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Improving rates of cotrimoxazole prophylaxis in resource-limited settings: implementation of a quality improvement approach

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Abstract

Objective. To demonstrate the effectiveness of quality improvement methods to monitor and improve administration of cotrimoxazole (CTX) prophylaxis to improve health outcomes among adults living with HIV/AIDS in low resource countries.

Design. Program evaluation.

Setting. HIV/AIDS health care facilities in Uganda, Mozambique, Namibia and Haiti.

Intervention. Performance measures based on national guidelines are developed in each country. These may include CD4 monitoring, ART adherence and uptake of CTX prophylaxis. CTX prophylaxis is routinely selected, because it has been shown to reduce HIV-related morbidity and mortality. Patient records are sampled using a standard statistical table to achieve a minimum confidence interval of 90% with a spread of ±8% in participating clinics. If an electronic medical record is available, all patients are reviewed. Routine review of performance measures, usually every 6 months, is conducted to identify gaps in care. Improvement interventions are developed and implemented at health facilities, informed by performance results, and local/national public health priorities.

Main outcome measure. Median clinic rates of CTX prophylaxis.

Results. Median performance rates of CTX prophylaxis generally improved for adult HIV+ patients between 2006 and 2013 across countries, with median clinic rates higher than baseline at follow-up in 16 of 18 groups of clinics implementing CTX -focused improvement projects.

Conclusions. Quality management offers a data-driven method to improve the quality of HIV care in low resource countries. Application of improvement principles has been shown to be effective to increase the rates of CTX prophylaxis in national HIV programs in multiple countries.

Keywords: quality improvement, performance measurement, quality management, pepfar

Introduction

The persistent burden of HIV/AIDS in many low- and middle-income countries calls for renewed efforts to identify effective and cost-efficient therapies to reduce morbidity and mortality associated with HIV/AIDS. Although antiretroviral therapy (ART) is a critical component of the global HIV/AIDS response, coverage in low- and middle-income countries continues to face notable barriers, with only 34% of the estimated 28.6 million eligible for ART covered based on 2013 World Health Organization (WHO) guidelines [1]. Cotrimoxazole (CTX) is an antimicrobial medication that reduces the risks in HIV-infected patients for a wide range of conditions, including pneumonias caused by *Pneumocystis jirovecii*, *Pneumococcus* and *Nocardia*; toxoplasmosis; diarrhea and malaria [2, 3]. People living with HIV/AIDS (PLHIV) may exhibit a

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slower decline in CD4 cell count and a slower rise in viral load after initiation of CTX [4]. Provision of CTX to pregnant HIV-infected women with CD4 counts ≤200 is associated with a reduced risk of preterm births, low infant weight for gestational age and neonatal mortality [5], and there is an association between CTX prophylaxis and decreased morbidity and mortality among HIV-infected patients receiving ART [6–8].

Cotrimoxazole is relatively inexpensive. Provision of CTX prophylaxis is among the most cost-effective, logistically feasible interventions to reduce morbidity and mortality in patients with HIV. Several studies have shown that the cost per year of life gained due to CTX prophylaxis is low in both adult and pediatric HIV patients [9–11]. It has even been suggested that in certain cases, universal CTX for HIV-infected patients would have a negative net cost, as a result of fewer hospital stays and a reduction in associated health-care costs [12].

The WHO published comprehensive guidelines for the use of CTX prophylaxis in 2006. These guidelines suggest the provision of CTX for all symptomatic HIV-infected people with mild, advanced or severe HIV disease based on clinical staging criteria (WHO clinical stages 2, 3 or 4) [2]. WHO also recommends CTX for HIV-infected people with CD4 cell count <350 per mm^3, with specific emphasis on low- and middle-income countries where other co-morbidities are prevalent [2]. According to the guidelines, countries with high HIV burden or other health-care delivery challenges may adopt universal CTX for all people living with HIV regardless of CD4 count or clinical stage [2].

