Elizabeth Glaser Pediatric AIDS Foundation

Until no child has AIDS.

HABA NA HABA

TECHNICAL BULLETIN ▪ JUNE 2016

TREATMENT FOR ALL

Cover photo: Robert Haydock/EGPAF, 2016
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Welcome to *Haba Na Haba*!

This publication provides a dynamic forum for the routine sharing of technical information and promising practices with our fellow colleagues and extended family of partners and like-minded organizations around the world. Each issue of Haba Na Haba highlights a topic of particular importance to the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF). The highlighted topic for this issue is Treatment for All.

What Does *Haba Na Haba* Mean?

The name of the bulletin, *Haba Na Haba* ("little by little"), is burrowed from the Swahili proverb *haba na haba, hujaza kibaba* ("little by little fills the pot") and was chosen to reflect the often incremental nature of progress in our field. As the experiences described on the following pages demonstrate, the smaller efforts of every one of us are the essential "ingredients" for mounting a strong and united global response to HIV and AIDS.

Feedback is welcomed from all readers, and contributions are accepted from all EGPAF staff. Please send your questions, comments, or content submissions to techbulletin@pedaids.org.

FEATURE ARTICLE

Treatment for All

Photo: Robert Haydock/EGPAF, 2016

Movement toward elimination of HIV and AIDS has entailed ceaseless clinical and operations research coupled with implementation of innovative health programs. The global health community strives to implement breakthroughs in the field of HIV and AIDS to eliminate the epidemic: scale-up of combination drug treatment regimens, enhanced prophylaxis, antiretroviral treatment (ART) initiation among those with more advanced disease progression, longer-course regimens of ART to enhance effectiveness, treatment as prevention, and so on. All of these breakthroughs, combined with large-scale operations research, have brought us to where we are today. We now know that immediate initiation of lifelong ART among all people who test positive for HIV, regardless of their level of disease progression, is beneficial for both individuals and populations. Following strong supportive evidence from large-scale studies, such as START, TEMPRANO, and HPTN 052, in 2015 the World Health Organization (WHO) recommended initiation of ART among all people living with HIV, regardless of CD4 count (an approach known as Treatment for All).[1-4] These guidelines are the first ever to recommend all HIV-positive persons have immediate access to lifelong treatment and the first to underscore the removal of all barriers to treatment initiation. Treatment for All represents an enormous shift toward the goal of globally ending HIV and AIDS.

Support to implement this all-inclusive treatment approach will give the global health community a powerful tool needed to close in on the ambitious United Nations targets, released in 2014, calling for 90% of all people living with HIV to know their status, 90% of all people with diagnosed HIV infection to receive sustained ART, and 90% of all people receiving ART to have achieved viral suppression by 2020 (the so-called 90-90-90 targets).[5] This tool is quite surely needed by HIV and AIDS program implementers, since to date only 54% of people living with HIV are aware of their HIV status, and only 41% of adults and 32% of children diagnosed with HIV are on ART.[6] Globally, we are far from realizing the full benefits of ART.

The 2015 WHO recommendations empower the global health community to ensure a lifetime of care and treatment among all those infected with HIV. The true effects of this guidance will be realized only through strong and sustainable health program implementation. In this issue of Haba Na Haba, EGPAF explores the global status of ART implementation, what is needed in order to realize the full benefit of Treatment for All, and shares early promising practices from supported countries.

WHERE WE ARE NOW

HIV Testing

The gap between those who are infected with HIV and those who are actually diagnosed is one of the largest within the HIV care and treatment continuum (HIV testing coverage is only 51%).[6] To reach the first of the 90-90-90 goals, we must improve the yield of HIV testing while addressing the norms and preferences of the communities in which we work. Studies examining HIV testing in high-prevalence communities have shown that 80% of individuals accepted testing, and of patients diagnosed HIV-positive, 80% were linked to care and 74% initiated on ART.[6] The increase of testing coverage and subsequent uptake of ART resulted in reductions in HIV incidence.[7]

To increase the yield of testing, HIV testing must meet patients where they are. For example, men do not access HIV testing as often as women—perhaps because women are in more frequent contact with health settings through pregnancy, labor, delivery, and child-rearing. Innovative strategies to make testing accessible to men (such as workplace testing and male community dialogues with HIV testing offered) are needed to close this gender gap. An example of improving male testing uptake from our work, is available on page 24.

Additionally, testing of HIV-exposed infants, children and adolescents is far from optimal with conventional HIV testing. Innovative strategies, such as scale-up of point-of-care (POC) early infant HIV diagnosis (EID) technology, integration of HIV testing with other childhood health services (e.g., immunization, growth monitoring), HIV self-testing, adolescent education and support group networks may ensure a greater HIV testing yield. Examples of activities which have created greater access to HIV testing among children, can be found on page 14.

HIV Treatment Initiation

We know that a significant number of patients (32%–54%) are lost to follow-up during the pre-ART phase, a period in which a person has been diagnosed, is perhaps coming to terms with his or her disease status, is in counseling to understand HIV and its treatment, and may be in the process of referral to a treatment center (if tested at a facility not accredited to offer ART).[8] Evidence shows that rapid initiation of ART, including same-day initiation, results in good clinical outcomes.[8] This approach has also been shown to increase virologic suppression at the population level because it decreases the number of patients lost to follow-up.[8] Informed by this evidence, Treatment for All recommends initiating treatment for all infected people as soon as they are diagnosed.[4]

Decentralization of ART to facilities beyond exclusive treatment centers and task shifting of ART initiation to other cadres of the health workplace (nurses and trained lay staff) create more opportunities for people to be tested and initiated on ART in a variety of health settings.[9] Clinicians in most resource-limited settings are few in number, high in demand,

and desperately overburdened, unable to ensure testing and treatment of every client they meet. Nurse-initiated and -managed ART has been shown to be at least as effective at achieving undetectable viral load and reducing mortality as standard clinician-initiated ART care.[10 11 12] Examples of increasing access to HIV testing and treatment through task-shifting in Lesotho and Malawi are described in this issue (beginning on page 12).

Viral Suppression

It is important to ensure countries are collecting viral load diagnostic results routinely from patients enrolled on ART. Routine monitoring of viral loads in HIV-positive patients helps to ensure all exposed to treatment are receiving its full benefit (an example of how routine viral load monitoring has led Kenya to understand viral suppression levels and how to encourage greater viral suppression in certain populations is available on page 21).

Focused methods of technical support, leadership, and accountability, which together promote high levels of adherence to and retention on ART, will be required in order to reach the third of the 90-90-90 goals. Reducing time between HIV diagnosis and ART initiation has helped increase retention.[13 14] New data show that same-day initiation results in even higher retention.[15] Home visits by community health workers soon after ART initiation can help decrease early loss to follow-up after ART initiation.[16] Drug refill reminders sent via SMS to cell phones result in significantly higher adherence for patients on ART.[17]

Models that decentralize or task shift ART continuation, such as community ART distribution points or community adherence support groups, also achieve levels of retention in care and viral load suppression as least as high as those achieved under facility-based care (examples of how community-based initiatives have improved ART adherence in Zimbabwe and the Democratic Republic of the Congo can be found on pages 25 and 35, respectively).[9 18 19 20] Pediatric patients do well in decentralized care models, with one cohort study of community- versus facility-based care showing no significant difference in survival rates between the two models and better retention under community-based than facility-based care (94.8% versus 84.7%) in Uganda.[21]

TREATMENT FOR ALL: TOOLS FOR SUCCESS

To save the most lives and maximally improve the health of people living with HIV/AIDS, we must diagnose individuals as early as possible, initiate treatment promptly, achieve and sustain virologic suppression, and retain individuals on treatment throughout their lives. To reach these goals, there is an urgent need to reengineer the operational agenda. As global health providers, we need to take stock of and learn from previous experience in order to understand what tools, strategies, and policies can successfully support the Treatment for All approach.

To date, several models that will guide us toward successful implementation of Treatment for All have emerged. Starting in 2003, the government of British Columbia, Canada, has used an approach known as Seek and Treat for Optimal Prevention of HIV/AIDS (STOP HIV/AIDS), which aims to expand testing and increase timely access to ART for all those living with HIV or AIDS. Since its launch, STOP HIV/AIDS has

TIMELINE - The Evolution of World Health Organization Guidelines Related to the Work of EGPAF

1987

- HIV treatment era begins.

1994

- AIDS Clinical Trials Group Study 076 (ACTG 076) finds that zidovudine (AZT)—when given to HIV-positive pregnant women starting at 14 weeks' gestation, intravenously in labor, and for six weeks postnatally to infants—reduced mother-to-child HIV transmission risk in nonbreastfeeding populations by 67.5%.[29] The WHO holds a meeting on ACTG 076, concluding that the best approach is to start randomized controlled trials of shorter and simpler regimens of AZT.
- AZT for prevention of mother-to-child HIV transmission (PMTCT) is rapidly introduced with considerable success in industrialized countries.

2000

- A study titled HIVNET 012 in Uganda demonstrates that a single dose of nevirapine (NVP) given to an HIV-positive mother at the onset of labor and to the infant within 72 hours of birth was effective in reducing HIV transmission risk by 47% at six weeks of age.[30]
- The WHO launches its 2000 guidelines. Recommended regimens include single-dose nevirapine single-dose NVP, AZT, or AZT + lamivudine (3TC) at the onset of labor, plus a single dose of NVP for the infant soon after birth.

demonstrated a marked and steady decrease in AIDS-related morbidity, and mortality.[22] Similar trends in HIV-related morbidity and mortality were seen when San Francisco General Hospital and the University of California, San Francisco, implemented the RAPID program (Rapid Antiretroviral Program Initiative for New Diagnoses), which offers immediate access to ART on the same day as HIV diagnosis and provides strategies to encourage retention in care. This program demonstrated a high quality of care, doubling the number of patients achieving virologic suppression.[23] Programs from resource-limited settings are demonstrating comparable results, with decreases in HIV incidence following increased and earlier ART initiation, and high levels of adherence even among asymptomatic patients and those with higher CD4 counts (a measurement of disease status in HIV-positive patients).[7-24]

Though it covers HIV-positive pregnant women exclusively, Option B+ represents an example of recommended universal, lifelong ART initiation in a specific population. EGPAF has led the way in supporting Option B+ programs and since 2011 has helped to roll out this approach in 12 countries (examples of our approaches toward implementation of Option B+ in Malawi, Lesotho, and Swaziland can be found in the Country Notes section of this issue).[28] Through implementation of Option B+, EGPAF has helped to demonstrate that initiation of ART for all patients, regardless of CD4 count, is feasible and effective in resource-constrained settings. This experience has underscored that clients enrolled in our programs are not always diagnosed early enough and a significant number of patients do not remain in care. For example, in Malawi, only 74% of women on ART (excluding those who transferred out) were retained in care after 12 months (see page 16).[25] Although progress has been made toward alleviating barriers to testing, counseling, and treatment, particularly through Option B+ in EGPAF-supported countries, there is still work to do to ensure that we are providing early, high-quality, and sustainable HIV diagnosis and treatment for all. We have an obligation to focus now on our implementation experience in order to expand HIV testing, care and treatment as well as promising strategies to enable the success of Treatment for All.

Differentiated Care Packages to Reach Treatment for All

We must develop models of care that expand access to and uptake of a comprehensive package of HIV services (including HIV testing, care and treatment) while also improving efficiencies, operating within a resource-limited environment. Implementation of differentiated care models may be an ingredient for success in the Treatment for All approach. Differentiated care models aim to put the patient at the center of care, deliver comprehensive care matched to patient needs while recognizing resource constraints, and still striving for efficiency and quality. These models examine and restructure the type and intensity of care that different groups of patients receive in the context of a comprehensive framework that also includes policy changes, health systems strengthening components, demand and financial forecasting among other enabling factors.[26]

For example, patients who are stable on ART may do well with a reduced frequency of clinical visits or laboratory monitoring. Thus, these patients are able to reduce the time they spend traveling to clinics and waiting for their appointments. Models of differentiated HIV

- Upon WHO urging, treatment is scaled up to all persons with advanced disease progression or clinical AIDS in resource-limited countries.

