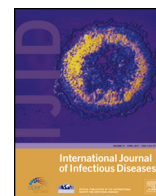




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Performance of the Antiretroviral Treatment Program in Ethiopia, 2005–2015: strengths and weaknesses toward ending AIDS



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ABSTRACT

Background: Ethiopia is one of the countries which has scaled up antiretroviral treatment (ART) over the past decade. This study reviews the performance of the ART program in Ethiopia during the past decade, and identifies successes and weaknesses toward ending AIDS in the country.

Methods: A review and synthesis of data was conducted using multiple data sources: reports from all health facilities in Ethiopia to the Federal Ministry of Health, HIV/AIDS estimates and projections, and retrospective cohort and cross-sectional studies conducted between 2005/6 and 2014/15.

Findings: The ART program has been successful over several critical areas: (1) ART coverage improved from 4% to 54%; (2) the median CD4 count/mm³ at the time of ART initiation increased from 125 in 2005/6 to 231 in 2012/13; (3) retention in care after 12 months on ART has increased from 82% to 92%. In spite of these successes, important challenges also remain: (1) ART coverage is not equitable: among regions (5.6%–93%), between children (25%) and adults (60%), and between female (54%) and male patients (69%); (2) retention in care is variable among regions (83%–94%); and, (3) the shift to second-line ART is slow and low (0.58%).

Interpretation: The findings suggest that the ART program should sustain the successes and reflect on the shortcomings toward the goal of ending AIDS. It is important to capitalize on and calibrate the interventions and approaches utilized to scale up ART in the past. Analysis of the treatment cascade, in order to pinpoint the gaps and identify appropriate solutions, is commendable in this regard.

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Background

The success of antiretroviral treatment (ART) programs is measured by a number of key performance indicators. Among others, these include: (1) access to and utilization of ART, (2) coverage of and equity for ART, (3) timely initiation of eligible patients on ART, (4) retention of patients in care, and (5) identification of people with treatment failure and switching them to second-line regimens (WHO, 2015a). These key indicators have been used to track the performance of ART programs both at country level, and globally.

Ethiopia is one of the countries which has been utilizing these indicators to monitor and evaluate the performance of its ART program over the past decade (Assefa et al., 2010; Federal HIV/AIDS Prevention and Control Office, 2013a). A user-fee-based ART program, officially started in the country in 2003; and replaced with a free national ART program in 2005 with support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), President's Emergency Program for AIDS Relief (PEPFAR), and others. ART provision involved public, private-for-profit and private-not profit providers. Task shifting has been utilized as an emergency response to the human resource for health crisis in the country. Nurses and health officers can prescribe ART to both adults and children. However, provision of second line ART is solely the task of medical doctors. This has enabled the rapid expansion of ART in the country (Federal Ministry of Health of Ethiopia, 2010).

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The eligibility criteria for ART have changed in Ethiopia over the past decade. Until 2012: patients with CD4 count less than 200 cells/mm³, or WHO stage 4. In 2012 and 2013: patients with CD4 count less than 350 cells/mm³, or patients with WHO stages 3 or 4. Since 2014: all adults with CD4 counts \leq 500 cells/mm³, adults with active TB disease, hepatitis co-infection, pregnant and lactating women, and children less than 15 years of age. The current ART monitoring guideline recommends viral load testing for all patients after six months on ART and annually then after (Federal Ministry of Health of Ethiopia., 2014). A strategic document was developed to leverage the health system and laboratory strengthening platforms including the specimen referral system with the latest developments in viral load technologies and pricing towards a public health approach to viral load monitoring (Ethiopian Public Health Institute, 2015a).

Second-line treatment was introduced in Ethiopia first in tertiary hospitals in 2005, then later in secondary hospitals in 2007. Second-line regimens are used after failure of first-line regimens, as measured by the patient's CD4 cell count, HIV viral load, or clinical features. Virological failure is defined as plasma viral load above 1,000 copies/ml based on two consecutive viral load measurements after 3 months, with adherence support, after at least six months of starting a new ART regimen (World Health Organization, 2015).

