SUPPLEMENT ARTICLE

Improving care for patients on antiretroviral therapy through a gap analysis framework

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Objective: To improve quality of care through decreasing existing gaps in the areas of coverage, retention, and wellness of patients receiving HIV care and treatment.

Design: The antiretroviral therapy (ART) Framework utilizes improvement methods and the Chronic Care Model to address the coverage, retention, and wellness gaps in HIV care and treatment. This is a time-series study.

Setting: The ART Framework was applied in five health centers in Buikwe District, Uganda.

Participants: Quality improvement teams, consisting of healthcare workers and expert patients, were established in each of the five healthcare facilities.

Intervention: The intervention period was October 2010 to September 2012. It consisted of quality improvement teams analyzing their facility and systems of care from the perspective of the Chronic Care Model to identify areas of improvement. They implemented the ART Framework, collected data and assessed outcomes, focused on self-management support for patients, to improve coverage, retention, and wellness gaps in HIV care and treatment.

Main outcome measure(s): Coverage was defined as every patient who needs ART in the catchment area, receives it. Retention was defined as every patient who receives ART stays on ART, and wellness defined as having a positive clinical, immunological, and/or virological response to treatment without intolerable or unmanageable side-effects.

Results: Results from Buikwe show the gaps in coverage, retention, and wellness greatly decreased a gap in coverage of 44–19%, gap in retention of 49–24%, and gap in wellness of 53–14% during a 2-year intervention period.

Conclusion: The ART Framework is an innovative and practical tool for HIV program managers to improve HIV care and treatment.

AIDS 2015, **29** (Suppl 0):S00–S00

Keywords: antiretroviral therapy, Chronic Care Model, gap analysis HIV care and treatment, quality improvement

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Received: 11 May 2015; revised: 11 May 2015; accepted: 11 May 2015.

DOI:10.1097/QAD.0000000000000742

Introduction

The United States President's Emergency Plan for AIDS Relief's (PEPFAR) goal of an AIDS-Free Generation places increasing focus on improving the quality of care for patients on antiretroviral therapy (ART), which is known to improve viral suppression and reduce transmission. As access to ART increases globally, policy makers and program managers are also becoming aware of the need to improve care for patients requiring ART. This includes decreasing the number of patients lost to follow-up or discontinuing treatment, as well as evaluating and improving the clinical status of patients on ART. For practical purposes, quality care for patients requiring ART was defined as every patient who needs ART starts treatment, every patient who receives ART stays on treatment, and every patient who stays on ART experiences a healthy clinical outcome.

This article describes an innovative management tool for HIV program managers utilizing a gap analysis framework, known throughout as the ART Framework. The framework looks at gaps in care between subsets of patients requiring ART. Specifically, the ART Framework addresses three key areas of ART care quality:

(1) Coverage
(2) Retention
(3) Wellness

The article also discusses the ART Framework and describes the initial proof of concept, with results from five Healthcare Center IVs (Health Care Center IVs are large healthcare facilities that services a county, often located further from the community) in Buikwe District, Uganda, where gaps in coverage, retention, and clinical outcomes for patients requiring ART were reduced and maintained beyond the period of the technical assistance from the United States Agency for International Development (USAID) Healthcare Improvement (HCI)-Project.

Background

Global funding for low-income and middle-income countries has increased six-fold since 2001 when the United Nations set global targets to respond to the worldwide HIV epidemic [1]; PEPFAR alone has committed 53 billion USD through 2013 [2].

ART, which inhibits the replication of the HIV virus and allows for immune reconstitution, has drastically improved survival and quality of life for those who access and remain in treatment [2]. An estimated 35.3 million people were living with HIV in 2012, which is an increase from previous years due to more people receiving ART globally [3]. In 2012, there were 8 million people on ART, a 60% increase from 2010 [4].

Numerous process indicators have been developed to assist in the monitoring and evaluation of HIV care and treatment programs. Without a broader framework for monitoring the overall effectiveness of treatment programs, improvement activities can lose focus and fail to identify or address particular problems, which contribute most to program weaknesses. The ART Framework provides a practical means to identify, prioritize, and act on specific areas in need of improvement [5].