2002-2003

2004

- Study titled Perinatal HIV Prevention Clinical Trial–2 (PHPT-2) demonstrates an 80% reduction in mother-to-child HIV transmission when sd-NVP is added to the standard AZT regimen (starting at 28 weeks' gestation). AZT + sd-NVP becomes the new PMTCT standard.[31]
- WHO releases 2004 guidelines urging countries to consider expanding their program regimens from sd-NVP to more effective dual-antiretroviral (dual-ARV) regimens.

2006

- WHO recommends combination of ARVs for more effective prophylaxis from 28 weeks' gestation through early postpartum for women with a low CD4 count.
- WHO expands guidelines, recommending lifelong ART among HIV-positive pregnant women with a CD4 count of 200 cells/mm^3 or lower.

service delivery that simplify and streamline care for stable patients have shown outcomes equal to or better than those achieved through standard care while at the same time reducing out-of-pocket costs for patients and saving health system resources.[26] This approach will help overburdened health systems to sustain management of current patients, and manage those who are not stable, while also accelerating intake of new patients (and many more new patients will be eligible for treatment under Treatment for All). Through practices such as spacing appointments, creating greater efficiency in adherence counseling sessions, and decentralizing stable patients, health care workers can gain time that may be applied to better meet the needs of those who are unstable.

Non-adherent patients may also require a different approach that involves bringing HIV care and treatment closer to their homes and communities. Non-adherence is very often the result of significant barriers, such as travel to clinics or getting time away from work to attend appointments. For these patients, community-based drug delivery points combined with more frequent monitoring and support provided at the community level by lay health workers may be appropriate interventions.

Care may be differentiated based on clinical status or viral load, but it can also be differentiated on the basis of demographic factors such as age. This is particularly pertinent for pediatric and adolescent populations because different age groups within the first 18 years of life experience different levels of risk of failure (see page 25). For example, children up to age five have high rates of treatment failure, morbidity, and mortality, while primary school–aged children have somewhat lower risks of failure and may be considered for more decentralized or community-based care.[27]

Just as differentiated care represents a move away from a one-size-fits-all approach for patient care, there is no one-size-fits-all approach to differentiated care for all settings. Each country must consider its specific context, resources and gaps, demographics, and epidemiologic trends to inform the design and implement models of differentiated care.

EGPAF, which operates in 19 countries, has made it an organization-wide priority to develop and implement models of differentiated care tailored to the context of each supported country. While these models may resemble the example in Figure 1, they will need to be adapted to different contexts. In developing and rolling out these differentiated packages of testing, care and treatment, it will be important to (1) ensure that needed policy changes are in place, resources available, and health systems strengthened to absorb the increased number of people in need of ART per the new treatment paradigm, enabling introduction and scale-up of differentiated models of care; (2) monitor these models and evaluate their impact at the patient and health system levels; (3) evaluate and describe novel approaches and successful practices that may be of use to other program implementers to ensure we are guiding forward movement toward UNAIDS targets; and (4) ensure that effective new tools and strategies are developed and incorporated into the models. A differentiated model of care currently employed by EGPAF is beginning to take shape in Malawi (see page 16).

2008-2009

- Results of the NA-ACCORD study released indicate that earlier initiation of ART among HIV-positive asymptomatic patients leads to improved health outcomes.
- Results of the MITRA and MITRA PLUS (2008), Kesho Bora (2009), and Mma Bana (2009) studies provide overwhelming evidence that ART sustained through breastfeeding substantially reduces risk of mother-to-child transmission, finally providing an effective approach to safer infant feeding for women living with HIV in developing countries.[32-34]
- The 2010 WHO guidelines are released and recommend earlier and extended use of multidrug regimens for PMTCT

2010

- WHO releases revised guidelines for the treatment of adults, pregnant women, infants and adolescents according to a public health approach. The guidelines recommended ART initiation for all persons living HIV, with a CD4 count of ≤350 cells/mm3 and for those with WHO clinical stage 3 or 4 if CD4 testing is not available.

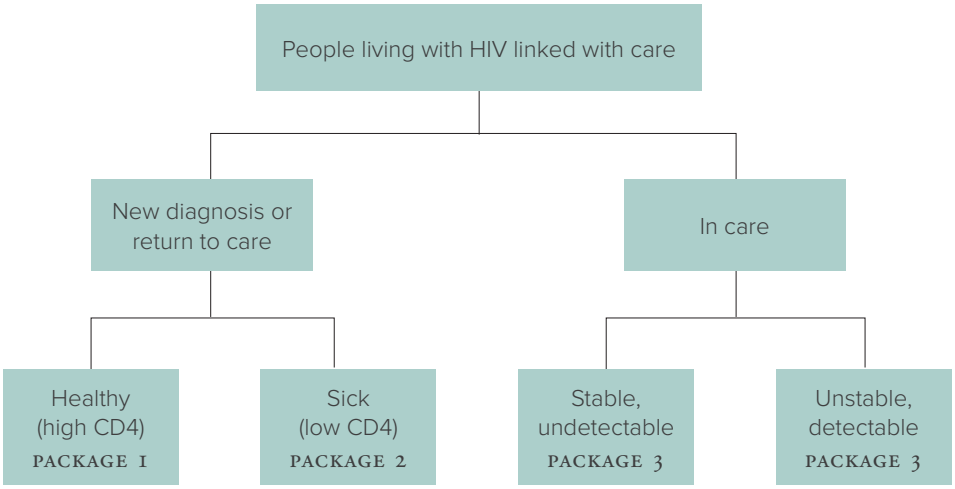

FIGURE 1

Differentiated model of treatment

Looking Ahead

As more people living with HIV are identified early, promptly initiated on treatment, and achieving sustained virologic suppression, the features of the global HIV-positive population will evolve toward a more homogeneous cohort of stable, virologically-suppressed patients. This homogeneity will make possible a simplified approach to managing patients, and a different strategy and treatment approach may be required at that time. While Treatment for All will generate long-term benefits and reduce costs overall, the strategy will initially require increased political commitment and financial capital investments.[25]

To reach the 90-90-90 targets by 2020, it is imperative that countries and operational partners rapidly implement Treatment for All. It is important to document best practices, while simplifying, decentralizing, and streamlining care to improve the rational use of resources for improved case finding and enrollment and to reach treatment success. To virtually end AIDS by 2030, a collective investment has to take place now, using our most effective tools, policies, strategies, and resources to operationalize Treatment for All.

2011

- The HPTN 052 study releases findings that a 96% reduction in risk of sexual transmission of HIV is seen among discordant couples while on ART.[36]

2012

- Based on evidence from HTPN 052 WHO releases guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV.[37]

2013

- WHO introduces Option B+, initiation of ART among all HIV-infected pregnant women throughout pregnancy and breastfeeding and continued for life, regardless of CD4 count.[28]

2015

- Results of the START study are published, revealing immediate initiation of ART was superior to deferral of such therapy until advanced viral load.[1]
- Observing mounting evidence from START and HPTN 052, the WHO releases Treatment for All guidelines, recommending that all people infected with HIV begin ART as soon as possible, and removing all limitations on eligibility for ART among people living with HIV.[4]

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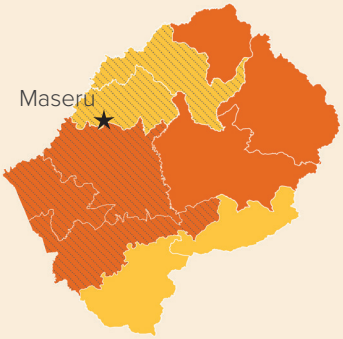
Photo: Eric Bond/EGPAF, 2016

LESOTHO

Lesotho Becomes the First African Country to Adopt Universal "To Adopt Treatment for All"

EGPAF has been a key partner with Lesotho's Ministry of Health (MOH) since 2004. Initially focused primarily on PMTCT services, the program has grown tremendously over the years since inception. With support from the U.S. President's Emergency Fund for AIDS Relief (PEPFAR) through both the United States Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC), EGPAF now supports comprehensive HIV prevention, care, and treatment services at the national, district, and site levels across the country in 10 districts, and serves as the main clinical HIV partner for Lesotho's MOH. Lesotho has become the first African country to adopt Treatment for All.



USAID-funded districts

CDC-funded districts

PEPFAR scale up districts

In Lesotho, 23% of the adult population is living with HIV or AIDS, the second-highest prevalence in the world.[1] An estimated 19,000 children in the country live with HIV, with approximately 33% on ART.[2] Despite significant national investment toward eliminating the HIV/AIDS epidemic, there has been no significant reduction in HIV incidence, and ART coverage has remained suboptimal. Only about 45% of adults and 30% of children living with HIV in Lesotho are currently on ART.[1] In addition, PMTCT coverage among HIV-positive pregnant women is 72%, and EID coverage for HIV-exposed infants hovers at 55%.[1] Poor coverage rates are due to a combination of factors, including lower-than-expected turnout among pregnant women for facility-based antenatal care (ANC) services, delayed presentation for ANC services (only 33% of women visit an ANC facility in the first trimester of their pregnancy), and frequent home deliveries (only 59% of women deliver in a health facility in Lesotho).[1] However, infant immunization rates are high (97% for the first round of vaccines and 95% for the last), suggesting there are missed opportunities for identifying HIV-exposed infants and testing them.[3]

Before implementation of Option B+, a recommendation of the WHO to ensure that all HIV-positive pregnant women access ART regardless of disease status, CD4 testing was a prerequisite for ART initiation in Lesotho. CD4 testing became a bottleneck in the scale-up of ART coverage in Lesotho. National laboratories had limited capacity to process CD4 samples, and the few point-of-care CD4 machines available in the country were undermined by frequent breakdowns. In addition, patients were often required to come back multiple times to access CD4 testing after testing HIV-positive by rapid tests, resulting in high loss to follow-up in the pre-ART period.

In 2015, the WHO announced new HIV treatment guidelines, recommending Treatment for All, which enables all people testing positive for HIV, regardless of CD4 count or clinical stage, to access lifelong ART. Subsequently, EGPAF, a lead technical adviser to the government of Lesotho,

AUTHORS

Esther Tumbare
etumbare@pedaids.org

Ashley Thompson

Mamorapeli Putsoane

David Holtzman

Appolinaire Tiam

immediately began advocating for national adoption of Treatment for All. EGPAF's Lesotho-based leadership worked with the MOH to present evidence in support of Treatment for All and to raise awareness of its advantages as well as strategies to mitigate any challenges in implementing the approach.

MOH leadership saw the potential change in guidelines as a significant opportunity to address the most serious health crisis facing the nation and to help the country reach the ambitious UNAIDS 90-90-90 targets. Because Lesotho was already implementing Option B+ and a test-and-treat approach for children under age five, discordant couples, and patients coinfected with tuberculosis (TB) and HIV, the universal Treatment for All approach was viewed not as a radical paradigm shift, but rather as a newly available, evidence-based tool to increase treatment coverage and improve the life expectancy and health outcomes for all Basotho living with HIV. In short, Treatment for All was seen as a simplification of the treatment algorithm already in place in Lesotho. Fortunately, 2015 drug forecasting for the national HIV program had already been based on 80% population coverage, and the gap in resources needed to implement Treatment for All was not seen as significant.

With technical assistance from EGPAF and financial support from PEPFAR through EGPAF's awards from USAID and the CDC, the national TB/HIV technical working group in Lesotho formed five task teams (clinical; advocacy, communication, and social mobilization; health systems strengthening; and monitoring and evaluation) mandated to adapt the WHO Treatment for All guidelines for use in Lesotho, work that was finished by April 2016.

The prime minister launched the country's Treatment for All guidelines on April 14, 2016, at Senkatana, an ART facility and center of excellence in Lesotho's capital city of Maseru. Parliamentarians, senior government officials, development partners, and members of the public attended the ceremony. In advance of the launch, several staff members of Senkatana were trained on the guidelines (the remainder of staff were trained in the following weeks). Eight patients previously on pre-ART (diagnosed as HIV-positive but with high CD4 counts and thus not yet eligible for ART) were initiated on treatment during the launch. To date, Senkatana has already initiated 57 new patients using the Treatment for All approach.

