulative total number of patients who ever started on ART;
- Keeping a list of all patients on ART and adding new patients to the bottom of the list upon enrollment;
- Tracking patients who transfer out to other facilities by writing "Transfer-Out" on the medical record with the date and place of transfer, then storing these patient files separately;
- Writing "Transferred Out" on the patient line in the ART register or pharmacy records;
- Keeping a separate spreadsheet of transfers with date and place of transfer;
- Tracking deaths of patients through a death register;
- Documenting date of death in the ART register;
- Keeping a separate spreadsheet of deaths with the date and place of death;
- Tracking patients keeping appointments either through an appointment book or a monthly ARV pick-up record (at the pharmacy);
- Using a "block schedule" for patients, meaning that a group of patients will be asked to return the same week every month so staff can predict patient load for each week and compare that to the actual number who show up at the clinic (Note: new patients would need to be added in separately, and staff would also have to track those patients who do not attend the clinic on their scheduled week);
- Setting aside the medical files of all patients on ART who attend the clinic that week and counting these files at the end of the week before filing;
- Creating a registry of patients who have poor clinical status and tallying that information at the end of the month;
- Selecting a random sample of files each month (in large facilities) and calculating the percentage keeping appointments; and
- At larger facilities, selecting a random sample of files each month and calculating the percentage with a good clinical status.

These are just a few examples of how to collect these data routinely. However, based on the context (care delivery, medical files, registers, pharmacy system, available resources, computer access, etc.) health workers should determine the most efficient method for generating useful data. Increasing the frequency with which data are collected (daily or weekly) and sharing the work among many staff decrease the overall burden of data collection.

Data gathered during ongoing data collection should be plotted and interpreted in the same manner as the baseline data. For more guidance, see above section III.A.6. Plotting and Interpreting Baseline Data.

IV. GENERAL APPROACH TO THE APPLICATION OF QI METHODS TO REDUCE GAPS

The main purpose of this manual is to provide instructions on setting up a gaps analysis framework for ART programs. An in-depth discussion on the improvement methods used to address quality gaps is beyond the scope of this document, but this section provides some general guidance on addressing each of the three gaps. Detailed guidance on applying modern QI methods is found in: *A Modern Paradigm for Improving Healthcare Quality*, available at http://www.hciproject.org/node/899.

In general, it is important to start by exploring the barriers to achieving maximum coverage, retention, and good clinical status for patients on ART. Changes specific to affect each of these three indicators of quality can then be designed and tested. Approaches to addressing each are presented below, followed by a description of developing and testing a change using the Plan-Do-Study-Act model. Interventions should always be context specific, however.

A. Coverage

Decreasing the gap in coverage can require a collaborative effort from different levels of the health system. By identifying the barriers that prevent eligible people from accessing ART, coverage can be addressed through interventions at the facility and in the community. Advocacy for changes at higher levels of the health system can also be very helpful to improve coverage. General interventions to improve coverage include:

- **National, regional and district levels:** HIV testing campaigns; publicity on the availability and effectiveness of ART; awareness-raising on the signs, symptoms, and risk factors for HIV; etc.
- **Facility level:** Increasing HIV testing at facilities, especially among high risk individuals; raising the awareness of patients and health care workers of the signs, symptoms, and risk factors of HIV; improving referrals and preventing drop-outs between testing and enrollment in HIV care; assuring that ART is not delayed for pre-ART patients who become eligible for treatment; etc.
- **Community level:** HIV testing campaigns, education on availability and effectiveness of ART, etc.

B. Retention

By understanding barriers that interfere with patients ability to keep appointments (which include transportation problems, conflicts with work schedule, forgetting appointment date, etc.) and by working with patients to design changes that will prevent the recurrence of missed appointments, retention can be greatly improved. By asking patients, *"Why did you miss your last appointment?"* and *"What can I do to prevent you from missing appointments?"* health workers can identify and implement changes that can be made to the health system to promote retention. This exchange can also be used as an opportunity to encourage patients to implement changes in their lifestyle to improve HIV management. The Pareto Chart, described in the *Paradigm* publication mentioned above, is one method of presenting data that can greatly help to prioritize barriers leading to the development of broad changes that have a positive impact on many patients.