Currently, the country is also planning to further strengthen its response toward ending AIDS by 2030, not least by ensuring 90% of people diagnosed with the virus are commenced on ART in 2020 (Federal HIV/AIDS Prevention and Control Office, 2014). In order to provide evidence toward this renewed ambitious goal, it is now critical to reflect on the lessons learned from a period of scaling up ART in Ethiopia. The objective of this study is to review the performance of the ART program, against globally accepted key performance indicators, in order to enable the country to sustain its successes and identify and improve on weaknesses toward the goal of ending AIDS.

Methods

Setting HIV/AIDS in Ethiopia

The HIV/AIDS epidemic in Ethiopia has passed through various phases from a concentrated epidemic among key populations (such as commercial sex workers), followed by rapid transmission to the general population, to the current phase of declining incidence in which HIV has become endemic (Ethiopian Public Health Institute, 2015a). The current containment and reversal of the epidemic has been possible due to the policies (Federal Democratic Republic of Ethiopia, 1998), strategies (Federal HIV/AIDS Prevention and Control Office, 2010) and implementation guidelines (Federal Ministry of Health of Ethiopia., 2014) which effectively guide the prevention and control efforts over the past two decades (Assefa and Kloos, 2008).

The number of new HIV infections declined from 30,700 in 2005 to 28,500 in 2014. In 2015, it was estimated that a total of 0.72 million people were living with HIV (PLHIV) with 1.22% adult HIV prevalence. Estimates show that HIV in Ethiopia is generalized and heterogeneous; there are regions with high (5.2%) and low (0.7%) prevalence. Oromia region has the highest number (204,000) of PLHIV while Harari has the least (4,700). Three regions (Oromia, Amhara and Addis Ababa) out of the total eleven accounted for 70% of PLHIV in the country. In the young age groups (15–24 years), there were 4,844 female PLHIV (0.055% prevalence) which was more than two times higher than males (with 2,143 PLHIV and 0.024% prevalence). Children aged 0–14 years make up to 12% of all PLHIV (Ethiopian Public Health Institute, 2015c).

Study design

We conducted a review and analysis of routine program data reported from all health facilities to the Federal Ministry of Health and its agencies from 2005 to 2015. These data were used to describe the progress in ART access, utilization, coverage and equity in the country (Ethiopian Public Health Institute, 2015d). Data from two retrospective cohort studies, conducted in a representative sample of health facilities in the country between 2005/6 and 2014/15, were used to assess the timely initiation of ART (based on patients' baseline characteristics) and retention in care after 12 months on ART. These studies used data collected from patient registers, a hybrid of electronic and paper-based patient management, and medical charts. Systematic random sampling technique was used to select individual patient medical charts to collect the data on patient characteristics such as WHO staging and CD4-cell counts.

The outcome variables of interest for our study are: access and utilization, coverage and equity, earlier initiation, retention in care and use of second-line ART. The operational definitions of these variables are based on the WHO standard definitions for monitoring and evaluating performance of ART programs:

Access and utilization: Number of people living with HIV who are receiving and utilizing ART.

Coverage and equity: % of eligible people living with HIV who are receiving ART disaggregated by different demographic characteristics.

Earlier initiation: % of people living with HIV who initiate ART with a CD4 count of $>$ 350 cells/mm³.

Retention in care: Number and % of people on ART who are retained on ART 12 months after initiation.

Use of second-line ART: % of people living with HIV failing on ART and put on second-line ART.

Data analysis

The routine program monitoring data were entered, cleaned and analyzed using Excel. The data from the retrospective cohort studies were entered, cleaned and analyzed using EPI-Info 2005 version 3.3.2 statistical software. Data entry involved two encoders who conducted double data entry. The data were checked for duplicates, consistency and missing values. Patients were de-identified using their unique identification numbers.

Ethical Approval

This study was approved by the scientific and ethical review committee of the Ethiopian Public Health Institute.

Results

The findings of this study are presented using the indicators recommended to monitor and evaluate performance of ART programs: access and utilization, coverage and equity, earlier initiation, retention in care and use of second-line ART.