Lesotho's MOH launches Treatment for All At Senkatana (Photo: EGPAF. 2016)

Training on the new guidelines, led by the MOH with implementing partners, started in April, immediately after the launch, at all ART sites. All ART facilities in the country have implemented the new guidelines as of June 1, 2016. Health care workers of various cadres have been trained, including nurses, doctors, pharmacy technicians, monitoring and evaluation staff, lay counselors, and community health focal persons. Nurses are a particular focus of these trainings because Lesotho encourages nurse-led ART initiation to alleviate highly burdened doctors. Training curricula, developed by the MOH with partner assistance, are tailored to the audience; for example, lay counselors and village health workers get a sensitization that is less technical than the training clinicians receive.

To support the successful implementation of these guidelines, Lesotho has developed a robust community sensitization and demand-generation strategy, which has, to date, targeted health care providers and patients with tailored messaging about the importance of testing and of immediate treatment for those who test positive. The MOH and its implementing partners are also holding meetings with community leaders, such as chiefs, to sensitize these influential individuals to the new guidelines. An alternative treatment initiation package has also been developed for patients who feel healthy and may want to postpone initiating ART.

Several factors enabled the successful launch of the Treatment for All guidelines in Lesotho, including political commitment by the government, support from development partners, and organization of resources and supply chain management fueled by recent implementation of the Option B+ guidelines. Lesotho's groundbreaking accomplishment of being the first sub-Saharan country to take the bold step of adopting Treatment for All will provide an essential learning platform for other countries with a high HIV burden to implement these guidelines in their own settings.

Photo: Heather Mason/EGPAF, 2015

SIDEBAR NO. 1

Provider-initiated HIV testing and counseling in children under five and linkage to care and treatment in Lesotho

AUTHORS

David Holtzman

Ashley Thompson

Florence Mohai

Esther Tumbare

Appolinaire Tiam

Lesotho began implementing Option B+ in 2013. In 2014, the country adopted WHO guidelines recommending treatment for all HIV-positive children under age five. These guidelines were considered key strategies to eliminate mother-to-child HIV transmission and pediatric AIDS. To ensure the success of these strategies, and with funding from the United Nations Children's Fund (UNICEF), EGPAF–Lesotho implemented a project in 2015 to increase the identification of HIV-positive children and to increase the number of identified HIV-positive children to ART by integrating routine provider-initiated HIV testing and counseling services at pediatric care focal points in the country, known as under-five clinics. The project strategy included training village health workers on messaging to mobilize communities in order to increase turnout for under-five services. Services at under-five facilities were strengthened in order to place a greater emphasis on HIV testing and immediate access to care and treatment; these efforts included implementation of a screening tool to assess a child's exposure to HIV and subsequent need for testing; placement of lay counselors at these facilities, equipped to offer HIV testing and counseling; and provision of rapid HIV test kits.

The project saw a significant increase in the number of children brought to project facilities for under-five services and 99% acceptance of testing by children's caregivers (Figure 1). After the initial spike, the gradual decrease in service utilization over time was attributed to possible saturation within communities—the entire population had

been reached, so no new children in need of testing/with unknown HIV status were being identified—and also the scheduling of mobilization activities only at the start of the project and not continuously after its launch.

Out of 7,297 children tested for HIV, 86% were tested with rapid tests and 14% with DNA polymerase chain reaction (PCR) testing, according to their age at the time of testing. Eighty-two HIV-positive children were identified (1.1% of those tested), and of these, 74 (90%) were initiated on ART. Despite intensive follow-up by program staff to obtain and immediately communicate HIV test results, four of the HIV-positive children (9%) died before ART initiation, all four of them under one year old. The caregivers of four other HIV-positive children (9% of those testing positive) refused ART initiation despite intensive counseling.

This project yielded several valuable lessons that can help inform the expansion of Treatment for All policies: (1) a significant number of people still do not know their HIV status; (2) incorporating a routine, simplified assessment of the need for HIV testing services is feasible in busy service delivery settings, such as under-five clinics, and can achieve high testing coverage; (3) increasing and maintaining high testing coverage as well as mobilization efforts are crucial to achieving the first of the 90-90-90 goals; and (4) despite close program monitoring and support for reducing the turnaround time of DNA PCR test results, unreasonably high mortality rates are still observed among infants with HIV between testing and linkage to treatment.

As countries adopt Treatment for All, experiences such as these must be documented and shared with the global community to inform strategies to scale-up and strengthen HIV testing and treatment services and to retain more people in treatment. Programs should emphasize the importance of immediate treatment initiation in HIV-positive young children.

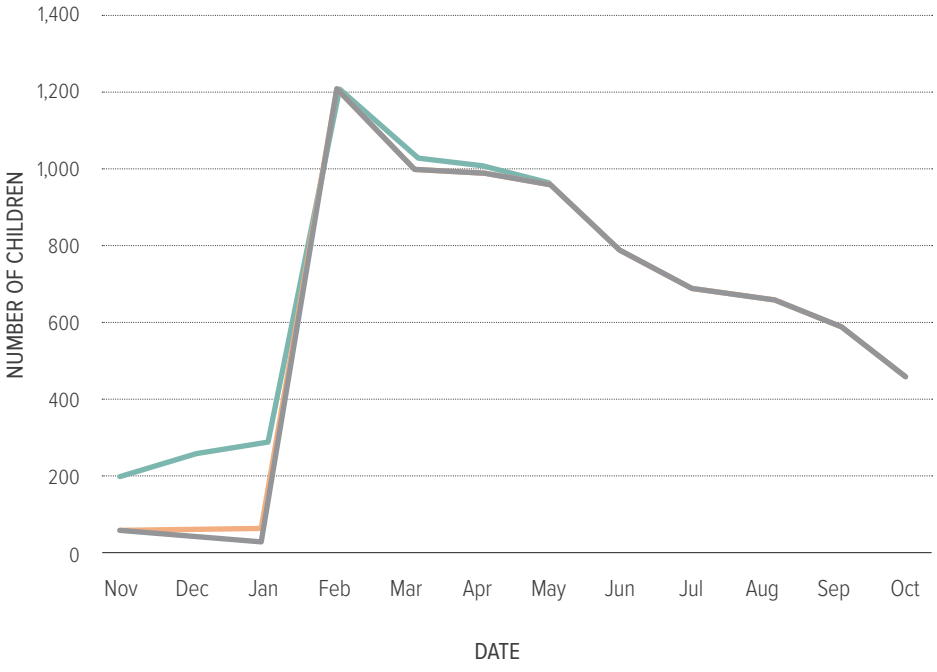


FIGURE 1

Number of children in under-five clinics in the three months before project activities began (November 2014–January 2015) and the nine months after the start-up phase (February–October 2015)[4]

- Children presenting in under five clinics
- Children counselled
- Children tested

MALAWI

Treatment for All in Malawi: Moving Guideline Adaptation to Program Planning

EGPAF began collaborating with local partners in 2001 to initiate one of Malawi's first programs to provide PMTCT services. Currently, EGPAF–Malawi provides technical assistance for adult and pediatric HIV prevention, care and treatment services to more than 150 MOH and faith-based facilities, including 78 priority sites, as well as district-level health teams and community-based organizations.

EGPAF-supported regions

AUTHORS

Isabel Garcia
igarcia@pedaids.org
Chomba Zenengeya
Joseph Njala
Martin Msukwa
Allan Ahimbisibwe
Elizabeth Hamilton

Malawi is among the countries most affected by the HIV epidemic, with an estimated 1 million people living with HIV, including 170,000 children under the age of 15.[5] The UNAIDS 2014 Global Report estimates that there were 34,000 new infections and 48,000 AIDS-related deaths in 2013 in Malawi.[5] Each year, approximately 58,000 HIV-positive women give birth in Malawi, and without treatment, an estimated 17,400 infants will be born with HIV.[6]

In 2015, Malawi released its new 2015–2020 Strategic Plan for HIV and AIDS, which details a clear, comprehensive, and ambitious way forward for the nation to address the HIV epidemic.[7] This plan was informed by the WHO's 2015 Treatment for All guidelines, which recommend immediate ART initiation among all HIV-positive individuals, regardless of CD4 count.

To support the MOH in implementing its plan toward elimination, EGPAF's technical assistance includes participating in the local adaptation of WHO guidelines; developing health worker training materials and tools for monitoring and evaluation; facilitating national training events; providing quarterly supportive supervision to implementing facilities; mentoring clinical and systems personnel at supported sites; supporting task shifting by hiring diagnostic assistants for provider-initiated testing and counseling; and performing service delivery mapping to track and enhance patient flow through health platforms.

The Role of Option B+ Implementation and Its Impact on Treatment for All

As of September 2015, approximately 585,660 patients, 59% of the estimated 1 million people living with HIV/AIDS in Malawi, were on ART. Estimated coverage is 50% for children (under 15 years old) and 68% for adults.[5] Significant reductions in mortality, morbidity, and HIV transmission followed the rapid scale-up of ART between 2004 and 2014.

As part of the national treatment program, in 2011 Malawi started implementing Option B+ (Malawi was the first country to implement these guidelines). This initiative contributed to a 66% reduction in mother-to-child transmission of HIV.[5] Malawi learned some key country-specific lessons that will help to ensure the success of Treatment for All.

Several of the challenges Malawi experienced in implementing Option B+, especially around retention and adherence, may also prove to be continued challenges under the

Treatment for All guidelines. Asymptomatic, stable patients, for instance, may not be ready to start ART: in Malawi, pregnant women who were enrolled on ART through Option B+ but felt healthy were less likely to initiate and be retained on treatment than those who felt sick (postpartum women were more likely to initiate treatment while breastfeeding, women starting ART for their own health were also much more likely to initiate and adhere to treatment). Option B+ was the first experience in treating asymptomatic and stable patients, and the community culture was not prepared for that.

In order to address this barrier, we need to advocate, engage in community sensitization, educate affected communities, and provide individual counseling. In addition, Malawi will need to consider optimal timing of treatment initiation for newly diagnosed patients because not all patients are ready to start on the day of diagnosis. One need will certainly be around patient education: community sensitization and patient foreknowledge of a health policy can affect early acceptance, especially once guidelines change and clients previously ineligible for treatment become eligible. Malawi will also need to develop alternative service delivery models for treatment in order to increase patients' ease of access to ART. In line with this need, the country will develop differentiated models of ART expansion in order to customize service delivery to patient needs.

Through implementation of Option B+, Malawi learned firsthand how providing treatment access to a greater volume of eligible patients can overburden highly specialized health cadres. Therefore, one important need will be to reinforce human resources for health through task shifting, particularly by training more nurses on HIV testing and ART initiation.

Adaptation of Treatment for All

In 2001, the MOH established an ART/PMTCT technical working group (TWG) to review service delivery needs and, more recently, to highlight key issues for the proposed 2016 Malawi Integrated HIV Guidelines. Recently, the TWG convened to discuss several implications of the Treatment for All strategy, including higher costs due to the greater volume of clients receiving ARVs, which may be offset by the cost reductions from eliminating CD4 testing and monitoring, as well as the potential for fewer advanced-disease hospital admissions for HIV-related morbidity. The TWG identified several key priority efforts needed to ensure the success of Treatment for All:

- Enhanced messaging of new guidelines to clients in advance of and throughout implementation to ensure early initiation of and adherence to ART, which includes messaging tailored to asymptomatic patients
- A revised counseling package that includes adherence counseling and tools to prepare children, adolescents, their caregivers, and Option B+ clients for ART initiation
- Creation of ART initiation appointment registers to help facilities manage their workload and track patients' appointment attendance
- Removal of CD4 testing criteria from the recommended HIV testing, care, and treatment cascade
- Discontinuation of pre-ART follow-up requirements
- Continued use of CD4 counts to aid in clinical management
- Drug forecasted by MOH based on the current pre-ART cohort, actual testing rates and ART initiation trends with a 6-month buffer

Conclusion

Malawi has always been an early adopter in its HIV response. It has experience and knowledge of expanded access to ART to offer to the global community. After a comprehensive look at current service delivery challenges and expected benefits, Treatment for All was launched in July 2016 and scaled up throughout Malawi using the body of knowledge developed through Option B+ implementation.