The framework looks at the gaps in care between subsets of the patients requiring ART. The three key areas that it addresses are the 'coverage' of patients eligible for ART, 'retention' of those patients receiving ART, and clinical outcomes for those retained in treatment or 'wellness'. Although these are not the only characteristics of a quality ART program, these three indicators characterize the core of what constitutes effective care. These indicators are meant to be a starting point for understanding treatment program gaps, which if monitored over time will provide key measures of success to guide ongoing quality improvement activities.

Through the application of the framework in five HIV treatment facilities in Buikwe District, Uganda, in conjunction with the Chronic Care Model (CCM), providers were able to identify problems at the operational level that resulted in program quality gaps. This information helped them to develop, test, and implement solutions to narrow these gaps.

Methodology

Gap analysis measures the difference between actual and potential performance. This type of analysis may be used to evaluate and reflect on their current situation and to identify the areas that need to be improved. Adapting this framework to healthcare allows for program managers to self-evaluate and improves the quality of care they are providing to patients. With so many process measures and quality indicators having been developed for the monitoring of HIV care and treatment programs, the ART Framework provides structure in identifying areas of improvement to the program. Specifically, in the case of guiding quality improvement in ART programs, program managers can monitor their efforts in the coverage, retention, and wellness of patients.

This study utilizes time-series charts to measure and track progress on the selected indicators. Time-series charts are a measurement system, which track an indicator over time. Data are plotted frequently; in this case monthly. This is a standard methodology used in quality improvement. Statistical significance of results lies in obtaining a series of data points behaving differently from preceding data points as per rules of the time-series chart [6].

Defining indicators

The ART Framework is built on the notion that good quality of care for patients consists of three components. First, every patient who needs ART, receives it. This first part of the definition corresponds to the coverage of ART. Second, every patient who receives ART stays on ART. This corresponds to the retention of patients in treatment. Finally, every patient who stays on ART does well on ART, which addresses the clinical outcome or wellness of patients.

Coverage

Despite impressive gains in improving access to treatment, less than two-thirds of people eligible for HIV treatment in low-income and middle-income countries received ART [7]. Some are unaware of their HIV status, others are aware but do not realize their ART eligibility, whereas others delay seeking care because of denial or fear. This may be due to the lack of or poor quality health education and prevention programs. Others may have not started on ART due to limitations of the healthcare system such as limited laboratory services or drug supply. By recognizing the coverage gap and addressing the reasons for it, providers can better identify patients who need ART and start them on treatment as soon as they become eligible.

When addressing the coverage gap, providers also must keep in mind the total patient burden in the future. As HIV is a chronic condition with no current cure, most patients started on treatment remain alive and require care for years to come. This means that, every year, the number of patients needing ART increases. A simple model is required for this framework for healthcare providers to project the estimated ART need for planning purposes, using available statistics such as catchment area population, percentage adults, HIV prevalence and years offering ART [6]. The coverage gap in the ART Framework is defined as the difference between those who are eligible for ART and those who are currently receiving ART.

Retention

To maintain long-term benefits from ART, patients must adhere to daily drug regimens and complete regular clinical requirements. Studies have shown that patients on ART must take the majority of scheduled doses for treatment to be effective [8–12]. Poor adherence can lead to drug resistance, rapid disease progression, and death [10]. Public health consequences are also significant, as patients with poor adherence are more likely to spread resistant and more commonly wild-type strains of HIV [13].

Unfortunately, retaining patients in ART programs remains a challenge. A review of ART programs in 13 countries in sub-Saharan Africa found that median ART program retention rates were only 86.1% at 6 months, and decreased to 80.2% at 12 months, 76.8% at 24 months, and 72.3% at 36 months [14]. Retention rates are affected by patients transferring between facilities [15]. The ART Framework defines the retention gap as the patients who have or are currently receiving ART and are continuing their ART. The retention gap can only be measured for patients that have been initiated on ART and have existing records.