Access to and utilization of ART

The number of health facilities providing ART increased from 72 in 2005/6 to more than 1,000 in 2014/15. The cumulative number of patients 'ever started' (ES) on ART increased from 47,422 in 2005/6 to 535,069 in 2014/15; this is a more than ten-fold increase over ten years. The cumulative number of patients 'currently on ART' (COA) also increased, from 39,535 in 2005/6 to 375,811 in 2014/15; this is also a more than eight-fold increase over the same period (Figure 1).

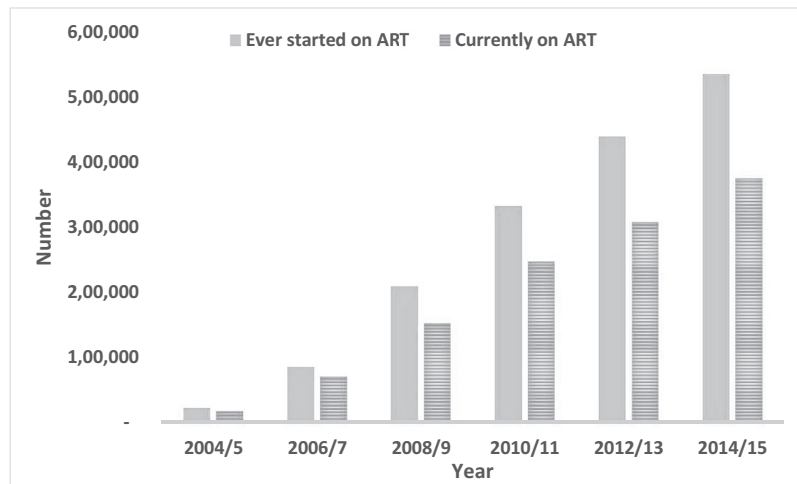


Figure 1. Utilization of antiretroviral treatment in Ethiopia, 2005/6-2014/15.

The number of patients newly initiated on ART annually increased from 39,777 in 2005/6 to 64,500 in 2010/11. However, this dropped to 42,420 in 2014/15, reflecting the declining number of people newly diagnosed with HIV annually. New diagnoses decreased from 175,500 in 2008/9 to 122,850 in 2010/11 and then dropped dramatically to 64,800 in 2014/15 (Figure 2).

Coverage of and Equity for ART

ART coverage, in general, increased in the country between 2005 and 2015. In adults living with HIV, the ART coverage increased from 4% in 2005/6 to 60% in 2014/15. There was also an increasing trend in both female and male patients: from 10% in 2005/6 to 69% in 2014/15 in male patients, and from 0.3% in 2005/6 to 54% in 2014/15 in female patients.

The ART coverage among children also increased from 1% in 2005/6 to 25% in 2014/15 although this clearly lagged behind adult coverage. The number of pregnant and breast-feeding women living with the virus who were taking ART increased markedly from 3,967 (5.3% coverage) in 2006/7 to 20,099 (71% coverage) in 2014/15 (Table 1).

However, there were significant regional disparities in ART coverage: from 5.6% in Somali (with 31,500 PLHIV) to 93% in Harari (with 4,700 PLHIV). Even among regions with larger populations, ART coverage was 63% in Amhara (with 181,500 PLHIV) while it was 43% in Oromia (with 204,000 PLHIV) (Figure 3).

Early initiation of patients on ART

Patients have been initiated on ART more promptly following diagnosis. The median CD4 count/mm³ at the time of ART initiation has increased from 125 (interquartile range (IQR)=68–189) cells in 2005/6 to 231, IQR=186–286 cells in 2012/13 (Figure 4). The percentage of patients with WHO stage I/II at the time of ART initiation has also increased from 15% in 2005/6 to 53% in 2012/13. The proportion of patients with CD4 count more than 350 cells/mm³ at initiation increased from 15% in 2012/13 to 34% in 2014/15.

Patient retention in care

The percentage of patients retained after 12 months on ART increased from 82% (81%–83%) in the 2006/7 cohort to 92% (88%–93%) in the 2014/15 cohort (Table 2). However, there was a variability in retention in care across health facilities (from 67% to 100%), and across regions (from 83% to 94%). This variability in retention in care across regions (83%–94%) is narrower than the variability observed in ART coverage (5.62%–93.28%). Regions with high ART coverage may or may not have high retention in care: Harari region had the highest ART coverage (93.28%) and very high retention rate (91%), while Somali region had the lowest ART coverage and retention in care. SNNP region had very low ART coverage, but very high retention rate.