C. Clinical Status

A similar process can be used to improve the clinical statuses of patients on ART. By reviewing medical records and identifying the factors contributing to poor health, interventions can be designed to prevent or alleviate the impact of these factors. The following are examples of interventions to address particular causes.

- If the causes for poor clinical status are strictly clinical (TB, cervical cancer, etc.), health workers can improve the systems wherein these conditions are identified, treated, and/or prevented.

- If poor adherence is suspected, adherence counseling and other elements of self-management support should be improved while monitoring the impact of these improvements on the clinical status gap. If the gap decreases, effective interventions may be adopted on a larger scale.
- If broader health systems or facility management issues seem to contribute to poor clinical status by way of late diagnoses and ART initiation, poor documentation of clinical indicators, etc.), health workers should concentrate on alleviating these problems.

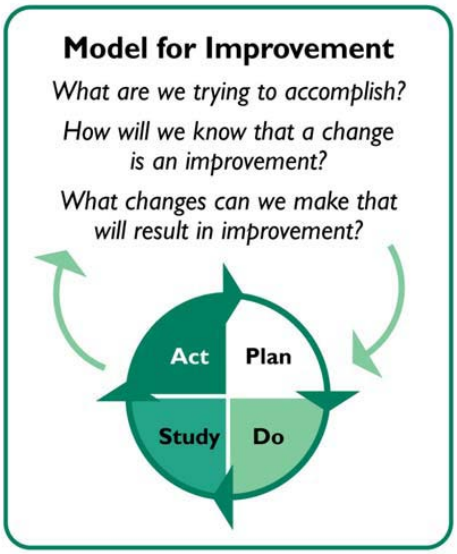
Involving patients is one key to improving the quality of HIV care. Since HIV is a chronic disease, daily treatment decisions are made outside the facility in patients' homes or communities by the patients themselves and by their family members. Engaging patients in their own care to the greatest extent possible will help achieve optimal outcomes. Appendix I describes changes and change ideas generated through HCI's experiences in implementing the Framework in Tanzania, Nicaragua, and Uganda.

D. Testing Changes Using PDSA Cycles

Plan-Do-Study-Act Cycle

After an improvement area has been identified, analyzed, and hypothetical interventions or changes have been posed, the next step would be to test if the proposed intervention yields the expected improvement. It is important to remember that large changes should be tested extensively and modified to reduce the risk of the intervention not working and that interventions may not yield immediate results even if they are effective. Allowing time for change to occur is important in the testing process. The results of this test determine the next step, which could be to implement, modify or abandon the change altogether.

Figure 4: Plan-Do-Study-Act cycle for testing changes



The scientific method generally involves planning a test, doing the test, and studying the results. Quality management, however, has expanded the scientific method to act upon what is learned: plan, do, study, and act (PDSA). PDSA, otherwise referred to as Shewhart's Cycle for Learning and Improvement,[1] is a four-step process included in the testing and implementation stage of many QI approaches. As shown in Figure 4, the PDSA cycle allows for continuous improvement as hypotheses are regularly created, tested, revised, implemented, and then adapted further. This continual process allows us to make constant changes and deepen our understanding of organizational improvement needs and solutions.

The steps in carrying out a PDSA cycle are described further in Table 8.

When designing changes or PDSA cycles, program implementers should make sure to answer the following questions:

- What is the change to be tested (be specific: who, what, where, when, how)?
- What scale is this change being tested on (for example, on how many patients)?
- How will you know if the change was successful?
- What is the start (and end date if applicable) of the change?
- After introducing the change, what was the outcome of change?

[1] Shewhart, W. 1931. *The Economic Control of Quality of Manufactured Products.* D. Van Nostrand Co: New York. Reprinted by the American Society of Quality Control in 1980.