Many countries have adopted national guidelines for CTX prophylaxis, but important barriers to implementation continue to impede its use [13]. In low- and middle-income countries, access to sufficient stocks of CTX remains a significant issue. Health infrastructure deficits may limit access in many rural areas, even if the drugs are available in more urban districts. Where supply of CTX is adequate, provider education may still be needed to facilitate prompt initiation of CTX for eligible patients. Support and education may be required for patients to adhere to treatment.

Few studies address the degree to which CTX guidelines have been implemented. Until the recent adoption of CTX program indicators by the US President's Emergency Plan for AIDS Relief (PEPFAR), no widely accepted measures for this area of adult HIV care had been developed. The main sources of information about coverage have been surveys and evaluations of clinical cohorts, which indicate that rates of administration vary. For example, rates of CTX prophylaxis in a cohort of ART recipients seen during 2004–07 in Mozambique was 31% [13], whereas in an indicator survey conducted in 2007, 75% of persons with HIV who knew their HIV status reported receiving CTX [13]. Data from that survey highlighted the fact that even when rates of CTX prophylaxis among persons in care are high, there remains a very substantial unmet need among persons who are unaware of their HIV status [14].

One approach to improving the implementation of critical interventions such as CTX prophylaxis is to implement quality improvement (QI) programs. HEALTHQUAL International (HQ-I) is a capacity building model designed to improve quality of care throughout national health systems. The HQ-I model adapts three main components of quality management—performance measurement (PM), QI and the quality management program (QM)—to build sustainable, self-sufficient local programs. Program implementation is directed by National Ministries of Health in partnership with HQ-I, in-country US government teams, and implementing partners. In this article, we offer the methodology from HQ-I as one strategy for National Ministries of Health to support improvement in rates of CTX prophylaxis in resource-limited settings. Using data collected by HQ-I implementing countries, we describe improvements in performance rates over time and describe simple clinic-level interventions to achieve enhanced health-care outcomes for PLHIV.

Methods

General methods for HEALTHQUAL International

HQ-I works with National Ministries of Health to develop clinic-based systems for collection and analysis of quality measures. These measures are based on national guidelines in each country and often mirror WHO recommendations (see Table A1 for eligibility criteria by country). Clinic staff then design, implement and evaluate the effectiveness of improvement activities.

HQ-I methodology is adapted in implementing countries, based on a model developed by the New York State Department of Health AIDS Institute in 1992, and expanded through the US Ryan White CARE program and which has been adapted in Thailand and other countries [15–17]. With the assistance of HQ-I and other implementing partners, indicators are developed in each country, based on national guidelines and region-specific challenges. Examples of indicators that have been chosen to reflect quality of HIV care include CD4 cell counts, monitoring, viral load, patient visits, adherence to treatment, ARV prescribing, isoniazid prophylaxis, food security and alcohol screening, among others.

To measure indicators related to quality of care, clinic staff examine charts from a random sample of patients derived from an active case list. Initially, this case list is developed from existing paper or electronic registries, depending on the system used by the clinic, and is based on eligibility criteria determined specifically in each country. Each country determines whether to include patients with a particular number of visits in a specific time interval. Ineligible patients are eliminated from the sample. A standard statistical table is utilized to determine sample size, which is calculated to achieve a 90 or 95% confidence interval (CI) with a spread of ±8% in each participating clinic (based on country preference). Three methods of sampling are used to identify the specific records for review at a given clinic based on available technology at that facility: (i) automatic randomizer programmed in the HEALTHQUAL software, a free data collection tool in MS Access that is designed to specifically capture data on the selected indicators; (ii) web-based random numbers generator or (iii) sequential sampling through ordering of charts by name or record number then selecting every 'nth' case. When an electronic medical record (EMR) is available, as in Haiti, all patients are

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included in the sample. Haiti's EMR, iSanté, includes alerts for wrong or missing values. The system is also used to generate summary reports, including any errors and/or missing data, which is presented to the facility's data manager for follow-up with the appropriate provider.