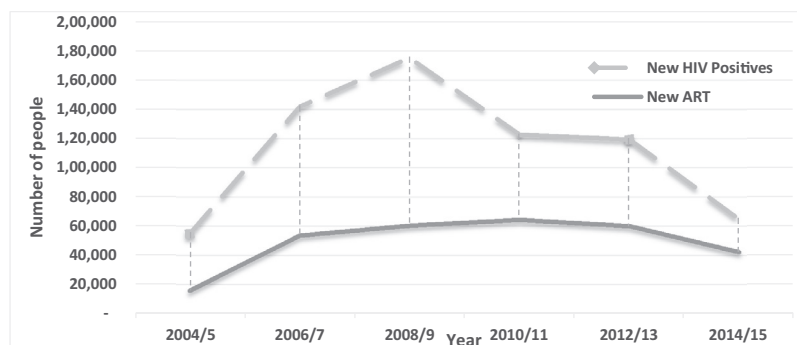


Figure 2. Number of people diagnosed with HIV and initiated on ART every year in Ethiopia, 2004/5-2014/15.

Table 1
Antiretroviral treatment coverage in people living with HIV in Ethiopia, 2005/6–2014/15.

Population group	2005/6		2007/8		2009/10		2011/12		2013/14		2014/15	
	Number of PLHIV	ART coverage	Number of PLHIV	ART coverage	Number of PLHIV	ART coverage	Number of PLHIV	ART coverage	Number of PLHIV	ART coverage	Number of PLHIV	ART coverage
Male adult	313,660	10%	283,885	28%	272,276	35%	272,924	47%	278,631	62%	278,863	69%
Female adult	484,419	0.3%	439,375	6%	422,545	25%	425,326	35%	436,136	49%	445,457	54%
Children <15yrs (%)	90,647	1.1%	76,132	14.1%	68,423	17.3%	63,210	20.1%	59,447	22%	57,946	25%
Pregnant and lactating woman	30,831	5.3%	28,091	16%	26,335	25%	25,891	45%	25,841	64%	25,931	71%

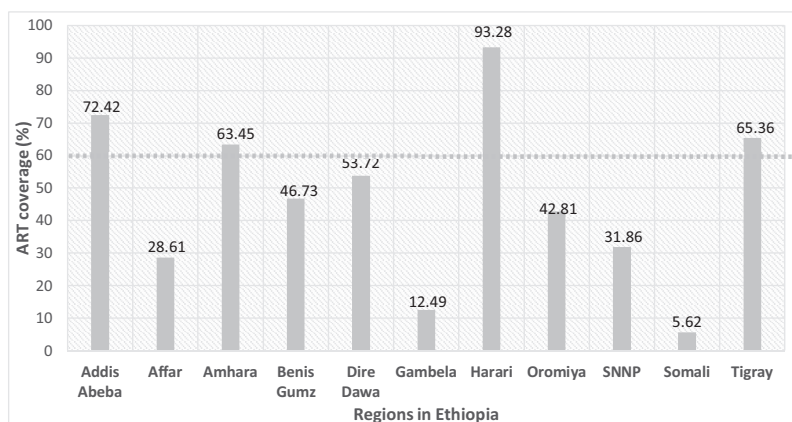


Figure 3. ART coverage among eligible adults (15+ years) in eleven regions in Ethiopia, 2014/15.