Wellness

Doing well on ART can be defined as having a positive clinical, immunological, and/or virological response to treatment without intolerable or unmanageable side-effects. Ideally, a virological and immunological response to ART would be confirmed through laboratory testing of viral loads and/or $CD4^+$ cell counts. However, many programs in developing countries do not have access to regular $CD4^+$ and/or viral load testing for HIV patients. Even in the presence of laboratory testing, these tests are done one to two times per year. Therefore, monitoring clinical signs, symptoms, and outcomes for patients on ART is particularly important. For the purpose of the ART Framework, it was assumed that, in the absence of laboratory results, providers can monitor for treatment failure through clinical manifestations such as new opportunistic infections, weight loss, and poor functional status.

Good clinical status or wellness was defined as when there were no signs of opportunistic infection, no weight loss in excess of 2 kg and the functional status of the patient working, or feeling well and able to do what they normally can do [16]. $CD4^+$ cell counts or viral loads, when available, were also used as a part of determining the wellness of the patient. The ART Framework defines the wellness gap as the number of patients who are on ART and are doing well on ART.

Measuring the gaps

In order to measure the gaps in coverage, retention, and wellness, an estimate of the number of patients requiring ART in a specified catchment area is needed. Each number required to calculate the indicators is a subset of the number preceding it.

Estimated number of patients requiring antiretroviral therapy

In order to calculate this amount, several factors must be considered. First, consider whether the catchment area of the healthcare facility is well defined. When a catchment area is well defined, or having little overlap of patients from other catchment areas, the number of ART eligible patients can be calculated at the facility level. However, in cases in which there is overlap, it may be more appropriate to estimate the number of ART eligible patients. The UNAIDS Spectrum [17] or other calculators can be used to determine the number of patients requiring treatment.

The number of patients started on antiretroviral therapy

Facilities should have already begun their baseline data collection at least 6 months before the gap assessment date. The cumulative number of patients who received

ART should be known to date, but recalculated monthly as new patients begin treatment. This value should include all patients who were on ART; received ART at the facility at some point but may have transferred out or passed away; or have been lost to follow-up. Data for these patients may be obtained from facility records, death registries, transfer records, electronic databases of patients on ART and official reports to PEPFAR, the Global Fund to Fight AIDS and, or other international AIDS institutions.

The number of patients expected to continue antiretroviral therapy

Of those number of patients started on ART, the cumulative number of patients who have passed away or transferred out must be calculated. This number should not be included in the number of patients who are expected to continue ART.

The number of patients retained on antiretroviral therapy

The total number of patients on ART, minus those who have transferred out of the program or died, will determine the number of patients who are expected to continue ART. Medical and pharmacy records, appointment books, and other record systems may be referred to determine the number of patients who regularly attend appointments.

Patients retained on antiretroviral therapy, with good clinical status

Of those patients determined in the number retained on ART, the number of patients doing well on treatment may be identified through medical chart reviews based on the good clinical status definition included in the previous section.

The gaps are calculated as follows:

(1) Coverage gap = 1−2
(2) Retention gap = 2−(3+4)
(3) Wellness gap = 4−5

The framework utilizes time-series plots with short time intervals. These can be daily, weekly, or every clinic day, as appropriate [6].

Applying improvement methods to bridge the gaps

Improvement methods are grounded in systems theory, which views the occurring results as a characteristic of the systems and processes that currently exist [18,19]. They also view external and internal customers, patients, and health workers, respectively, as key to improving these processes and systems.

Aligned with the World Health Organization's People-Centered and Integrated Health Services Global Strategy [20], improvement efforts facilitate conversations between patients and their providers to jointly understand the causes of the gaps and to come up with possible solutions to bridge them. Healthcare providers, together with their patients, may then develop and test solutions using the Model for Improvement [21].

The CCM has been widely applied and proven extremely beneficial to improving care for patients with chronic illnesses [22]. The CCM considers four integral components to improving quality of care: decision support, clinical information systems, delivery system design, and self-management support. In improving the quality of the chronic care of patients with HIV, the CCM has proven valuable for improving ART at the facility level [23].