For countries using paper records, individual client-level data are entered on a focused medical record abstraction form, tailored to reflect the country's particular indicators. Values are then entered into the HEALTHQUAL software. When all values are entered, a clinic can generate its own data report directly from the software. This allows a clinic to identify its own areas for improvement. In addition, each report is sent to the Ministry of Health (MOH), which aggregates the data for further analysis absent patient identifiers and then calculates mean facility scores for each indicator. Benchmarking reports comparing these facility scores are distributed to participating clinic teams. In general, performance goals are established and measured at each clinic, with support at the national level for clinics to achieve their specific goals, as opposed to supporting achievement of a defined overall rate of performance.

Selection of health-care facilities varies by country but generally includes sites of varying size, type (community health center and large district hospital) and geographic location (by region) to ensure urban and rural diversity (Table 1).

Quality improvement activities are informed by performance results, clinic-based process investigation and local or national public health priorities. The HQ-I approach to clinic-level process improvement flows from common improvement principles [18], imparting a systematic approach focused on patient care and outcomes. HQ-I teaches improvement skills and imparts tools to support facilities as they move through the improvement process. Analysis of both processes and the system as a whole is one of the core skills necessary to connect gaps to the appropriate intervention. HQ-I US-based staff provide technical assistance for mentoring of QI coaches through in-county clinic visits, telephone/webinars, email and regional QM group meetings. Improvement coaching is a skills- and knowledge-building strategy to ensure integration of QI principles and tools into routine program work, planning and leadership in each HQ-I implementing country. Coaching techniques are taught and modeled by HQ-I staff through mentoring during site visits and interactions with clinic teams.

Monitoring of CTX prophylaxis in HEALTHQUAL programs

Rates of prescription of CTX prophylaxis were measured in four participating countries among clinics implementing HEALTHQUAL in Uganda, Mozambique, Namibia and Haiti. Table 1 includes the total number of HQ-I implementing health-care facilities in each respective country, describes sampling methodologies and target CIs, and defines clinical performance data review intervals in each country included in this article. The specific indicators reflect the national guidelines adopted in each country. Guidelines for CTX prophylaxis for all HIV-infected adult patients have been adopted in both Haiti and Uganda, whereas Mozambique and Namibia administer CTX based on CD4 cell count/WHO stage. Country-specific measures are generally defined as the proportion of eligible adult patients enrolled in HIV care who meet national guidelines for CTX and who are prescribed CTX during the review period (see Table A1 for full eligibility criteria and adult indicator definitions).

Analysis of CTX prophylaxis data

Countries were included in this analysis if they had adopted a CTX indicator for adult HIV programs (Table A1), had collected national aggregated performance data for this indicator at least twice and had compiled associated clinic-level interventions. For the purposes of this analysis, we describe performance data in terms of 'Rounds' and 'Waves'. A 'Round' corresponds with a specific review period and identifies the chronological progression of data collection for a given wave of clinics. A 'Wave' designates the introduction of a new group of clinics for the purposes of data submission. Waves progress across multiple rounds and review periods, corresponding to staggered implementation of data submission. We summarized rates of CTX prophylaxis during each round and wave of reporting in participating countries by calculating median performance rates and ranges for participating clinics. We report on improvement as defined by a positive directional change in performance.

Four countries (Uganda, Mozambique, Namibia and Haiti) met criteria for inclusion; in these four countries, 20 distinct Waves of clinics initiated CTX PM for eligible adults living with HIV, 18 of these had at least 2 measures of performance that could be compared, that is, they had baseline (Round 1 for any given Wave) and at least one follow-up round. Review periods ranged from March 2006 to December 2010 (Uganda), January 2007 to June 2011 (Mozambique), January 2008 to March 2013 (Namibia) and January 2008 to September 2013 (Haiti). Baseline data were unavailable for Wave 1 of clinics in Namibia because of technical problems.

Statistical significance testing was conducted using Fisher's exact test (Namibia, Uganda and Mozambique) and Chi-square with Yates correction (Haiti) for clinics that reported CTX data both at baseline and during the most recent review period.

HEALTHQUAL activities are approved by the Ministries of Health in all participating countries. Protocols describing this work in each participating country were reviewed by the Center for Global Health at CDC and granted non-research status, because the primary purpose was program evaluation.