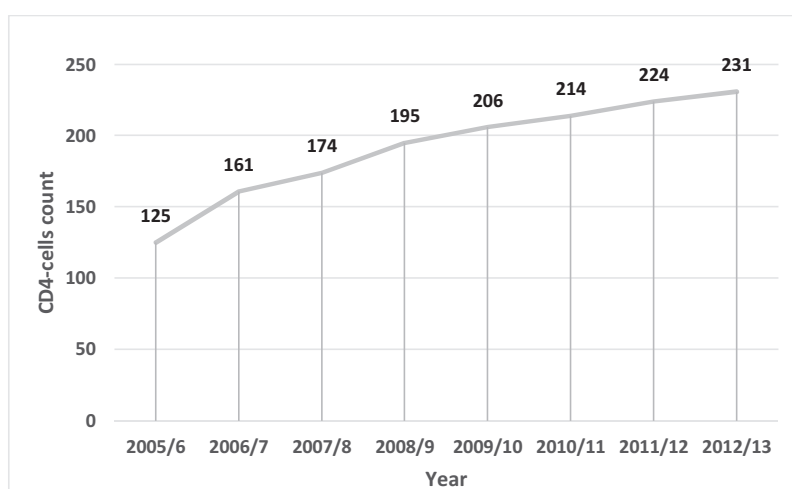


Figure 4. Baseline median CD4 count of patients initiated on ART in Ethiopia, 2005/6–2012/13.

The number of annual AIDS deaths dropped dramatically by more than 75% from 73,000 in 2005/6 to 20,500 in 2014/15. Over 80% (15,600) of the PLHIVs deaths in 2014/15 occurred among those not on ART. AIDS related deaths in children also decreased by more than 60% from 11,600 in 2005/6 to 4,200 in 2014/15.

Table 2
Retention rates in the ART program in Ethiopia, 2006/7–2014/15.

Year	12-month retention rate	Adult ART coverage
2006/7	82%	9%
2008/9	84%	22%
2010/11	86%	35%
2012/13	88%	47%
2014/15	92%	60%

Shift to second-line treatment

The shift to second-line ART has been slow and remains low over the period analyzed. Despite high numbers of patients on ART for over 10 years (Figure 1), only 1.5% of the patients on ART have been transitioned to second-line treatment. The shift to second-line ART in 11 tertiary and secondary level hospitals was only 0.58% after 12 months on ART in 2013/14.

Discussion

In this study, we found that the ART program in Ethiopia has been successful over many critical indicators: (1) the trajectory of increasing ART coverage; (2) the progressive improvement in

retention in care; and (3) earlier initiation of patients on ART over time. However, there are also gaps: (1) the ART scale up has not been equitable among regions, between adults and children, and between male and female patients; (2) the retention rate is variable among regions; and, (3) the shift to second-line ART has been slower and lower than forecasted.

Ethiopia's success in increasing ART coverage has been in line with the global trend. By the end of 2015, globally, 17 million PLHIV were accessing ART, up from 0.4 million in 2003 (UNAIDS, 2016). This has been possible due to leadership commitment, community mobilization, partnership, increased funding and innovations (WHO, 2014). The public health approach for ART delivery (Gilks et al., 2006), and investments on health system strengthening have enabled ART scale up in Ethiopia. Provision of care and support services has, likewise, contributed to increased utilization of ART (Assefa et al., 2014a).

Ethiopia, along the same lines, demonstrated a marked improvement in scaling up ART for PMTCT: 71% of pregnant and lactating women living with HIV were on ART in 2015 (Table 1). This has been possible due to a number of system-wide and program-specific interventions including improving services for maternal and child health, integrating ART service delivery with maternal health services, strengthening health systems, and engaging the community and mothers living with the virus in services provision in areas such as treatment literacy, and care and support (Federal Ministry of Health, 2015a).

ART coverage of children (25%) in Ethiopia lags behind that of adults (60%) (Table 1). In a recent ART program review in Ethiopia (unpublished data), several factors affect ART provision in children. These problems also have been identified in many other studies: (1) the delay in early infant diagnosis, (2) the inadequate provider-initiated testing and counseling, (3) the challenges in linking children diagnosed with HIV to care, and (4) continued emphasis on specialized and centralized models of care (WHO, UNICEF and UNAIDS, 2013). If the target of putting 90% of children on ART is to be achieved by 2020, the Ethiopian ART program needs to decentralize testing for children, as with adults, raising clinicians' awareness of HIV in infants and urgently prioritizing neonates at risk of maternal transmission, and linking those diagnosed to care.