Photo: James Pursey/EGPAF, 2012

MALAWI

Use of Dedicated Lay Providers to Strengthen HIV Testing Services in Malawi

Photo: Robin Wyatt/EGPAF, 2015

Background

Despite Malawi's success in expanding HIV prevention, care, and treatment services, the proportion of people living with HIV who know their HIV status is only 53%,[6] well below the 90% target set in the country's Strategic Plan for HIV and AIDS.[7] To reach the 90% target, Malawi is scaling up provider-initiated counseling and testing and has successfully implemented it at some service delivery points, including ANC settings. However, program monitoring has highlighted the need for more staff dedicated to expanding ART access. To address this challenge, in 2015 Malawi introduced a new lay cadre called HIV diagnostic assistants (HDAs) to focus on provider-initiated testing and counseling, identification of people living with HIV, and linkages to care and treatment.

Description

EGPAF and the MOH collaborated on the requirements, training, accreditation, and remuneration levels for HDAs. With funding from CDC/PEPFAR, EGPAF–Malawi engaged two local organizations, Lighthouse and the Malawi AIDS Counseling and Resource Organization, to recruit, train, and deploy 164 HDAs to 63 priority health facilities in seven districts. The HDAs were deployed between July and September 2015 after undergoing intensive training in HIV testing and counseling. The HDA role complements the work of existing HIV testing and counseling providers in maternity, outpatient, and pediatric departments. EGPAF reviewed routinely collected and aggregated HIV testing data from the MOH for the six-month period prior to and following the introduction of HDAs.

AUTHORS

Meria Million
mmillion@pedaids.org

Kundai Moyo

Martin Msukwa

Joseph Njala

Allan Ahimbisibwe

Elizabeth Hamilton

Nicole Buono

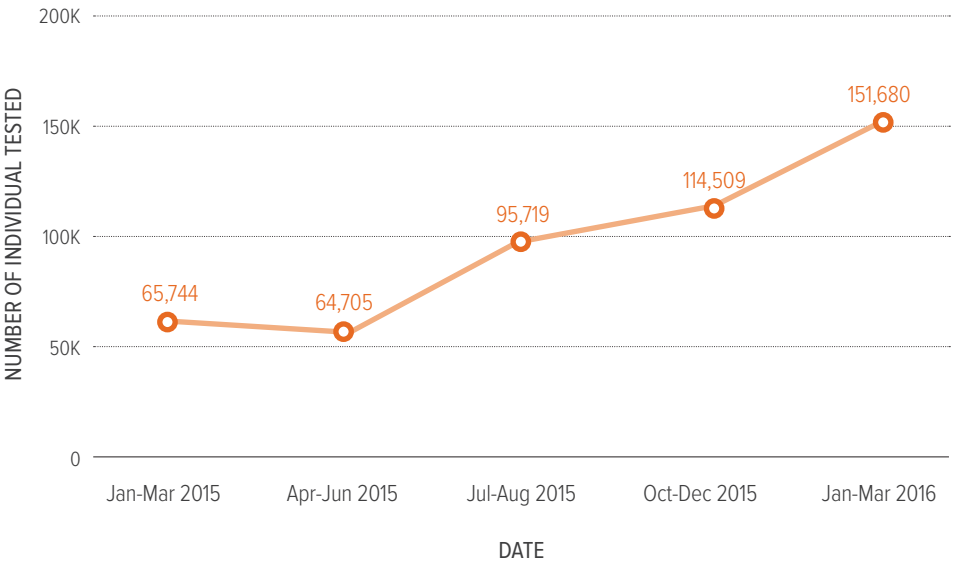


FIGURE 1

HIV testing in individuals in all 63 sites

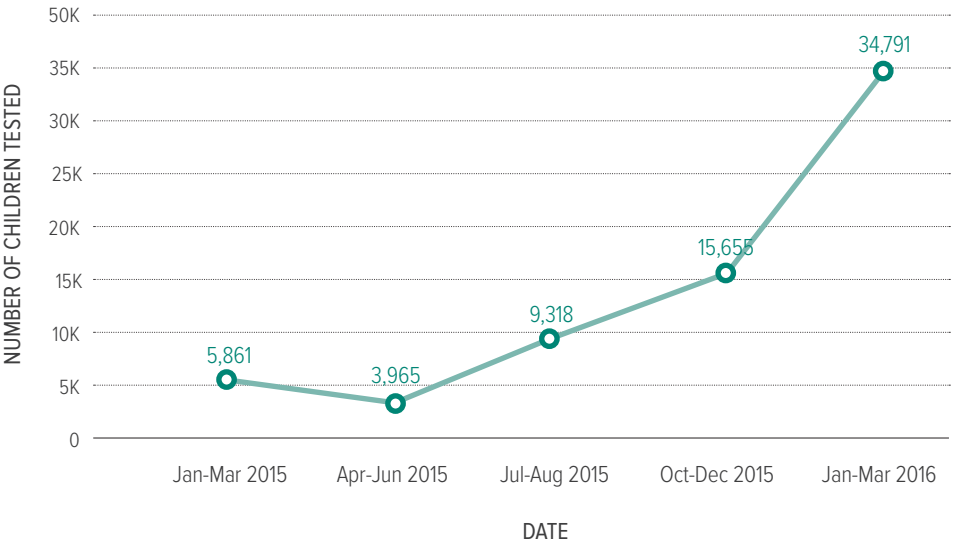


FIGURE 2

HIV testing in children in the 63 sites

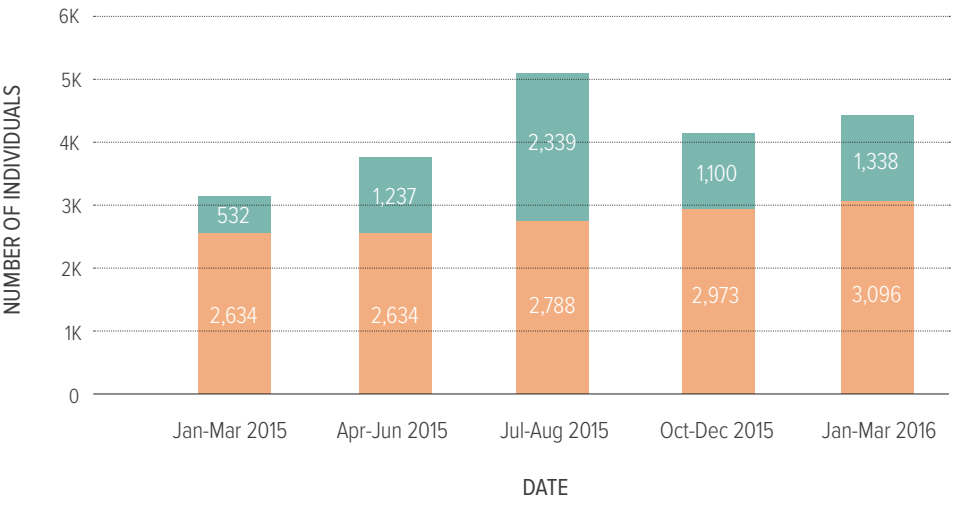


FIGURE 3

Number of HIV-positive individuals identified and linked to ART

Initiated on ART

Not linked to ART

Results

Following the intervention, the number of individuals in the 63 sites tested for HIV increased from 130,449 during January–June 2015 to 210,228 during July–December 2015 (Figure 1). The number of children tested more than doubled, from 9,826 in January–June 2015 to 24,973 in July-December 2015 (Figure 2). As indicated in Figure 3, there was a 31% increase in the number of individuals diagnosed as HIV-positive and a 9.4% increase in those linked to ART. Use of HDAs has increased the availability of data on HIV testing services by service delivery point. The TB clinic (11%), male ward (9%), and female ward (8%) had the highest yield of HIV-positive individuals tested.

Challenges

One of the initial challenges for expanding HIV testing was inadequate space in clinics to provide private, confidential HIV testing services. In response, EGPAF is coordinating with site management at these supported facilities to identify unused rooms that can be refurbished for this purpose. For facilities that have no free space, EGPAF is exploring the option of using tents.

Another challenge is that the existing HIV testing service providers in some facilities abandoned their testing responsibilities with the introduction of the new cadre. In response, EGPAF is working with the MOH to re-engage the traditional HIV testing providers to continue services.

One especially concerning observation is a widening gap between the number of people identified as HIV-positive and those initiated on ART. A partial explanation for the gap may be the proportion of individuals who are not currently eligible for ART according to current national guidelines. The ART eligibility gap will be addressed as Malawi implements the WHO's Treatment for All policy. Another explanation for the gap may be weak linkage systems and the loss to follow-up of individuals not linked to care. A third explanation may be that patients may not be ready (emotionally) to start ART, particularly as more healthy-feeling patients become eligible. EGPAF–Malawi is working with the MOH to strengthen linkages to ART by developing standard operating procedures for providers on tracking and physically accompanying HIV-positive individuals to ART clinics. There have also been trainings for HIV testing and counseling providers in advance of before universal treatment roll-out (June 2016), allowing expanded access to testing and early diagnosis, a fundamental need in the Treatment for All paradigm.

Lessons Learned and Next Steps

The introduction of HDAs has significantly increased the number of clients tested for HIV and identified as HIV-positive within a short period. The availability of properly trained, dedicated cadres of lay health workers to provide HIV testing and counseling services enables implementation of provider-initiated HIV testing and counseling and will help accelerate progress toward reaching the first 90 target as we move toward implementing the Treatment for All guidelines to reach the second 90.

A provider-initiated HIV testing and counseling evaluation will be conducted to collect more rigorous data to understand HIV testing yields and linkages to care. EGPAF will continue to share lessons with MOH; advocate for wider adoption of the new cadre; and find solutions to the challenges of space, the use of existing human resources for HIV testing services, and linkages from expanded testing to expanded treatment access for all.

KENYA

Reaching the Last "90": Actively Monitoring Viral Load

EGPAF began working in Kenya in 2000. The program started as a small, privately-funded PMTCT initiative and has since grown into one of the largest HIV prevention, care and treatment programs in the country. To date, EGPAF programs in Kenya have given access to PMTCT services to over 1,850,000 women, tested more than 1,830,000 individuals for HIV, including 25,000 male partners, and provided ART to over 380,000 individuals.

Kenya has a population of over 44 million; 1.4 million individuals are living with HIV in the country. From its inception in Kenya in 2000, EGPAF has worked hand-in-hand with the country's MOH to scale-up access to a range of health services and has helped initiate over 380,000 HIV-positive individuals on ART, including 39,500 children under the age of 15. Kenya's government has taken an active role in eliminating HIV and AIDS, enacting policies to ensure health workers are providing HIV prevention, care and treatment in line with current WHO recommendations.

Kenya's national guidelines have provided the framework and recommendations for viral load testing, since 2004. At that time, viral load testing was performed only when patients were experiencing suspected treatment failure. Since, viral load testing expanded and testing of all patients enrolled on ART became a country-wide policy in June 2014. Guidelines recommend testing patients 6 months, 12 months, and annually thereafter post-ART initiation.

As viral load monitoring became routine in HIV service delivery, EGPAF began to track this data longitudinally, in 2014, in 91 supported sites under its Pamoja Project in Homa Bay and Kisumu counties. Trends in viral suppression appeared through routine monitoring. These trends indicated that the number of patients active on ART, experiencing virologic suppression has steadily increased from 2014 to 2016 across Kenya (Figure 1). As seen in Figure 2, patient age plays a strong role in viral suppression, with young adults and adults experiencing a high virologic suppression compared to youths and adolescents.

National guidelines call for enhanced adherence counseling on ART and second/third line regimens when suppression has not occurred, or when patient viral loads climb once more. From January 2016 to June 2016, in 17 high-volume, supported clinics, EGPAF assessed suppression rates after adherence counseling and found that only 88 of 404 (22%) patients began to experience viral suppression after adherence counseling was provided. Of those who re-tested at high viral loads, 222 were initiated on second or third line regimens.