Results

Cotrimoxazole-specific PM data were available for analysis in ~415 adult clinics representing 402 911 chart reviews in the participating countries, reflecting care provided between March 2006 and September 2013.

Table 2 depicts the median performance for CTX prescription for each of the 20 unique combinations of wave of clinics/round of observation, including the 18 where it was possible to compare follow-up with baseline. Baseline median performance ranged from 17% (Mozambique, Wave 1) to 100% (Namibia, Wave 3). Performance generally improved over time; median clinic scores were higher than baseline at

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Table I Participating clinics, sampling methodologies, confidence interval and review period by country

Country	Number of clinics	Type of clinics	Sampling methodology	Target confidence interval	Review interval
Haiti	102	Mix of departmental hospitals, community health centers, university hospitals and non-governmental health facilities.	The National EHR allowed all eligible patients to be reviewed. No sampling is needed.	N/A	6-month review periods Before December 2011: January–June July–December After December 2011: October–March April–September
Uganda	101	Mix of referral hospitals, community hospitals and district health centers. Ministry of Health assigned clinics to participate and reassigned in subsequent rounds.	Case lists were generated based on country-specific eligibility criteria. Using the case load, sample sizes were determined from a standardized HEALTHQUAL sampling table. Clinics with paper records systematically sampled (every nth patient) and collected data using manual reporting forms. Electronic clinics generated a random list of charts to sample using the HEALTHQUAL software randomizer. Data were aggregated in excel.	90 ± 8%	5- and 6-month review periods Before August 2008: March–August April–September February–August After August 2008: January–June July–December
Namibia	38	All district hospital ART clinics (31), 3 intermediate hospitals and 3 health center-based ART clinics.	In Namibia, electronic health records were queried for eligible patients based on country-specific eligibility criteria to generate a case list. Information was transferred to an excel spreadsheet and duplicates were removed. Using the case load, sample sizes were determined from a standardized HEALTHQUAL sampling table. A random list of charts for the sample was generated using the HEALTHQUAL software randomizer. Data were aggregated using the HEALTHQUAL software.	95 ± 8%	6-month review periods Before June 2010: January–June July–December After June 2010: October–March April–September

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Mozambique	174	ART clinics in both hospitals and health centers representing all provinces in the country; assigned by Ministry.	Case lists were generated based on country-specific eligibility criteria. Using the case load, sample sizes were determined from a standardized HEALTHQUAL sampling table. Clinics either generated a random list of charts to sample using the HEALTHQUAL software randomizer or systematically sampled (every nth patient). Data were aggregated using HEALTHQUAL software.	95 ± 8%	6- and 12-month review periods Before June 2007: January–June After June 2007: July–June

most recent follow-up in 16 of 18 groups of clinics where baseline and follow performance could be compared. The most dramatic improvement occurred in the Wave 3 clinics in Haiti, where the median rose from 58% ($n = 7347$) to 96% ($n = 11\,077$) between Rounds 1 and 9 for that Wave.

The proportion of patients prescribed CTX increased significantly among clinics reporting both at baseline and most recent review in Namibia (86–93% of eligible patients, $P < 0.0001$, January 2008–March 2013), Uganda (87–91% of eligible patients, $P < 0.0018$, March 2006–December 2012) and Haiti (65–96%, $P < 0.0001$, January 2008–September 2013). In Mozambique, aggregate performance was unchanged (June 2008–June 2011, $P = 1.0$).

Participating clinics initiated a variety of activities to improve rates of CTX prescription. Interventions are listed in Table 3 and categorized by intervention type. Efforts to improve rates of CTX prophylaxis included structured patient education, regular quality team meetings to reinforce collection of performance data, provider education, efforts to improve documentation, partnerships with community outreach organizations to promote adherence, organizational change and improved data processes.

Facility-level improvement: case studies

The following case studies serve as illustrative examples of clinic-level QI implementation and generally focus on process analysis and small tests of change to improve processes of care and patient outcomes.