Table 8: Steps to carry out a Plan-Do-Study-Act cycle

PLAN	Develop a plan of change to address - What changes will occur and why? - Who is responsible for making the change? - When and how will the changes occur? Collect baseline data to measure the effects of change. Monitor the effects of change through a data collection system Educate and communicate: Inform people about the test of change; include those people involved in the change and be sure they accept the change
DO	Test the change Verify that the change is being tested according to the plan Collect data about the process being changed: - Check that the data are complete - Document any changes that were not included in the original plan
STUDY	Verify that the change was tested according to the plan See if the data are complete and accurate Compare data with the baseline information to determine whether an improvement has occurred Compare actual results with predicted or desired results
ACT	Summarize and communicate what was learned from the previous steps If the change does not yield desired results, modify or abandon the plan and repeat the PDSA cycle if necessary Implement the change as standard procedure if it proved to be successful Monitor the change over time to check for improvements and problems Consider implementing the change throughout the system (as opposed to testing the change on a small scale)

After evaluating the outcome of the change, program implementers will need to decide whether to:

- Abandon the change completely, if total failure
- Modify change based on test and try again
- Test change again on a larger scale (greater number of patients)
- Implement the change for all patients (i.e., make the change permanent, introduce into routine practice)

Program implementers would collect data on the small tests of change to see if the changes are successful and worth implementing at the facility on a small scale. Determining the success of a change should also be linked with one of the areas of quality ART care (coverage, retention or wellness). As changes are introduced on a larger scale, improvements should also be seen in the measures for coverage, retention and clinical status over time. Intermediate process indicators can also be designed to determine if the change is an improvement for short-term decision making. If improvements are not seen in process and outcome measures, program implementers should reassess the changes introduced and decide whether the change should be modified or abandoned.

APPENDIX: SUCCESSFUL CHANGES AND CHANGE IDEAS FOR IMPROVING THE QUALITY OF ART SERVICES FROM PILOTING THE FRAMEWORK IN TANZANIA, NICARAGUA, AND UGANDA

Table A-1: Changes to improve coverage or access to ART[2]

Barrier or Area for Improvement	Change
Inconvenience of HIV clinic visit and time required	• Providers attributed an increase in coverage to enabling patients to receive all services (lab tests, drug supply, and clinic visit) at one location in the facility. Patients had less waiting time (Tanzania).
Lack of knowledge regarding HIV disease and treatment (in a low-prevalence country)	• A doctor spoke on a local radio show for ~1 hour to promote early access to care and treatment for patients with HIV, urging people not to wait until symptomatic to seek care and conducting a question/answer session on the topic. The doctor was invited to return following week (Nicaragua). • A doctor called a meeting of an HIV support group to speak about the importance of support to PLWHA and emphasize the need to seek care and treatment early and to share information on HIV testing and treatment to other high-risk individuals (Nicaragua).
Lack of HIV testing/missed opportunities for testing in hospital departments	• Promote and emphasize importance of HIV testing at the next staff meeting; offer HIV testing to staff as well as patients (internal medicine, surgery, etc.) to reduce stigma around testing (Nicaragua). • *Change idea: Offer testing to patients in the hospital outpatient clinic.* • *Change idea: Use technical hospital meetings to promote HIV testing in other hospital departments (e.g., the emergency room, surgery, and outpatient).*
Fear of stigma and discrimination around accessing care for HIV	• Relocate the clinic into a separate area with a private waiting area, entrance, and exit; divide the clinic area into four sections to facilitate patient flow: 1) waiting area, 2) clinician consult, 3) adherence counseling with nurse, and 4) patient files. Note: Addresses both coverage and retention. • *Change idea from patients who accessed care during late stages of HIV in Nicaragua: Focus on reducing stigma and discrimination in the community because then patients will be less fearful of accessing HIV care.*
Lack of testing at primary health centers	• *Change idea: Circulate a letter from the Ministry of Health (MOH) and/or hold meetings with directors of health regions and health centers to emphasize at the local level the importance of HIV testing and of referring patients for care (Nicaragua).* • *Change idea from patients who accessed care during late stages of HIV in Nicaragua: Offer HIV testing house to house.* • *Change idea: Offer HIV testing and counseling to all patients seen in the sexually transmitted infection clinic.* • *Change idea: Work in collaboration with community outreach programs to reach high-risk individuals.*

[2] Note: Italics indicate change ideas that have been proposed but not yet implemented by actual teams.