Following the Model for Improvement and integrating the CCM, quality improvement teams, made up of care providers and expert patients, work together to address challenges. It is necessary to solve administrative issues such as patient flow, patient records, and waiting times. Members of improvement teams must be able to analyze clinical data as a prerequisite for this work. Quality improvement teams in a facility meet on a weekly or biweekly basis but regularly work on improving care. In the context of the ART Framework, teams must consider challenges for achieving maximum coverage, retention, and wellness for patients receiving ART. After these challenges have been identified, the team must detect the most common problems and identify solutions. For example, in the case of improving patient retention, healthcare providers may ask patients why they missed their last ART visit. If 56% of patients answer that transportation or distance barriers was the main cause, 25% respond that it conflicts with their work schedule, and the remainder reply that they feel fine and do not believe they require further treatment, quality improvement teams should first work to find solutions to the most frequently reported response, which, in this example, would be solving distance and transportation barriers.

Building off the previous example, quality improvement teams may ask patients what they can do to help patients come to their next ART visit. The most common response received is often the first change the quality improvement team will test. However, teams must critically consider the feasibility in addressing that barrier. The most frequently reported barrier may not be the easiest to address and therefore may not be the best starting point to improve care. Therefore, the quality improvement team should consider the responses received from the patients and identify a change to test, weighing all factors. The teams then track progress using time-series plots in real time with annotations showing when different changes were tested and what the effects

were. This is an ongoing process and should not end once the most common challenges to increasing coverage, retention, and wellness are improved. Instead, teams should continuously be surveying their patients' needs to increase coverage, retention, and wellness.

Results

Buikwe, Uganda

Buikwe District in Uganda was selected in conjunction with the Ugandan Ministry of Health (MOH) after a Chronic Care Design Meeting in May 2010, where the MOH laid out a strategy for improving quality of care for HIV and other chronic illnesses [23]. Five Healthcare Center IVs participated in a collaborative improvement initiative [24], where they were trained in the CCM. The collaborative improvement, with technical assistance from the USAID HCI Project, began in October 2010. Technical assistance ended in September 2012. Providers were encouraged to analyze their facility and systems of care from the perspective of the CCM to identify areas of improvement. Quality improvement teams, consisting of healthcare providers and expert patients, were established in all five Healthcare Center IVs.

Healthcare Center IV teams believed they were strongest in the areas of clinical information systems, decision support, and delivery system design for patients receiving ART care. However to improve coverage, retention, and wellness, teams felt they needed to focus on self-management support for their patients. Each site tested changes in their setting and monitored their own results. They collected data on a daily basis and healthcare providers shared their learnings through various mechanisms in the collaborative, such as coaches traveling to sites and in-person learning sessions within facilities. Quality improvement teams implemented the ART Framework, collected data, and assessed the outcomes with technical assistance from the USAID HCI Project team. After the USAID HCI Project ended, quality improvement teams continued to monitor and evaluate the coverage, retention, and wellness gaps of their facilities.

As can be seen in Fig. 1, the five Healthcare Center IVs began improvement work with approximately 3000 ever enrolled patients in October 2010, with a 44% coverage gap, a 49% retention gap, and a 53% wellness gap. At the end of the intervention period in September 2012, the five Health Center IVs had approximately 6000 patients ever enrolled. Coverage, retention, and wellness gaps decreased to 19%, 24%, and 14%, respectively. Patients ever enrolled continuously increased after the intervention and quality improvement teams continued their work to decrease the coverage, retention, and wellness gaps. Teams continued to collect data, as well as test and implement more changes, which resulted in further bridging the quality gaps.

Discussion

Coverage, retention, and wellness gaps in Buikwe District, Uganda, were identified and addressed through the testing of changes in existing processes, specifically