Haiti

Performance rates for the number of patients receiving CTX prophylaxis at Grace Children's Hospital improved from a baseline measure of 33 to 75% within 1 year. Clinic staff utilized an improvement approach involving process analysis to determine specific areas of care associated with CTX requiring improvement. This analysis informed a series of changes designed to enhance care, including staff posting of CTX prescription guidelines in examination rooms, emphasis on entering of CTX data in the EMR and strengthening of hospital staff's knowledge about CTX prophylaxis.

Mozambique

At Moamba Health Center, performance rates for CTX administration improved by 75% from a 2008 baseline of 25% to 100% at most recent follow-up. A formal quality committee was formed to analyze current processes and develop interventions to improve performance. The team created a job aid defining eligibility criteria for CTX prophylaxis and placed it in all exam rooms, instituted refresher training for all clinicians on CTX prescribing protocol, implemented coaching and mentoring of clinic staff by the local HIVQUAL team to assure prioritization of improvement activities, established a permanent clinic-level QI team and reinforced systematic review of patient charts to review CTX prescribing for eligible patients.

Namibia

At Otijwarongo State Hospital, a multidisciplinary team improved rates of CTX prophylaxis by >70% within 1 year

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Table 2 Cotrimoxazole preventive therapy provision in 5 countries based on HEALTH QUAL reports, 2007–13

Country	Median clinic score (range) no. of clinics | no. of eligible patients															
Haiti	January–June 08		July–December 08		January–June 09		July–December 09		January–June 10		July–December 10		January–June 11		July–December 11		October 11–March 12	
Total	72 (23–88)	18 | 10 316	80 (0–98)	24 | 13 782	84 (0–99)	24 | 16 038	79 (3–99)	48 | 23 654	81 (4–98)	48 | 23 301	84 (10–99)	51 | 25 104	89 (7–99)	49 | 26 534	92 (9–100)	51 | 29 430	95 (32– 100)	51 | 30 167
Wave 1	72 (23–88)	18 | 10 316	74 (0–98)	18 | 11 862	84 (0–99)	18 | 13 598	83 (28–99)	18 | 13 632	85 (28–98)	18 | 13 468	92 (37–99)	17 | 13 985	95 (40–98)	17 | 14 704	95 (41–99)	17 | 15 611	95 (41–99)	17 | 15 818
Wave 2		-	83 (61–88)	6 | 1920	90 (79–97)	6 | 2440	94 (83–99)	6 | 2675	93 (84–97)	6 | 2675	93 (74–99)	6 | 2754	94 (89–97)	6 | 2976	96 (92–100)	6 | 3298	98 (96–100)	6 | 3422
Wave 3		-		-		-	58 (3–95)	24 | 7347	70 (4–94)	24 | 7214	71 (10–98)	24 | 7610	86 (7–99)	22 | 8052	88 (32–99)	24 | 9457	93 (34–100)	24 | 9835
Wave 4		-		-		-		-		-	58 (25–95)	4 | 755	52 (21–98)	4 | 802	56 (9–99)	4 | 1064	60 (32–98)	4 | 1092
Wave 5		-		-		-		-		-		-		-	97 (71–100)	6 | 1387	92 (82–99)	6 | 1651

Haiti	April–September 12		October 12–March 13		April–September 13	
Total	95 (30–100)	64 | 46 595	96 (21–100)	73 | 47 834	97 (0–100)	92 | 55 759
Wave 1	96 (30–100)	18 | 17 173	96 (81–99)	18 | 17 406	96 (81–99)	18 | 18 354
Wave 2	98 (94–100)	6 | 3638	99 (93–100)	6 | 3902	98 (97–99)	5 | 4017
Wave 3	96 (31–100)	21 | 10 132	95 (38–100)	19 | 9199	96 (53–100)	19 | 11 077
Wave 4	84 (45–98)	3 | 1629	92 (72–99)	4 | 2040	92 (83–99)	4 | 2243
Wave 5	94 (90–99)	6 | 2057	95 (90–100)	6 | 2291	97 (94–100)	5 | 1995
Wave 6	93 (63–98)	10 | 11 966	96 (21–100)	11 | 11 677	97 (48–100)	12 | 14 083
Wave 7		-	92 (71–99)	9 | 1319	95 (59–100)	17 | 3161
Wave 8		-		-	97 (0–100)	12 | 829