Lack of HIV knowledge contributing to decreased coverage	• *Change idea: Provide HIV education in outpatient clinics on the HIV test, the availability of free treatment, etc. (Nicaragua).* • *Change idea: Air a public service announcement using a mobile unit to promote the link between HIV testing and ART programs since many patients would test positive but then be unaware of or not seek HIV treatment (Nicaragua).* • *Change idea: Educate providers (at all levels of care) and outreach to community about all risk factors for HIV, so that those with these factors are routinely tested (Nicaragua).* • *Change idea from patients who accessed care during late stages of HIV in Nicaragua: Educate and offer testing to community youth groups (high-risk).*
People fail to collect their test results	• *Change idea: Speak with health center lab personnel to identify ways to shorten the time between test taking and the release of results (Nicaragua).* • *Change idea: Test a 1-hour timeframe for returning HIV test results to patients by using lab personnel responsible for emergency room lab tests to process HIV tests (task-shifting) (Nicaragua).* • *Change idea: Build capacity and confidence (possibly through training) of health post personnel to provide HIV test results; referring patients to a higher level facility for post-test counseling had contributed to having patients not return for results (Nicaragua).* • *Change idea: Advise health center personnel that searching for patients to provide test results does not conflict with the privacy law (Nicaragua).* • *Change idea: To ensure that patients are enrolled in the HIV program once they have tested HIV-positive, compare lists of PLWHA identified at health centers to those enrolling in HIV programs to ensure 100% enrollment after referral, and search for those who are missing, which requires improved communication with the regional health office and health centers.*
Provider stigma and discrimination	• *Change idea: Sensitize providers toward HIV to decrease stigma and discrimination through workshops at the facility (Nicaragua).* • *Change idea: For providers uncomfortable or uncertain on how to relay positive test results, conduct a workshop with practice on real HIV-positive patients who are comfortable with HIV status.*
Late access to care	• *Change idea: Meet with leaders of PLWHA support groups to make plans on capturing patients early, especially for high-risk, marginalized groups (men who have sex with men, commercial sex workers, etc.) (Nicaragua).*
Limited access to ART due to long distance from facilities that provide ART	• *Change idea: Decentralize ART—make it available at local health centers (currently only available at regional hospitals); addresses both coverage and retention (Nicaragua).* Note: addresses both coverage and retention.

Table A-2: Changes to improve retention on ART[3]

Barrier or Area for Improvement	Change
Tracking of patients who miss appointments	• Verify address and phone number of patients at each clinic visit to facilitate follow-up of patients (since at times patients tend to give incorrect information due to fear of stigma or information is not up-to-date) (Tanzania). • Coordinate with local nongovernmental organizations (NGOs) to track patients (Tanzania). • The hospital reports the patient who missed an appointment to the health region, which then notifies the local health center (in the municipality). In Chinandega, the local health center must then attempt to locate the patient within 72 hours of notification (Nicaragua). • Hospital shares a list of patients who are missing appointments with directors of local health centers during routine monthly visits to the hospital (Nicaragua). • Representatives from each health center in a region are invited to participate in monthly QI team meetings at the hospital. Through these meetings, the local health centers learn about the patients who are missing appointments or LTFU. Also, plans for home visits are arranged among personnel of the health region, hospital and health centers. At times, HIV support group members are also involved in these meetings and home visits. Information on barriers is used and shared during the QI team meeting (Nicaragua). • *Change idea: Circulate a list of patients who are LTFU among the different health facilities in the district to see if they self-transferred.*
Understanding the gap in retention	• Start to document reasons for missed appointments (after tracking patients or if patients return after a missed appointment).
Data collection on retention	• Ask patients who missed appointments in the previous month if they received care and picked up ARVs at a different facility. Document this information in patients' medical record.
Poor documentation of clinic visits	• After tracking a few patients (through phone calls, home visits) who seemed to have missed appointments, discovered that patients had actually attended the clinic and received drugs. Discovered that one particular provider was not documenting clinic visits (for friends, relatives) emphasized with provider the importance of documentation (Tanzania).
Patients not returning on appointment date Patients forgetting appointments	• Providers attend to patients who have an appointment first (unless someone needs immediate attention) and unscheduled patients will need to wait until after all scheduled patients are seen (Tanzania). • For patients who forget appointments, providers label the drug packs with next appointment date (Uganda). • Share schedule with someone else who will remind patient of appointments (Tanzania).