Next Steps

EGPAF Kenya is putting in place initiatives to address adolescent challenges. One of

EGPAF-supported regions

AUTHORS

Allan May
amayi@pedaids.org

Eliud Mwangi

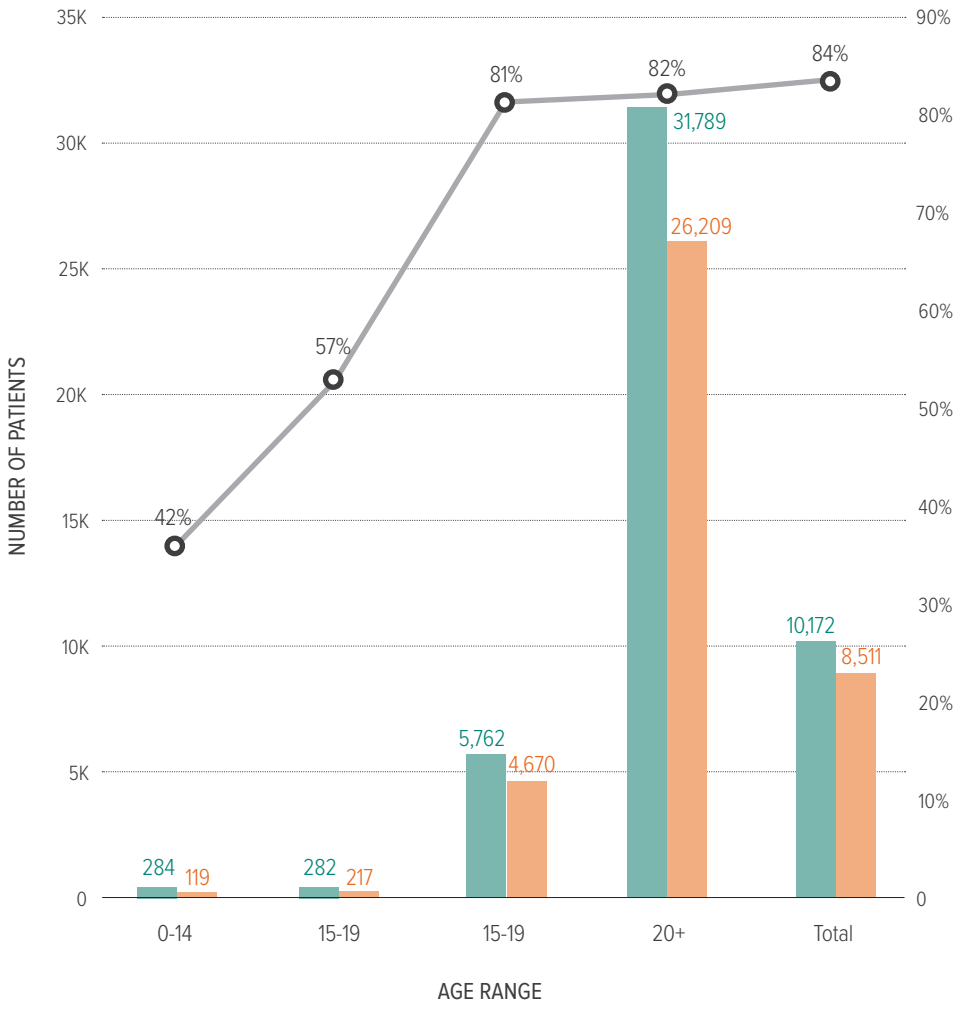


FIGURE 1

Viral load test and suppression levels across 91 supported sites 2012-2016

Viral loads tested

Patients with suppressed viral loads

Suppressed

these initiatives is the Red Carpet Program (launched in December 2015). Funded by ViiV Healthcare Positive Action for Adolescents Fund, this project aims to improve long-term health outcomes of adolescents (ages 14-18) and young adults (ages 19-21) with HIV in Homa Bay County, Kenya. To accomplish this, the project implements adolescent- and youth-specific comprehensive linkage to care and early retention programs utilizing interlinked facility and community-level components. The program hopes to strengthen the meaningful involvement of adolescents and young people in their HIV prevention, care and treatment programs and increase the capacity of health care workers in the provision of these services.

Lessons Learned

- National policies requiring viral load testing resulted in impressive coverage of viral load monitoring
- Regional laboratories were inundated with samples for processing when the policy recommending routine viral load monitoring was first enacted, which slowed response time in late 2014. However, since, these regional facilities have revised systems to more efficiently process samples - scaling down turnaround time from one month to two weeks

Photo: Eric Bond/EGPAF 2016

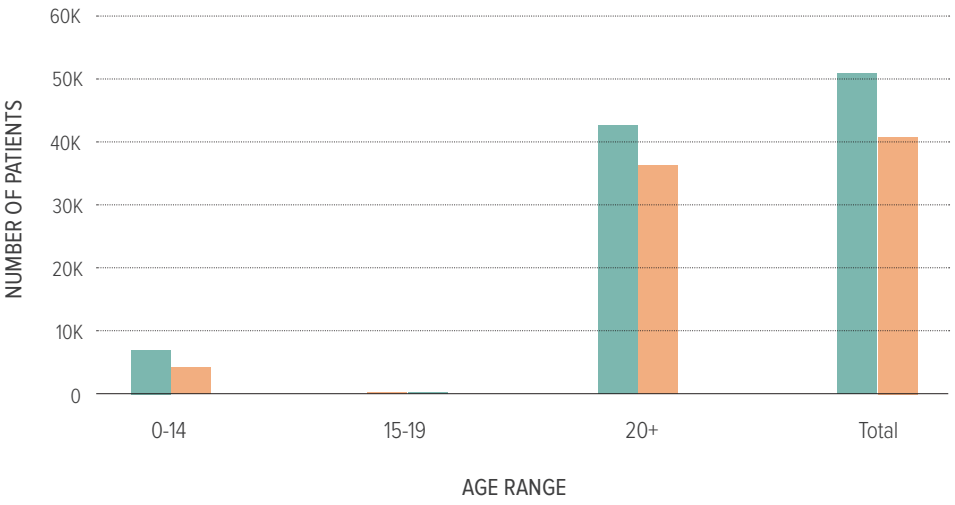


FIGURE 2

Viral load testing and suppression by age (Jan 2015 to Mar 2016) in 91 supported sites

Test done

Suppressed

- Using longitudinal tracking, allowed us to note very important trends in viral suppression, especially challenges in viral suppression among children and adolescents
- Improving chart reviews, longitudinal viral load follow-up and clinical teams' support through mentorship helped in the proper management of patients with high viral load, directing staff to follow guidelines and initiate second or third line regimens, when needed

Conclusion

As we move toward the last 90 of the UNAIDS targets: viral suppression among 90% of those on ART, HIV program implementers will not only have to implement effective treatment paradigms under current WHO recommendations, but will also have to ensure routine viral loads testing among those on ART. Creating a policy that makes viral load monitoring a part of routine care, is an important element needed to monitor and affect viral suppression. This monitoring can point us to challenges which will need to be addressed to pull us closer to the 90% target.

SIDEBAR NO.2

ACCLAIM: meaningful male involvement

In 2014, EGPAF developed an approach under its initiative titled Advancing Community-Level Action for Improving Maternal and Child Health and PMTCT (Project ACCLAIM) that uses innovative, community-based strategies to overcome barriers to maternal, newborn, and child health (MNCH) and HIV prevention, care, and treatment in three countries (Zimbabwe, Uganda, and Swaziland). One of the major issues confronted by program implementers in these three countries, and a significant barrier to MNCH and HIV testing, care, and treatment, was low male HIV testing rates and low male involvement in MNCH programs, which has been shown to affect family utilization of health services.[8] Results from an ACCLAIM survey, employed in these three countries at the start of the project, attributed low male involvement to the fact that most MNCH services are not designed to accommodate men—many men did not feel comfortable attending MNCH clinics, which were viewed as "for women and children only."

ACCLAIM implemented community interventions aimed at empowering men to make informed health decisions to protect their families. At the community level, men were engaged through the intervention of community leaders. At the individual level, men were engaged through community dialogues and peer group interventions, which taught them to be informed, powerful men who are champions for healthy families.

Community Leaders

In total, 262 men with influence in their communities were nominated through traditional community structures to participate in this intervention. Selected leaders were trained over a five-day period and mentored throughout the duration of the project to advocate for MNCH and PMTCT use in their communities. Male leaders were chosen for this role to break the barriers and the belief system that MNCH and PMTCT were female-only issues.

Community Dialogues

Photo: Eric Bond/EGPAF, 2016

The ACCLAIM team developed guides for initiating community dialogues for men, facilitated by ACCLAIM team staff alongside district and community leaders. Facilitators led discussions on how men could take control of their health and participate meaningfully in the health of their families. The dialogues, held in a four-part series, addressed myths and misconceptions, dispelling them with facts from the trained ACCLAIM dialogue facilitators, community leaders, and health workers attending the sessions.

Across the three ACCLAIM countries, 25,026 male participants attended the dialogues. Men discussed such topics as the importance of family planning, becoming a father, sexually transmitted infection and HIV transmission risks and treatment, and early childhood care and development. At these dialogues, 6,042 males were tested for HIV, and many were also able to have their blood pressure checked and were linked to other services for general health care. More than 90% of participants attended all four parts of the community dialogue series, showing heavy community interest in these educational meetings. ACCLAIM results, including those indicating a strong positive outcome on male engagement and utilization of MNCH and PMTCT services through empowering community leaders/existing community structures, will be published in a forthcoming manuscript.

ZIMBABWE

Accelerating Treatment for Children Living with HIV: Lessons Learned from Implementation in a Targeted District in Zimbabwe

Since 2001, EGPAF has been the lead implementing partner supporting the national PMTCT and pediatric HIV care and treatment programs in Zimbabwe. In 2011, Zimbabwe's Ministry of Health and Child Care (MOHCC) made elimination of pediatric HIV and AIDS a national goal and renewed its commitment to decreasing the rate of new HIV infections among children to 5%. The MOHCC adopted the WHO's 2012 PMTCT guidelines, which recommend Option B+. By the end of 2015, through policy development, program implementation, and operations research activities, EGPAF–Zimbabwe had helped the country come closer to the goal of virtual elimination of new pediatric HIV infections.

EGPAF-supported regions

AUTHORS

Auxilia Muchedzi
amuchedzi@pedaids.org

Addmore Chadambuka

Reuben Musarandega

Tichaona Nyamundaya

Caroline Zinyemba

Agnes Mahomva

Background

In 2014, in partnership with the Children's Investment Fund Foundation (CIFF), PEPFAR launched the two-year Accelerating Children's HIV/AIDS Treatment (ACT) Initiative, targeting countries with a high burden of pediatric HIV, low access to pediatric HIV treatment, and great disparity in HIV treatment coverage for children compared with adults. While Zimbabwe is not officially one of the 10 ACT countries, CIFF tasked EGPAF–Zimbabwe with carrying out ACT activities in one district to demonstrate how ACT can be successfully implemented there.

EGPAF–Zimbabwe implemented ACT in Hurungwe District, a rural district in Mashonaland West Province, Zimbabwe. Hurungwe was selected due to its high proportion of HIV-positive children under two years of age (15%) and its low level of pediatric ART uptake (about 40%). The goal of this project was to demonstrate the feasibility of scaling up pediatric HIV treatment through intensified case finding and health worker capacity-building for ART initiation and retention. The initiative sought to increase the number of children (from birth to 19 years old) tested for HIV, initiated on ART, and retained in care in Hurungwe.

EGPAF conducted a baseline assessment in the district in January 2015, collecting retrospective data for January–December 2014, prior to the implementation of activities. This baseline assessment set a benchmark against which to evaluate the effectiveness of ACT. Key performance indicators assessed included the number of infants and children from birth through age 19 in the district total, the proportion of these infants and children who tested for HIV, and the number of those children who were initiated on ART initiation and

retained in treatment. Data were collected from all 31 health facility registers in Hurungwe at baseline and routinely thereafter.

Implementation of ACT

The ACT Initiative uses three key approaches to increase ART enrollment among children and adolescents: strengthened community involvement in pediatric HIV testing and treatment, improved HIV identification, and improved monitoring and evaluation functions to accurately track results. The first is achieved by targeted community dialogues, wherein all community members are invited to attend a meeting at a central location to discuss pediatric HIV testing and treatment. It also entails increasing community outreach through training village health workers, who liaise between health facilities and communities to ensure greater access to testing and retention of those enrolled in ART. The second approach focuses on increasing HIV testing yield among children by increasing the number of sites offering HIV testing and by providing HIV testing along with other routine health services (such as immunizations) for infants, children, and adolescents through age 19. The final approach is achieved through staff trainings on data collection, management, and use to inform program decisions.