Uganda	March–August 06		April–September 07		February–August 08		July–December 08		January–June 09		July–December 09		January–June 10		July–December 10	
Total	89 (73–100)	20 | 1318	96 (78–100)	20 | 1695	92 (0–100)	72 | 5838	95 (64–100)	16 | 1438	95 (46–100)	51 | 4721	94 (41–100)	53 | 4393	96 (47–100)	31 | 2529	96 (24–100)	59 | 4994
Wave 1	89 (73–100)	20 | 1318	96 (78–100)	20 | 1695	99 (55–100)	12 | 952	99 (86–100)	5 | 478	96 (46–100)	15 | 1389	93 (47–100)	7 | 600	98 (65–100)	9 | 746	98 (53–100)	11 | 1024
Wave 2		-		-	90 (0–100)	60 | 4886	95 (64–100)	11 | 960	93 (61–100)	27 | 3332	94 (41–100)	33 | 2685	95 (47–100)	12 | 991	93 (24–100)	32 | 2632
Wave 3		-		-		-		-	90 (63–100)	9 | 683	92 (68–100)	8 | 651	96 (64–100)	4 | 327	98 (95–100)	9 | 775
Wave 4		-		-		-		-		-	89 (65–97)	5 | 457	97 (89–99)	3 | 250	96 (79–100)	4 | 370
Wave 5		-		-		-		-		-		-	95 (93–100)	3 | 215	94 (89–100)	2 | 140

Namibia	July–December 07		January–June 08		July–December 08		January–June 09		July–December 09		January–June 10		October 10–March 11		October 11–March 12		April–September 12	
Total	N/A	N/A	91 (50–100)	16 | 1145	93 (70–100)	16 | 1040	91 (53–100)	31 | 1659	92 (30–100)	33 | 1560	97 (54–100)	36 | 1879	96 (62–100)	36 | 1486	95 (52–100)	36 | 1397	96 (74–100)	35 | 1181
Wave 1	N/A	N/A	91 (50–100)	16 | 1145	93 (70–100)	16 | 1040	91 (69–100)	16 | 932	93 (77–100)	14 | 730	97 (84–100)	16 | 863	97 (62–100)	16 | 696	94 (80–100)	16 | 706	96 (83–100)	16 | 585
Wave 2				-		-	91 (53–100)	15 | 727	92 (43–100)	15 | 647	93 (54–100)	15 | 762	95 (67–100)	15 | 614	93 (52–100)	15 | 534	94 (74–100)	15 | 468
Wave 3				-		-		-	77 (30–98)	4 | 183	95 (84–100)	4 | 200	94 (82–100)	3 | 122	96 (91–100)	4 | 123	95 (91–97)	4 | 128

Namibia	October 12–March 13	
Total	95 (74–100)	37 | 1170
Wave 1	95 (76–100)	16 | 515
Wave 2	94 (74–100)	16 | 462
Wave 3	100 (89–100)	4 | 151

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Mozambique	January–June 07		July 07–June 08		July 08–June 09		July 10–June 11		
Total	-		72 (0–100)	39 | 1436	69 (0–100)	102 | 2220	83 (0–100)	135 | 7157	
Wave 1 (ART)	35 (10–65)	31 | 2897		-		-			
Wave 1 (pre-ART)	17 (0–63)	29 | 1244		-		-			
Wave 1	-		74 (10–100)	25 | 937	88 (21–100)	19 | 513	80 (0–100)	25 | 1526	
Wave 2	-		72 (0–100)	14 | 499	69 (0–100)	14 | 242	94 (32–100)	8 | 394	
Wave 3	-			-	63 (0–100)	69 | 1465	77 (11–100)	55 | 3337	
Wave 4				-		-	86 (0–100)	47 | 1900	

Shown is each country's median clinic score for the cotrimoxazole preventive therapy indicator. Note that each country's indicator definition varies slightly and that rounds of data collection correspond to different review periods.
ART, Antiretroviral therapy.