ART coverage was also not equitable across regions (Figure 3). This is thought to be due to gaps related to health systems and community factors which lead to lower access to and utilization of services, and higher stigma associated with HIV in regions with lower ART coverage (Ethiopian Public Health Institute, 2014; Central Statistical Agency, 2012). Regions with better ART coverage have often recognized that HIV is their public health problem and have an enabling environment (such as leadership commitment, community participation and better health systems capacity) which supports access to and utilization of services (UNAIDS, 2016). Positive deviance studies on the strategies to improve retention in care in the Ethiopian ART program, which has been challenged by inadequate and heterogeneous retention in care, have shown the effectiveness of matching successful clinics to those not performing as well, resulting in overall improvement in performance (Assefa et al., 2014b). Scaling this up to a district and regional level through the national ART program would provide necessary additional support mechanisms, tested locally, to capacitate regions lagging behind the national average.

The number of people initiated annually on ART decreased after 2010/11 (Figure 2). This was due to the declining number of people diagnosed with HIV annually (Figure 2), even though the number of people tested for HIV annually was stable. This might be due to the reversal of the epidemic in the country, or the lack of focus on key populations. Nonetheless, it is imperative that the program has greater focus on key populations, and ensures that these

populations are tested for HIV and linked to care and treatment facilities. Moreover, it is necessary to strengthen pre-ART care.

Patients have been initiated on ART earlier over time (Figure 4). This is an improvement that follows greater uptake of HIV tests and strengthened links between HIV diagnosis and ART initiation. This may also be due to the changes in thresholds at which ART is offered: it increased from below 200 in 2005–2012 to below 500 since 2014 (Federal Ministry of Health of Ethiopia, 2014). There is, in general, a clear and generalized shift toward initiating ART earlier in LMICs (IeDEA and ART Cohort Collaborations et al., 2014). Nevertheless, the ART program in Ethiopia should still identify mechanisms to initiate patients on ART much earlier, as patients are still initiated on ART at a very low CD4 count.

Retention in care, after 12 months on ART, improved significantly in Ethiopia (Table 2). Decentralization and interventions, including patient education, self-management, care and support services and case management, are effective in improving retention in Ethiopia (Federal HIV/AIDS Prevention and Control Office, 2013b; Brennan et al., 2014). Approaches such as reducing number of clinic visits, shortening waiting times at clinics, using point-of-care CD4 testing, and providing supplementary services, also contribute to improved retention (Govindasamy et al., 2012). While retention in care is variable (83%–94%) across regions in Ethiopia, regions with high retention are not necessarily those with high ART coverage. It is thus important that regions design context-specific interventions that support ART scale up and/or retention in care, and harnessing the experience of successful regions will facilitate this.

The shift to second-line ART has been slow, and patients on second-line ART accounted for only 1.5% of all patients on ART in Ethiopia. The global estimate shows that 5% of adult patients are on second-line ART (Stover and Adesina, 2015). In Ethiopia, after 12 months on ART, only 0.58% of patients are transitioned to second-line ART, reflecting lower levels of viral load testing. Moreover, evidence from a cohort study in seven University teaching hospitals in Ethiopia shows that 7.3% of patients on ART failed on their first-line regimens after 12 months on ART (Fekade et al., 2017). In sub-Saharan Africa, the number of patients on second-line ART is expected to increase with the roll-out of routine viral load monitoring (Lecher et al., 2015). The provision of second-line ART is currently limited to tertiary and secondary hospitals, and this may contribute to the low proportion of patients on second-line ART. The ART program in Ethiopia is scaling up viral load testing services following the WHO recommendation (WHO, 2015b). It is estimated that this will incur the country around \$13 million per year (Ethiopian Public Health Institute, 2015b). This, therefore, requires strategic planning and financing so that routine viral load monitoring will not be at the expense of putting a greater proportion of patients on first-line ART.

In general, the ART scale up in Ethiopia has been possible with improved financing and human resources for health (HRH). The funding for HIV/AIDS increased over time: \$207 million in 2006/7, \$307 million in 2010/11 and \$329 million in 2014/15. More than 86% of this was from PEPFAR and the Global Fund. It is estimated that \$1.4 billion will be required between 2016 and 2020. However, the support from PEPFAR is declining from \$200 million in 2015 to \$104 million in 2020 (FMOH, 2014; Federal Ministry of Health, 2015b). It is thus important that the program sustains the gains achieved through a resource mobilisation strategy (that helps to mobilize resource from both domestic and international resources) towards predictable and increased financing and efficient approaches which improve 'value for money'.