EGPAF implemented several community activities, including four community dialogue days in January and February 2015, in which a total of 5,000 people were reached and 1,052 people were tested for HIV. Several trainings and mentorship opportunities for health staff were provided in early 2015 to strengthen the district's capacity to deliver HIV care and treatment services for children from birth through age 19 in Hurungwe District. EGPAF supported the following activities:

- EID and rapid HIV testing trainings for nurses
- In-service training for nurses on opportunistic infection and ART management
- Pediatric ART clinical mentorship of trained nurses
- Supportive supervision, focused on data management, for the 31 health facilities in the district

All age groups in all 31 facilities were tested for HIV using rapid tests. Counseling was provided to the parent/caregiver of children 12 and under, and to adolescents 13 and up. EID was integrated into the WHO's program on immunization (EGPAF advocated for this program). HIV-positive children in all age groups were initiated on ART and provided with services specific to their age group. ART services were made available on a daily basis to ensure adequate access and reduce client wait times.

To ensure retention in care, workers followed up with those in all age groups who missed consultations. Parents and children were routinely counseled on the importance of adherence at treatment initiation. Staff followed up on children 2 and under diagnosed as HIV-positive to ensure initiation and continuation of treatment, and they tracked and traced children and adolescents ages 2–19 to assess their retention in care and treatment. Health workers used appointment diaries and enhanced registers to ensure follow-up of clients testing positive for HIV and enrolled on ART.

Results

The total number of infants, children, and adolescents through age 19 who were tested for HIV through the ACT Initiative (January–September 2015) was 19,162 (Figure 1)—more than double the 6,391 tested during at baseline (January–September 2014). The highest increase in number of children tested for HIV was among the 2–5 age group, from 378 to 5,947. The high

HIV Among Children in Zimbabwe[2]

146,826 children under 15 living with HIV; 57% of them are in urgent need of ART

9,086 new HIV infections in 2014

6,713 annual deaths among children under 15

increase could be a result of confirmatory testing for HIV-exposed infants after breastfeeding cessation as the national infant feeding guidelines recommend breastfeeding up to age 2.

There was also an increase in the number of infants, children, and adolescents (from birth to age 19) initiated on ART (Figure 2). This could be attributed to improvements in health worker confidence in initiating ART in children, as well as improved counseling.

Retention at six months after ART initiation also improved across all age groups (Figure 3), after enhanced use of appointment diaries and registers, strengthened tracking and tracing through community health workers who intensified client follow-up, and increased community awareness of the importance of staying in care. Retention also improved after strengthening health worker skills in counseling and health education.

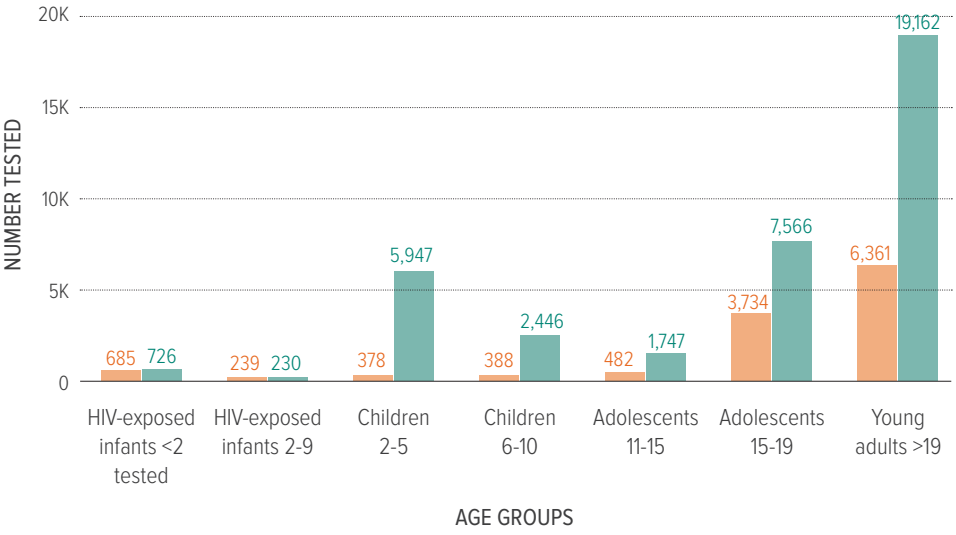


FIGURE 1

Number of infants, children, and adolescents tested for HIV at baseline (July–December 2014) versus during ACT implementation (January–September 2015)

Baseline (Jan-Sept 2014)

End line (Jan-Sept 2015)

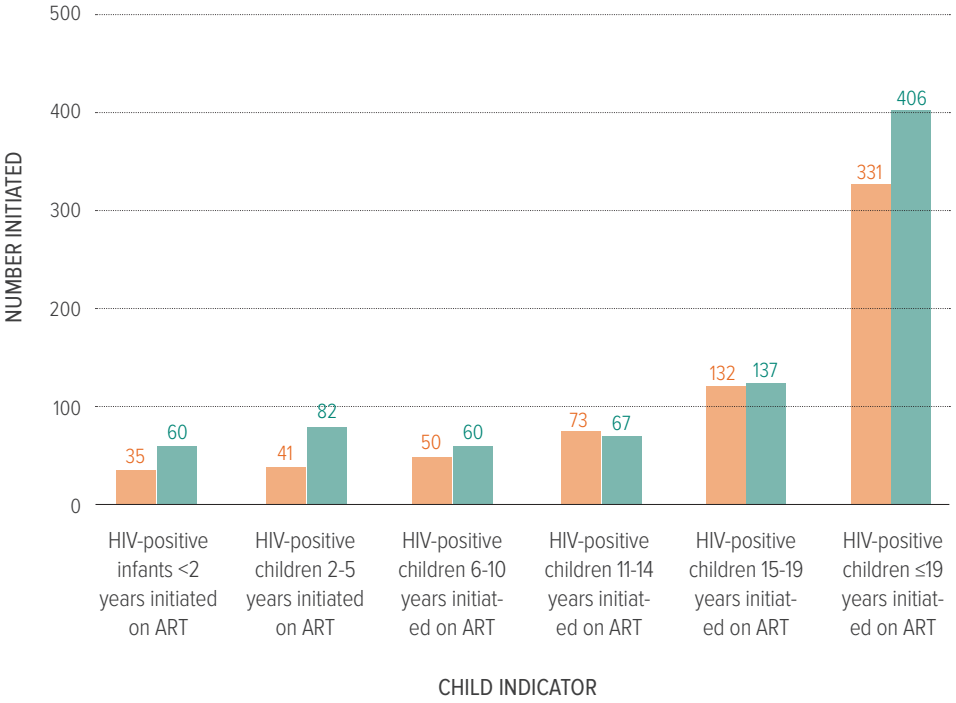


FIGURE 2

Number of HIV-positive children initiated on ART at baseline (July–December 2014) and following ACT implementation (January–September 2015)

Baseline (Jan-Sept 2014)

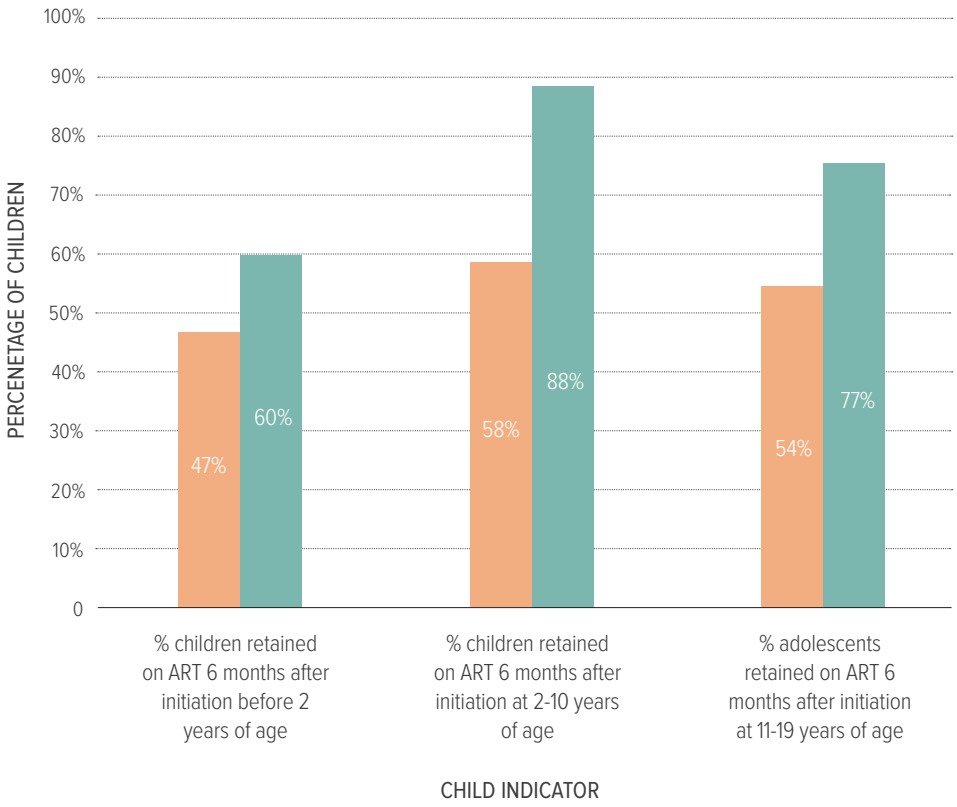
End line (Jan-Sept 2015)

FIGURE 3

Six-month retention of infants, children, and adolescents on ART at baseline (July–December 2014) versus during ACT implementation (July–September 2015)

July-Sept 2014

July-Sept 2015



Conclusions

The implementation of ACT tripled the number of children tested for HIV in Hurungwe. Through integration of HIV testing into pre-existing and well-utilized immunization services, HIV testing among children under five and enrolment of HIV-infected children in this age group improved. Opportunities exist in the district to accelerate HIV care and treatment for the 5–19 age group through capacity building of health care workers to provide integrated services, and expansion of integrated service delivery to communities far from health facilities.

Increasing the yield of pediatric testing and ART enrollment requires concentrated efforts and unique approaches in integration. These approaches will be necessary as we move toward Treatment for All era.

SIDEBAR NO.3

Rapid implementation of Treatment for All for children and adolescents under 15

Photo: James Pursey/EGPAF, 2012

Through the ACT Initiative, Tanzania will enroll an additional 38,848 HIV-infected children on ART by September 2016 in four CDC-funded regions (see map).[9] In order to reach this ambitious target, Tanzania prioritized early adoption of ART access for all children. By April 2015, Tanzania released new guidance on treating HIV-infected children younger than 15. Rapid deployment of clinical mentorship and support helped to accelerate the implementation of these new guidelines at scale.

Immediately after the Tanzania MOH released the national policy, EGPAF actively distributed it to all sites providing care and treatment services, along with a job aid summarizing the recommended regimens for children. The job aids were distributed to health workers at the pediatric, reproductive, and child health wards, and at care and treatment clinics. To complement these efforts, EGPAF facilitated database analyses to identify the number of HIV-infected children in need of ART per supported site. In partnership with district health management teams, EGPAF supported and coordinated clinical file reviews of HIV-infected children in order to identify any HIV-positive child not on ART. The file reviews also offered an opportunity to give health care workers at these sites in-person pediatric care and treatment mentorship in accordance with revised guideline recommendations.

By May 2016, the number of HIV-infected children attending HIV care and treatment clinics who were on ART increased from 577 out of 1,827 (32%) to 3,638 out of 4,226 (86%). Facilitating early adoption through open communication and the creation of job aids, data analysis and tracking, and coordinated technical support and mentorship have enabled rapid implementation of pediatric care and treatment scale-up under ACT. These are lessons we can apply as Tanzania moves into adoption of the Treatment for All guidelines.