[3] Note: Italics indicate change ideas that have been proposed but not yet implemented by actual teams.

	• Issuing appointment cards to patients (multiple countries). • *Change idea: Use HIV support groups to remind patients to keep appointments and continue treatment (Nicaragua).* • *Change idea: Collect patient telephone numbers to provide reminders for appointments (Nicaragua).* • *Change idea: Increase communication with providers between visits; have provider call patients as a reminder for appointments and for support.*
Lack of transport or far travel distance to clinic Strict work schedules Home responsibilities Lack of social support	• Providing more than one month's supply of ART (to patients with ≥ 95% adherence) (multiple countries). • Having one patient collect ART for a group of patients to decrease visits and travel to clinic (Uganda). • Having treatment supporters / friend/ relatives collect ART on behalf of patients (multiple countries) • If a patient representative picks up ARVs, collect information on patient clinical status from this representative (multiple countries). • *Change idea: Decentralize ART—make it available at local health centers (currently only available at regional hospitals) (Nicaragua).* • *Change idea: Ask adherent patients to share experiences with patients who abandoned or those with poor adherence (Nicaragua).* • *Change idea: Compile a list of available resources that match needs of HIV patients: legal services, nutritional / food, battered women support, financial support, etc.* • *Change idea: Confirm services to be reliable and willing to respect patient confidentiality.* • *Change idea: Establish referral and counter-referral for management of social issues experienced by PLWHA that lead to abandoning treatment*
Lack of money for transportation	• Coordinate transport using the MOH vehicle or local NGOs (Nicaragua). • Obtain travel passes through the mayor or other local institutions (for example in Rivas, for those who live on an island, the QI team was able to obtain free ferry passes for the patients) (Nicaragua).
Lack of support from family or spouse	• Invite patients to join the support group (multiple countries). • Integrate family members into support group (emphasizes importance of family support) (Nicaragua). • Involve the Ministry of Family to pressure husbands/fathers who do not permit the mother and/or child to continue ART (multiple countries).
Alcoholism or drug use	• Raise awareness in the patient and family and provide support through the support group (Nicaragua).
Migration for work to neighboring countries	• Dispense ARVs for 2–3 months to patients who are highly adherent (>95%) (multiple countries).
Adverse reactions to medication	• Reinforce counseling, educating patient and family members / treatment supporters about adverse reactions and when to seek care, make recommendations on food, secondary medication, or options to switch drug regimens (Nicaragua).

Lack of knowledge on HIV	• Educate patient and treatment supporters (family, friends, etc.) on HIV, treatment and when to seek care (for example, with complications, side effects, opportunistic infections, etc.), adherence, follow-up, etc.
Support to patients with poor adherence	• A doctor called a local health clinic to visit three patients in a rural setting with poor adherence (Nicaragua). • During home visit, specifically ask patients about and report back information on: ART regimen, number of pills left, and date of next appointment (Nicaragua).
Coordinate home visits to HIV patients	• Create a standard form for home visits of patients missing appointments and abandoned (include information on importance of adherence, attending visits, documenting barriers, etc.) (multiple countries). • Share the form with PLWHA and local health officials to coordinate their home visits. • Strengthen the PLWHA support group (with help from a local NGO) to provide more support to patients in the community.
Fear of stigma and discrimination around accessing care for HIV	• Relocated clinic into a separate area, with private waiting area, entrance and exit; divided this clinic area into four section to facilitate patient flow: 1) waiting area, 2) clinician consult, 3) adherence counseling with nurse, and 4) patient files. Note: Addresses both coverage and retention.
Depression, especially among new patients	• *Change idea: Self-help PLWHA group to coordinate home visits for new patients and/or depressed patients.*