The response to the HRH crisis in Ethiopia has also been fundamental in scaling up ART since 2006. Initially, 'task shifting' was utilized as an emergency response (Federal HIV/AIDS Prevention and Control Office, 2007); and, later, in 2009, the

Ministry of Health developed a comprehensive strategy for HRH which has brought an increase in the HRH density from 0.84 to 1.3 per 1,000 population between 2008 and 2013 (Banteyerga et al., 2010). The HRH density will be more than 2.3 per 1,000 population in 2020 (Federal Ministry of Health, 2010). It is estimated that 12 full-time equivalent (FTE) health workers (defined according to WHO as all people engaged in actions whose primary intent is to enhance health) (World Health Organization, 2006) are required for 1,000 patients on ART in Ethiopia currently (Tagar et al., 2014). It is thus projected that the country requires around 7,640 FTE health workers to provide ART for the 636,638 eligible patients in 2020. We think that task shifting and increased production of HRH will enable the country to achieve this target for ART toward ending AIDS provided that there is also commitment to retain and motivate the HRH.

This study has both strengths and limitations. The strengths are that (1) it is based on data from a real life situation of a large scale ART program; (2) it looks at the different aspects of the ART program (coverage, equity, timely initiation, retention in care and shift to second-line ART). The limitations are that (1) the routine program data may lack quality because of inadequate documentation. However, this is not systematic (the types of missing data are not uniform across health facilities and over time) to affect the conclusions; (2) the study did not assess the performance of the ART program for adolescents due to lack of data; and (3) the study did not assess retention in care comparing adults with children, and male with female. We thus recommend future research to evaluate the ART program systematically along the treatment cascade from testing to viral suppression comparing different population groups.

In conclusion, the success of the ART program in Ethiopia needs to be sustained, through its public health approach, health systems strengthening, community engagement, partnership and financing, to enhance HIV testing and ART delivery. But, critical to this is addressing the weaknesses, systematically analyzing the treatment cascade (from testing to viral suppression) to further pinpoint critical gaps, and initiating appropriate solutions. Such work needs to advance as requisite toward the goal of ending AIDS as a public health concern in the country.

Research in context

Evidence before this study

We searched the PubMed database to March 31st 2016 to identify publications in the English language on performance of ART programs. We used “HIV” or “AIDS” with the following key words: performance; ending; fast-track; antiretroviral treatment; cascade; and, indicators. There were few studies (none from Ethiopia) which assessed the performance of national ART programs, using a comprehensive list of indicators to identify successes and weaknesses that can be lessons for ending the AIDS epidemic. The performance of ART programs is, in general, measured by a number of key indicators: access, coverage, equity, timely initiation, retention in care and second-line ART. Ethiopia is one of the countries using these indicators to monitor and evaluate its ART program. By the end of 2015, close to 17 million people were taking ART globally. Based on lessons from the past decade, global leaders have agreed on the fast-track (90-90-90) targets by 2020 toward ending AIDS by 2030.

Added value of this study

The added value of this study is that it identifies successes (increasing ART coverage and retention in care and earlier initiation of patients on ART) and weaknesses (inequitable ART

coverage across regions, gender and age-groups, low proportion of patients on second-line ART) of the ART program in Ethiopia. These findings will help the country to prioritize its interventions to sustain the strengths and improve on the weaknesses toward the fast-track targets and the goal of ending AIDS.

Implications of all the available evidence

The evidence from this study has implications for practice: the public health approach, including task shifting and decentralization, has been utilized and needs to be further employed toward the fast-track targets. It has policy implications: health systems strengthening, financing, and retention of health workers need due attention if the country is to achieve the fast-track targets. The study also has implications for future research: analysis of the treatment cascade (from testing to viral suppression) in order to pinpoint critical gaps and identify appropriate solutions.

Competing interests

The authors declare that they have no competing interests.

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