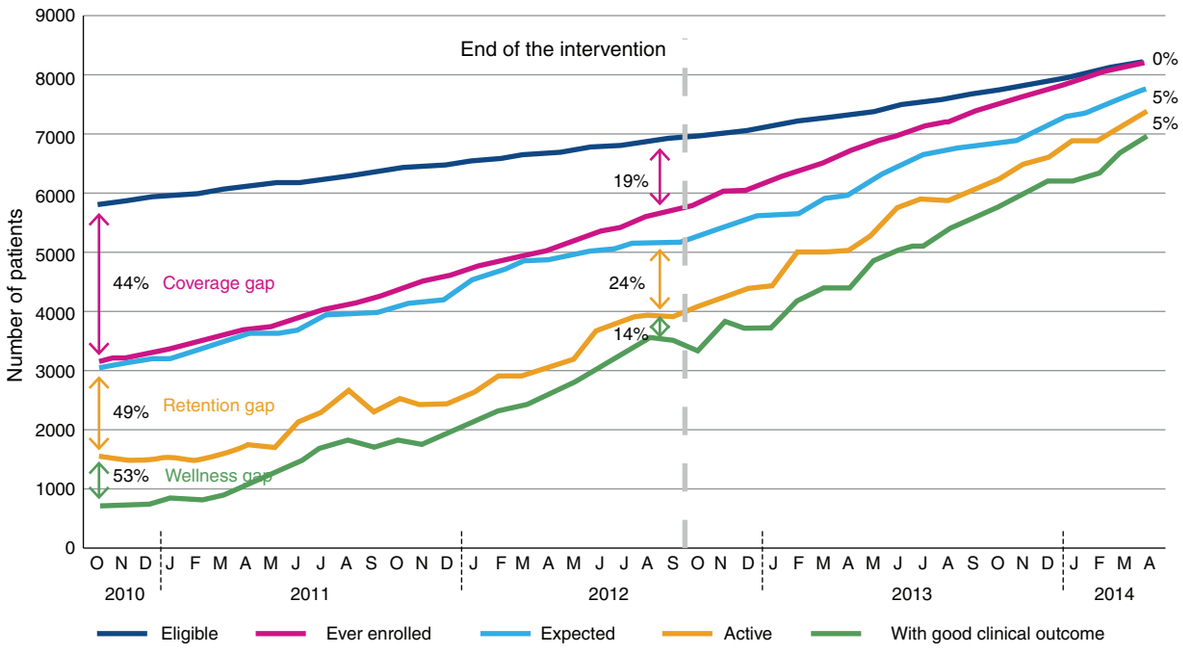

Fig. 1. Uganda: coverage, retention and wellness gap analysis showing improvement at five sites implementing the ART Framework and Chronic Care Model in Buikwe District (October 2014 to April 2014).

Table 1. Examples of changes introduced to improve antiretroviral therapy care in five facilities in Buikwe, Uganda.

Coverage gap	Retention gap	Wellness gap
Health workers and expert patients sensitized community members on chronic care for HIV through local radio, at churches, and in health facilities	Health workers and expert patients traced patients lost to follow-up by conducting home visits	Educated patients about their condition and treatment as well as allowed patients to share their experience
Village health teams mobilized communities for random counseling and testing Conducted HIV counseling and testing to all patients who came to the facility	Introduced outreach visits to reduce travel distance for patients Conducted group classes for patients who defaulted from care	Conducted health worker guided health education sessions Introduced self-management classes
	Assigned each patient two treatment supporters	Health workers and patients set health goals together and monitored progress

targeting the four basic principles of the CCM. This approach requires an initial investment in time and effort to conduct the improvement. However, beyond that, the work becomes more streamlined such that the health workers are better able to deal with the increased number of patients. This is particularly the case when both the ART Framework and the CCM are applied together. With more patients retained on treatment, there will be a need for a larger amount of antiretrovirals.

The four principles of the CCM were targeted through first speaking to the patients who missed appointments; second, calling patients who missed appointments to come to the healthcare center; and, in some cases, conducting home visits to patients and speaking to them and their families. Examples of specific changes that were implemented by the quality improvement teams in the five facilities to improve coverage, retention, and wellness are listed in Table 1. In addition to the changes listed, other changes were introduced to improve patient outcomes. Some facilities increased the number of clinic days for ART, introduced triaging, moved drugs closer to the community where patients could easily access them, retrieved patient files early to reduce patient wait time, and shifted tasks from health workers to identified expert patients. It is believed that these changes also led to improved coverage of ART. Patient records existed for those included in the retention gaps data.

Data on the coverage, retention, and wellness gaps in the five facilities showed large reductions over the course of the intervention. As can be seen in Fig. 1, the results continued to show improvements in closing the gaps for more than 18 months beyond the end of the intervention. This time-series chart does not follow a cohort, but rather includes all the patients receiving services in the health centers.