AUTHORS

Martha Mukaminega
mmukaminega@pedaids.org

Gretchen Antelman

Roland Van de Ven

SWAZILAND

Swaziland's Transition to Option B+, Early Results, and Implications

EGPAF began supporting the Kingdom of Swaziland in 2003 in providing PMTCT as well as HIV and AIDS care and treatment services. EGPAF–Swaziland's work aims to ensure that every client has access to HIV testing, high-quality counseling, linkage to effective treatment, and psychosocial support within a variety of easily accessible health settings throughout the country. EGPAF supports Swaziland's MOH in planning, implementing, and monitoring programs according to epidemiologic patterns of the disease across the country. Currently, EGPAF–Swaziland supports 66 health facilities in the Hhohho and Shiselweni regions with delivery of PMTCT, HIV testing and counseling, ART, and TB services.

Background

In 2012, Swaziland developed its Treatment as Prevention Framework, which outlined how the country would move toward Treatment for All. The framework, aligned with the 2013 WHO guidelines, moved Swaziland into adoption of Option B+. Lessons learned from the Option B+ phased roll-out in Swaziland will be essential for the shift to the WHO's 2015 recommendations.

The Option B+ phased roll-out involved several components, ranging from training, mentorship, and mass communication to monitoring and evaluation, supply chain management, and program management. Swaziland government tasked the MOH and partner organizations, such as EGPAF, to facilitate the national roll-out of Option B+ to all health facilities. The phased approach began in October 2014.

Early Results

EGPAF focused on roll-out of Option B+ within its 66 supported PMTCT and ART facilities. This roll-out involved extensive communications campaigns in communities and at health centers to sensitize individuals to their risk of acquiring HIV and the testing and treatment options now available to them. Routine monitoring and evaluation data from 62 out of 66 supported facilities providing PMTCT services (Figure 1) showed that during the pre–Option B+ period (January–December 2014), of the total 2,820 HIV-positive pregnant or breastfeeding women eligible for ART, only 41% were initiated. After the roll-out of Option B+, 2,464 such women were identified as eligible for ART, and 92% were initiated (January–December 2015).

From January to December 2015, EGPAF clinical mentors collected cohort data for quality improvement purposes in 53 of the 62 sites to measure early Option B+ retention among pregnant and lactating women initiated on ART. A total of 935 three-month cohorts of pregnant and lactating women were initiated on ART in the 53 EGPAF-supported sites (Figure 2).

ACS, UNITAID regions

AIDSFree, ELMA regions

AUTHOR

Christopher Makwindi
cmakwindi@pedaids.org

Of those, 79% returned for their two-week follow-up appointments. By one month after ART initiation, the proportion of women returning for follow-up had increased to 84%. At two months, retention on ART decreased slightly to 81%, and then further decreased to 74% by three months after ART initiation. The reduced retention at two weeks was likely due to nurses' prescribing a one-month supply of medications at initiation rather than the recommended two-week supply; women may postpone coming for an appointment when they still have a supply of drugs on hand.

Lessons Learned

- The first region to complete the phased roll-out was Lubombo. Regional MOH managers were heavily involved in the facility-based sensitization and health trainings. Site managers and workers were well accepting of Option B+. The region witnessed a 95% uptake of the Option B+ regimen among pregnant or breastfeeding HIV-positive women in 2015—the highest of any region to date—potentially indicating that MOH involvement is essential in promoting acceptance and use of new treatment guidelines.
- High acceptance of Option B+ among patients almost immediately after launch was noted in every region, perhaps attributable to strong early community sensitization and patient education.
- There is a need to intensify preparation and counseling of HIV-positive women to improve uptake, adherence, and retention in care, as noted in Figure 2. Since this analysis, the MOH has scaled up training of lay counselors (mentor mothers) to support adherence counseling for patients enrolled on ART.
- There arose a need to clearly map out client flow at each facility to maximize the efficiency of service provision. Facility staff held discussions on how best to adjust the client flow and align it to recommended client flow models that supported the integration of ART into antenatal, labor and delivery, and postnatal care service points. Better facility flow will help site managers handle a larger influx of patients visiting for ART initiation and to pick up medications. Facility flow can and should be adjusted on a site-by-site basis.

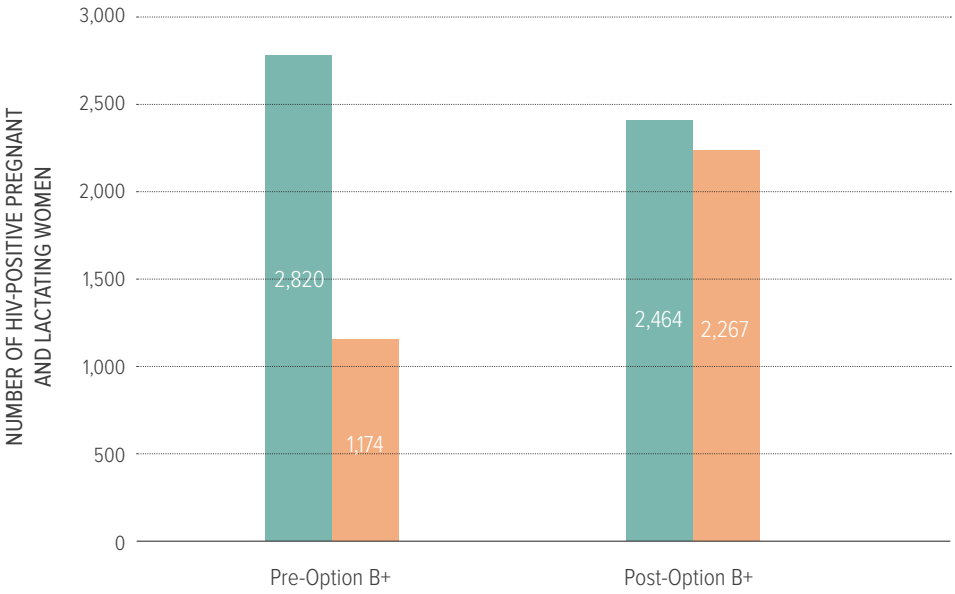


FIGURE 1

Uptake of ART among HIV-positive pregnant and breastfeeding women before and after Option B+ implementation (2014 and 2015 data)

Eligible for ART

Initiated on ART

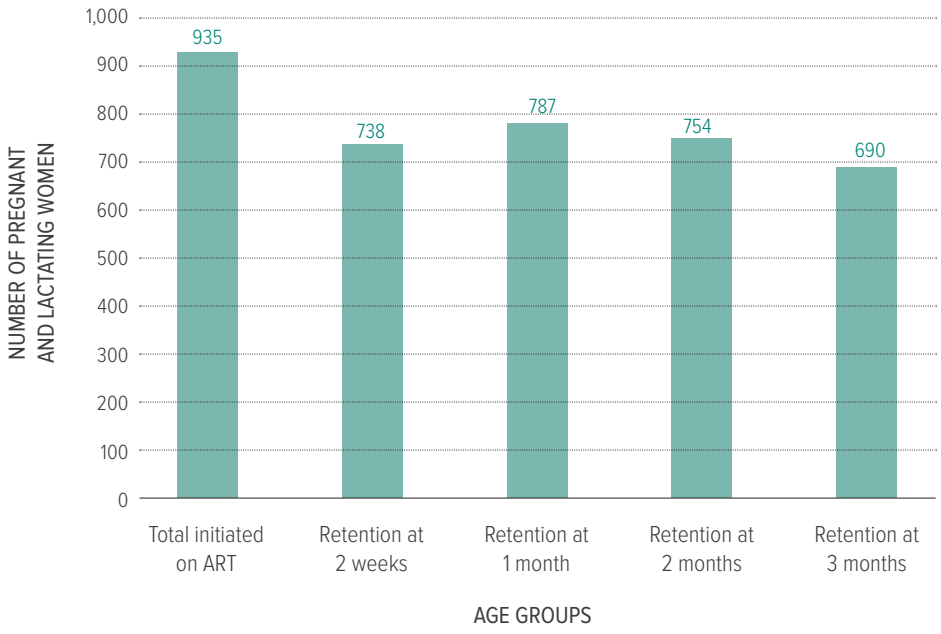


FIGURE 2

Retention in care among Option B+ patients, using early retention indicators

Conclusions

Active collaboration between the implementing partners and the MOH was key to the success of Option B+ implementation. Open dialogue to troubleshoot issues at the facility (client flow for example) was an important ingredient in a well-coordinated scale-up of this WHO recommendation. Looking forward, partners in Swaziland will need to place more focus on retaining women on ART. This is an important lesson to consider while Swaziland transitions to Treatment for All. Partners will continue to work cohesively with the government to apply these lessons learned. With EGPAF support, the MOH in Swaziland is utilizing these lessons learned on high acceptance and uptake of Option B+ to pilot Treatment for All in 23 selected facilities (14 in the Hhohho Region, led by the Clinton Health Access Initiative, and nine in the Shiselweni Region, led by Médecins Sans Frontières).

SIDEBAR NO.4

Establishing a national system for early Option B+ retention monitoring in Uganda

In Uganda, the mother-to-child HIV transmission rate varies from 2% at six weeks to 8% by the end of the breastfeeding period. This variance is largely attributed to poor retention in care and adherence to ART due to weak follow-up systems for clients at all levels. In 2014, through funding from EGPAF's Delivering Technical Assistance (DELTA) project, a global CDC technical assistance mechanism, EGPAF–Uganda set out to support the MOH in strengthening retention monitoring in the country. EGPAF–Uganda worked with the MOH to develop a "data dashboard", a source for all cumulative PMTCT data, electronically entered and housed, and easily accessed by program managers for improved monitoring and evaluation tracking of adherence on lifelong ART. At the national level, members of the MOH Monitoring and Evaluation Technical Assistance (META) team were trained on use of the data dashboard in February 2015.

To pilot this new monitoring and reporting system, 30 health facilities in five districts were selected, based on the presence of implementing partners, available funding for at least 10 months, fully engaged district health officers, and availability of district quality improvement teams and regional/district coaches. Health workers from the 30 sites were provided with phones so they could report indicators to MOH weekly via SMS. The indicators assessed included number of HIV-positive pregnant and lactating women initiated on ART; number of HIV-positive pregnant and lactating women known to be in care and on ART treatment at the end of the reporting period; and client retention on ART, including the number of mother-infant pairs expected for an appointment in the month and the number of mother-infant pairs who missed an appointment.

The META team collected and reviewed these indicators monthly, including them in a weekly report to the MOH, sites and partners. By March 2015, data were accessible as well as easy to analyze and interpret for use at health facilities, by the MOH, and by implementing partners. Early promising practices included use of the dashboard reports to inform and prioritize mentorship of health facilities that needed support, and greater communication between facility managers on performance.

This pilot demonstrated that with use of technology, it is possible to establish a real-time monitoring system in a low-income setting with high HIV burden. Health workers in the settings where this pilot was implemented are now able to more closely follow each client enrolled on lifelong ART over time.

AUTHORS

Godfrey Esiru
gesiru@pedaids.org
Mohammed Mahdi

DEMOCRATIC REPUBLIC OF CONGO

Tracking HIV Patients Through Task Sharing in the Democratic Republic of Congo

EGPAF began supporting critical prevention services in the Democratic Republic of the Congo (DRC) in 2001, providing funding and technical assistance to PMTCT programs implemented by the Kinshasa School of Public Health and the University of North Carolina. Since then, EGPAF has supported, implemented, and scaled up access to adult and pediatric HIV care and treatment, EID, TB and HIV coinfection management, sexually transmitted infection management, and sexual and gender-based violence services. To date, EGPAF has supported over 390 sites across 26 provinces of the DRC, tested more than 409,000 pregnant women for HIV, provided over 428,000 pregnant women with access to critical PMTCT services, enrolled 14,000 people into HIV care, and started more than 7,900 patients on ART, including 1,983 children under the age of 15.

As we move into an era in which more and more HIV-positive patients are eligible for treatment for life, we will be faced with the challenge of how to realize the full benefits of Treatment for All: how do we reach all HIV-positive individuals not only with testing, diagnosis, and treatment, but also with information on the importance of adhering to this treatment for life? Until recently, health facilities in the DRC have reported to the MOH substantial challenges in retaining HIV-positive pregnant and breastfeeding women and children in care and treatment programs, due to capacity and resource constraints. To fill this gap, in 2013, EGPAF–DRC began training mentor mothers and other HIV-positive peer educators to encourage HIV-positive pregnant and breastfeeding women to remain in care and treatment programs. These peer educators also encourage patients to return to the health facility for postnatal care; counseled patients on bringing their newborn babies to clinics for growth monitoring, immunizations, and early infant HIV testing and diagnosis; and dispensed guidance for appropriate infant and young child feeding approaches.