(29% at baseline to 100% at follow-up). Staff focused on improving documentation to capture CTX data and initiating systematic reminders to complete all forms in entirety at each patient visit. Staff implemented a system to trace all patient's laboratory results to speed determination of eligibility for CTX. In addition, an agreement was reached with the pharmacy to make CTX available in nurse-counselor's rooms to improve access. Pharmacists were tasked with ensuring CTX availability to prevent stock outs.

Table 3 Clinic-based interventions to improve quality of care in CTX administration and measurement

Type of intervention	Examples
Education	Educate patients on role and importance of CTX Advocate for use of CTX in eligible patient population Educate all clinic staff to flag eligible patients to be seen for CTX prescription Direct providers to check for CTX use Remind providers to capture CTX in Electronic Medical Record (EMR)
Data processes	Translate manual files into EMR Improve documentation Improve capture of patients already on CTX Routinize capture of lab data, including CD4 and Viral Load
Partnering with community organizations	Engage support group community outreach visit Establish community to help remind patients about regularly scheduled drug pick-ups Enforce awareness by people living with HIV/AIDS
Organizational changes	Standardize prescribing of CTX using a written protocol Standardize language about CTX and eligibility Make CTX available in the nurse-counselors' station Ensure timely availability of CD4 results Hold monthly meetings to identify eligible patients Create a clinic-wide list of eligible patients and their identification numbers

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Discussion

This report documents substantial, sustained improvements, over multiple periods of data collection, in rates of CTX prophylaxis to adult PLHIV in clinics implementing a QM defined by routine PM and systematic, multimodal improvement interventions. Performance rates are clinic specific and reflect the goals, challenges and local environment at each individual facility, limiting comparability. Aggregated performance rates at the national level capture combined activities of these clinics, and these results provide important information about implementation of CTX as a cost-efficient and effective method of decreasing morbidity and mortality in PLHIV and achieving important public health goals. The specific interventions implemented in different clinics and different programs varied widely as expected based on local need and context, but they may provide important ideas for consideration in settings where there is a need to improve rates of CTX prophylaxis.

Quality management offers a measurement-driven methodology using existing resources to build capacity to measure performance and implement evidence-based interventions. These methods have demonstrated a positive net impact on several critical measures of HIV care [19]. Our experience with improved rates of CTX prophylaxis reinforces the need to consider an improvement approach as part of a comprehensive health-care systems strengthening strategy that includes continuous cycles of monitoring and improvement. Improvements facilitated through QI may also lead to enhancement of information systems for data collection and analysis, educational programs, better efficiency through realignment of staff responsibilities and reorganization of service flow, such as improved pharmacy services to increase effectiveness or prevent medication stock outs.

Interpretation of aggregated QI data should be undertaken only with caution since participating sites may not be representative of national programs. Since clinics are not selected randomly, the aggregate data do not represent a true national score. The aggregate data can, however, provide important information about implementation of key clinical interventions, especially given the representation of large volumes of patients and multiple regions in a country. In certain countries, clinics may represent all HIV specialty centers, such as in Namibia, or the majority of clinical centers, as in Haiti, where data are captured directly from a nationwide EMR. While the treatment landscape is rapidly changing, these data provide some information about rates of CTX prophylaxis in a wide range of urban and rural HIV treatment settings, including hospitals, community health centers, partner and non-partner facilities, and clearly demonstrate that WHO guidelines for CTX prophylaxis are being implemented. As HIV services become integrated into general medical systems over time, these baseline rates will be important for monitoring whether the quality of HIV care is maintained.

Our reliance on self-reporting of data represents a primary limitation of this article. Although the validity of self-reported data has previously been questioned, self-reporting has been shown to be a reliable method of reporting performance data and yields insights about data quality to clinic staff during the data collection process which in turn facilitates improvements in both documentation and information systems [20, 21]. Administration of CTX is not usually directly observed, and we are unable to definitively demonstrate whether patients were consistently taking their medications. Case-list standardization and differences in national standards and guidelines also vary between countries, limiting true comparability.