At the end of 2012, Fig. 1 shows a large difference in expected enrollment and ever enrolled in the Healthcare Center IVs. This difference is due to seven Healthcare Center IIIs that were accredited to provide ART in Buikwe. Healthcare Center IIIs are smaller health facilities located closer to communities, providing easier access to treatment for patients. Many patients who previously received care in the five Healthcare Center IVs transferred to one of the newly accredited Healthcare Center IIIs. This explains the reduction in the expected number of patients starting at the end of 2012 as can be seen on the graph. The transfer of patients to other healthcare facilities is occurring more frequently as antiretrovirals become more common [18]. This should be taken into account when estimating expected patients.

Strengths and weaknesses

The application of the ART Framework has weaknesses to the approach. It is a time-series study, without a comparison group. However, the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project (the USAID ASSIST Project builds off the work of the USAID HCI Project) is currently applying improvement methods to HIV care and treatment in other sites in Uganda and other countries. The USAID ASSIST Project has not experienced such dramatic improvements as the five Healthcare Center IVs, which applied the ART Framework in Buikwe District. The work in Buikwe is an example of a series of complex social interventions.

The approach also has strengths. The application of the ART Framework was conducted by the healthcare providers in conjunction with patients. This enables and empowers them to make changes using data. The results in Fig. 1 show the gaps continued to improve beyond the technical assistance provided by the USAID HCI Project team. The ART Framework can and is currently being applied to other sites in Uganda. This framework can be applied to areas other than improving care for patients on ART. In contrast to the Cascade Model, which provides a snapshot in time [25], the ART Framework provides ongoing data in real time, enabling the testing of changes. Therefore, it is not just a measurement framework but an improvement framework.

Conclusion

The ART Framework is built on a method called ‘gap analysis’. This type of framework can be applied when dealing with subsets of the same population and where the

gaps reveal system or program defects. Adapting this thinking to care for patients on ART allows providers to monitor and analyze, in real time, the causes for program gaps or defects and to develop appropriate solutions in collaboration with patients themselves. This can be clearly seen through the results in Buikwe District, Uganda, which show the gaps in coverage, retention, and wellness greatly improved over time, including beyond the intervention period. The application of this framework, in conjunction with the core principles of the CCM, is a practical approach for guiding improvement activities in HIV care and treatment programs. The ART Framework can be applied beyond HIV care and treatment.

Acknowledgements

This work would not have been possible without the outstanding contributions from Dr Godfrey Kayita, Dr Eric Ikoona, and Dr Elizabeth Namagala of the AIDS Control Program and Quality Assurance Department of the Ugandan Ministry of Health. These individuals and institutions played a crucial role during site coaching and learning sessions and ensured we achieved these results. We would also like to acknowledge the health workers in Buikwe District for taking on this improvement work and more importantly maintaining it after we exited the district. This work would not have been possible without them taking pride and ownership of improving the quality of care for HIV patients.

The work described was made possible by the generous support of the American people through the United States Agency for International Development (USAID) with funding from the US President's Emergency Plan for AIDS Relief (PEPFAR) through the Healthcare Improvement (HCI) Project under Contract No. GHN-I-01-07-00003-00 and Applying Science to Strengthen and Improve Systems (ASSIST) Project under the terms of Cooperative Agreement Number AID-OAA-A-12-00101. Both the USAID HCI and ASSIST Projects are managed by University Research Co., LLC.

Author contributions: M.R.M. conceptualized and operationalized the ART Framework, as well as participated in the initial testing of the framework. L.J. and N.L. participated in conceptualizing the framework. F.S., R.J.-B., N.L., and S.G. participated in operationalizing the framework and the initial testing of the framework. M.M., J.N., H.M., E.K.-N., and P.M. tested the framework in Buikwe District. All authors participated in the development of the manuscript. A.O. compiled the final manuscript.

Source of funding: This work was funded by United States Agency for International Development through its Healthcare Improvement Project, implemented by University Research Co, LLC under Contract No. GHN-I-01-07-00003-00.

Conflicts of interest

There are no conflicts of interest.

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