Table A-3: Changes to improve the clinical status of patients on ART

Barrier / Area for Improvement	Change
Shortage of drugs to treat / manage opportunistic infections	• Discussed with director of the facility regarding this shortage; able to allocate funds specifically to order necessary drugs (Tanzania).
Routine monitoring of CD4 count	• Previously referred patient for blood draw and to pick up results; now collect samples every Tuesday at facility, and lab technician sends all samples together (no longer referring the patient) and receive test results straight to the clinic (Tanzania).
Monitoring clinical status of unwell patients or poor adherence	• Patients with poor clinical outcomes given appointments with increased frequency (for example, in two weeks) to follow up with them more closely compared to patients who were doing well. Include ongoing counseling, importance of daily care and adherence.
Documenting and monitoring clinical status of patients during visits	• Created and used a follow-up sheet that includes CD4 and viral load test results, active problems (side effects and opportunistic infections), weight, and functional status (key clinical measures that should be documented at each visit).
Screening, diagnosis and treatment of TB	• Start assessing all HIV patients for TB using BAAR and chest x-ray and increase TB prophylaxis and/or treatment (Nicaragua). • Routinely screen all HIV patients for TB using clinical using clinical criteria.
Monitoring clinical status of patients	• Continue to assess patient's clinical status at each visit (even if only picking up ARVs from nurse).
Monitoring adherence	• Use four-day recall to assess adherence, and understand causes for poor adherence to develop future interventions (Nicaragua). • Have patients track daily intake of ART using a patient-held adherence card (Uganda). • *Change idea: Intensify follow-up for certain patients; offer follow-up of new ART patients or patients who switched regimens every 15 days at the primary health center.*
Patients with poor clinical status unable to come to the clinic	• Conduct home visits to HIV-positive neighbors with poor clinical states to check on their health.
Triage system	• At the facility, attend to TB suspects before others (Nicaragua).
Poor documentation in medical records resulting in poor follow-up of patients	• Files numerically ordered: easier to locate, facilitates documentation and clinical management / follow-up of patients
Lack of family involvement and support	• *Change idea: Inform both patient and family member about patients' condition during hospital visits.*

Table A-4: Health system strengthening QI activities resulting from implementing the Gaps Analysis Framework

Barrier / Area for Improvement	Change
Staff shortage / task-shifting	• Expand QI meetings for HIV to include all departments in the facility (for example, outpatient ward); improved willingness of other departments to treat HIV patients for non-HIV related illness (for example, malaria), which increases HIV clinic patient capacity (Tanzania). • Assigned a medical records assistant to help pull files on HIV clinic days (Monday–Thursday) (Tanzania). • Involve expert patients to support the HIV clinic by taking on certain responsibilities (assessing weight, TB status, ART adherence counseling and community follow-up) (Nicaragua): idea came from treatment clubs at hospitals (doctors and patients).
ARV drug stock-out	• Providers met with local government leaders and the Municipal Pharmacist (who oversees drug supply management for the municipality) and realized most drugs were being held in storage (Tanzania). • Discussed requiring municipal pharmacist to dispense all drugs he receives from Dar es Salaam to all the facilities in the municipality to prevent stock-outs (Tanzania).
Patient flow	• Medical records assistant locates files for all patients (Tanzania). • Conduct general health education and adherence talks in the waiting area (Tanzania). • Patient meets with clinician for clinical assessment, prescription, and documentation in ART card (Tanzania). • Nurse provides drugs and adherence counseling and documents information in registers (Tanzania).
Facility space	• As patient load increased, expand waiting area (by decreasing clinic space) to accommodate increased # of patients (Tanzania).

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