Implementation of the QI approach was not randomized, and we are unable to definitively demonstrate that the improvements in rates of CTX coverage resulted specifically from the QI interventions. In fact, it is likely that at least in some instances, improvement activities may have coexisted with external changes, for example, improved CTX supplies. Conversely, performance rates might not improve despite well-conceived and executed improvement activities, for example, because of national-level stock outs of essential medicines or fluctuations in the national political environment. Nonetheless, system-level changes still need to be addressed; system performance varies even when medications are available.

Another challenge is that simultaneous implementation of multiple interventions may result in important improvements, making it difficult to determine the impact of any one strategy. Our data do not permit this kind of detailed analysis since each national program collects and tracks information which is often not standardized. Moreover, evidence supports the benefit of multimodal interventions to achieve improvements in patient care [22]. Furthermore, ethical imperatives preclude formal randomized controlled trials of improvement implementation, which remains critical to the lives and well-being of PLHIV, especially when focusing on the implementation of life-saving prophylactic therapies such as CTX. Development of management processes to capture system-level improvements and correlating them on a broad scale with national performance data becomes increasingly important.

This article provides evidence supporting implementation of a quality management methodology as an effective way to help achieve desirable program outcomes. As demonstrated through HEALTHQUAL-supported initiatives, and reinforced by recent literature focused on improvement in quality of care in resource-limited settings, a key component of a successful improvement-based health systems strengthening approach involves implementation of multidisciplinary strategies by staff at the local, regional and national care levels [19]. This approach includes the sharing of improvement knowledge and methodologies, successes and challenges across clinics and between countries. Measurement of effects of change should be part of a methodical process involving clinic staff and patients on an ongoing basis, with effective models shared widely within and across country programs. Improvement strategies advance national health-care systems not only by driving existing systems to achieve optimal performance, but also by integrating a culture of QI into routine monitoring and evaluation as part of the public health sector to realize system-wide achievement. Quality improvement remains underutilized as a national strategy to achieve public health goals and can effectively achieve these goals when embraced by providers and facilitated through systems of care.

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Appendix

Table A1 Cotrimoxazole prophylaxis eligibility criteria and indicators

Country	Eligibility	Numerator	Denominator
Uganda	All HIV-infected adults >15 years old with at least one clinical visit during the 6-month review period.	The number of HIV-infected patients who have been prescribed CTX during the 6-month review period and are still receiving it at the end of the review period or at the time of death (all HIV-infected patients are eligible)	The number of patients with at least one visit during the 6-month review period
Mozambique	Round 1: all HIV-infected patients on ART with at least one clinical visit during the 6-month review period. All HIV-infected patients not on ART with at least one clinical visit during the past 12 months. Round 2: All HIV-infected patients over 5 years of age with at least one clinical visit during the first 6 months of the 12-month review period. Rounds 3 and 4: All HIV-infected patients over 15 years of age with at least one clinical visit during the first 6 months of the 12-month review period. Definition: A clinical visit is an encounter between a patient and a doctor, tecnico, agente or nurse.	The number of eligible (HIV-infected WHO III or IV or asymptomatic with CD4 <350) patients receiving CTX during the 6-month review period	The number of HIV patients meeting eligibility requirements for CTX (HIV-infected WHO III or IV or asymptomatic with CD4 <350) with at least one visit during the 6-month review period
Namibia	All HIV-infected patients with at least one clinical visit during the 6-month review period.	The number of patients who have been prescribed CTX during the past 6 months and are still receiving it at the end of the review period or at the time of death or transfer out (CTX is recommended for all HIV-infected patients with CD4 <300)	The number of patients with CD4 <300 in the past 6 months
Haiti	All HIV-infected patients with at least one clinical visit during the 6-month review period. Adult: >15 years old.	The number of patients (>10 years) having received CTX during the past 6 months (all HIV-infected adults and adolescents are eligible for CTX)	The number of patients (>10 years) having received at least one medical visit in the past 6 months

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