The program serves women in six provinces. Overall, 217 mentor mothers and other volunteers were trained to collaborate with health care workers to encourage, educate, and empower HIV-positive women. They also facilitate HIV education through peer support group meetings, provide support to HIV-positive couples, and follow-up with HIV clients who have missed clinic visits or who have been lost to follow-up.

The program significantly improved retention of HIV-positive women in EGPAF-supported facilities. There was a 20% attrition rate in 2013-2014 noted in EGPAF-supported sites. The DRC MOH has adopted this approach and integrated it into the national PMTCT protocol, requiring all implementing partners to use this methodology. As we move into the Treatment for All era, methods to ensure viral suppression through adherence to effective HIV and AIDS treatment will be essential.

EGPAF-supported regions

AUTHORS

Aimé Loando
amloando@pedaids.org

Jo Mushitu

Jean Robert Ntsukunyu

Photo: Eric Bond/EGPAF, 2016

SIDEBAR NO. 5

Introducing and assessing expanded approaches to increase identification of HIV-infected children across EGPAF's programs

AUTHORS

Judith Kose
jkose@pedaids.org

Bernard Ochuka

Theresa Wolters

As of December 2014, only 23% of children living with HIV worldwide were receiving lifesaving ART. While several gaps along the pediatric HIV cascade contribute to low pediatric ART coverage, identification of HIV-infected children remains one of the most significant barriers to initiating children on ART. Several countries have adopted the 2015 WHO testing guidelines for children, but these recommended approaches are not optimally implemented in every country.[10] Additionally, although the WHO testing guidelines and supporting evidence base demonstrate the potential effectiveness of a range of pediatric testing approaches, more evidence is needed to develop comprehensive strategies for pediatric HIV case finding differentiated by age, prevalence, and setting. As we develop new strategies, we can learn much about how to effectively implement the newly WHO-recommended Treatment for All approach.

To improve identification of HIV-infected children and provide evidence to inform a more comprehensive pediatric testing strategy, EGPAF has introduced a range of evidence-based pediatric HIV testing approaches across its country programs:

- Universal pediatric provider-initiated testing and counseling—Kenya, Lesotho, Tanzania, and Malawi

  Facility-based pediatric and adolescent provider-initiated HIV testing and counseling has been introduced and scaled up at all entry points to health services. EGPAF's support includes development of standard operating procedures and job aids for health workers; training on pediatric and adolescent

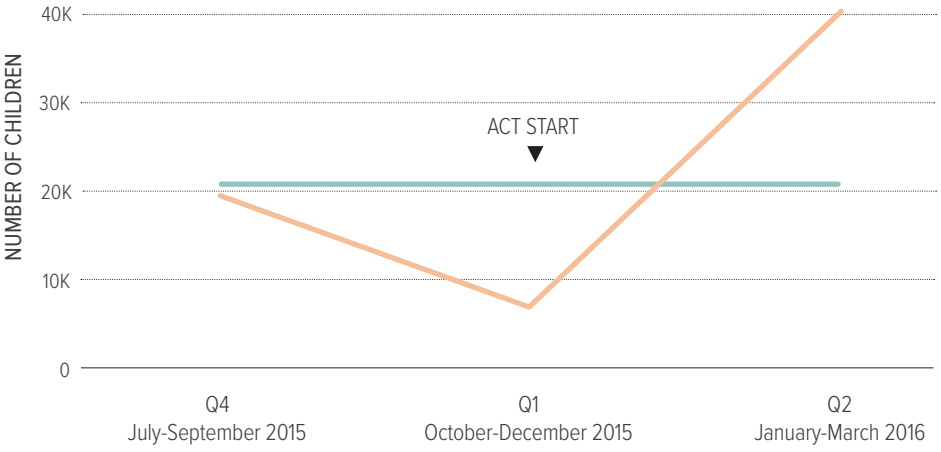
Photo: Robin Wyatt/EGPAF, 2015

FIGURE 1

Pediatric HIV testing and counseling uptake and yield in Kenya (2014–2015 data)

Pediatric Testing Targets and Children Tested

Children tested



provider-initiated HIV testing and counseling for health workers; strengthened linkages to counseling, adherence support, and HIV care for HIV-infected children and adolescents; and provider-initiated HIV testing and counseling data collection and monitoring.

- Community- and facility-based pediatric testing for family members of adult index patients—Zimbabwe and Mozambique

  Under this family-based model, HIV-positive "index clients" are tracked on a spreadsheet called a line listing, and their family members are targeted for testing at facilities, in the community, or at homes.

- Integrated and targeted community-based pediatric and adolescent testing—Zimbabwe (integrated into the Expanded Programme on Immunization) and Côte d'Ivoire (targeted to orphans and vulnerable children)

  HIV testing is integrated into child-centered outreach programs such as community-based immunization and deworming activities.

These different approaches have led to intensified pediatric case finding and revealed some important programmatic lessons. The universal pediatric provider-initiated testing and counseling approach, for example, was successful in Kenya, but only when

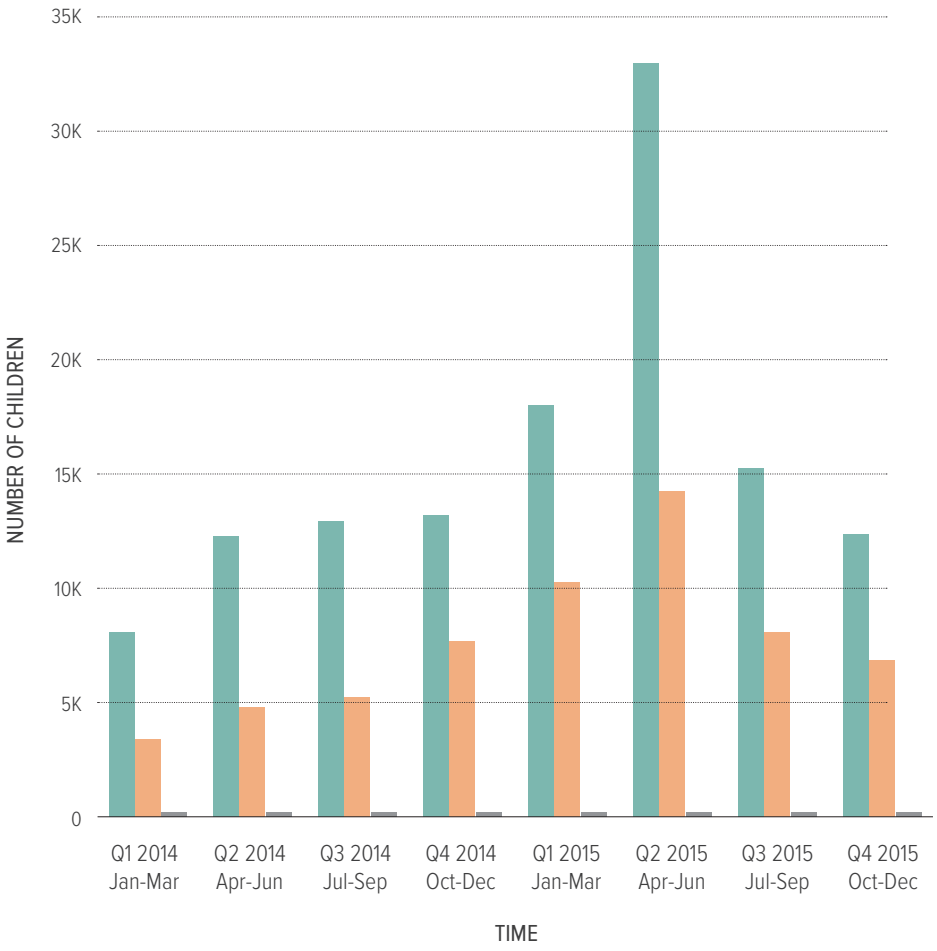


FIGURE 2

Pediatric HIV testing and counseling uptake and yield in Tanzania (2014–2015 data)

Admitted

Tested

Positive

implemented with other methods (community testing actually resulted in poor linkage to care, but allocation of pediatric-specific HIV testing and counseling workers and setting of facility targets increased the number of children screened [Figure 1]).

The approach used in Tanzania (implemented in March of 2014) proved very successful due to buy-in by HIV management teams coupled with inclusion of testing and counseling in facility quality improvement projects (Figure 2). Moreover, the latter promoted better documentation of strategies for improving inpatient pediatric testing.

Several countries experienced issues with staffing or commodity shortages and documentation issues. The countries that increased their numbers of lay providers saw increased numbers of children tested. In Kenya, for example, the program led to a higher yield than routine EID. Increased HIV testing yields in Uganda, Lesotho, Côte D'Ivoire, and Zimbabwe were not as high as expected, perhaps because the estimated number of exposed or infected children was not accurate (not as high as we had thought) or because fewer children are becoming infected thanks to ongoing PMTCT activities. There is a need for further evaluation to ensure high-yield targeted pediatric HIV testing and counseling. Linkage to ART among young children also remains a challenge across countries and this will need to be addressed, particularly as we move into the new world of Treatment for All.

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Q&A

John Ditekemena

Photo: EGPAF. 2016

John Ditekemena is EGPAF's country director in DRC. He has been with EGPAF for over seven years. Dr. Ditekemena started his career as a clinician working under Amo-Congo, where he learned about country-level needs around HIV and AIDS care and treatment. In the course of this work, through direct encounters with the many suffering from AIDS and HIV, he made a lifelong commitment to HIV and AIDS prevention, care, and treatment programming in DRC, working with Kinshasa University's School of Public Health and with PEPFAR and CDC partners and programs.

Please define your role at EGPAF and your history in the field

I started working with EGPAF in 2009 as a PMTCT specialist under the Integrated HIV/AIDS Project in the DRC (ProVIC), a USAID-funded PMTCT / care and treatment scale-up initiative. In 2012, I became country director of EGPAF–DRC, and I currently oversee four projects that focus on increasing access to PMTCT and HIV care and treatment, as well as on managing TB/HIV co-infection. Two major projects, Project Kimia and Project Malamu, are being implemented in three high-prevalence provinces, with PEPFAR funding through CDC. One project serves military populations, with funding from PEPFAR and Populations Services International. ProVIC is an ongoing consortium project focused on care and treatment and PMTCT scale-up.

Why did you decide to work in this area?

Early in my career, I realized there was a great need to scale up HIV prevention, care, and treatment in my country. The health indicators related to HIV were bad in the DRC as well as in other countries. After becoming aware of the needs and challenges encountered by HIV-positive patients through my direct work with them, I became passionate about this field and wanted to make a difference.

How do you think that Treatment for All will affect the HIV epidemic?

I remember most of my patients from when I was a clinician. I remember the amazement I felt when I saw the effects of ART. In 2004, I was treating one young women, 22 years old, who was very sick and almost totally rejected by her family. She was HIV-positive, had a high viral load, was drastically losing weight, and was unable to work. I initiated her on ART. Six months later, I couldn't recognize

her, her health was so improved. She was at a healthy weight and she could resume work and daily life functions. This is what ART can do.

But there's another hidden benefit of ART: There is a 96% reduction in the risk of HIV transmission in discordant couples when the infected partner is under ART. Scaling up HIV treatment reinforces prevention. Other prevention strategies should of course be maintained and reinforced, but treatment can play an important role here. Most of the clients in EGPAF's PMTCT programs are firsthand witnesses to this important benefit or ART. Their HIV-exposed infants of 18 months or older are living proof of the benefits of treatment as prevention (treatment given through the mother-to-child HIV transmission risk period).

How do you think Treatment for All will affect your work?

It will have a large impact on our work. This new strategy simplifies the treatment protocol and eliminates eligibility criteria. It will let us substantially increase ART coverage to a large population in need. In addition, we are still working to increase the low male involvement in our PMTCT program. Treatment for All will lead us in that direction as well.

What is needed to make Treatment for All a success at the global and country levels?

I think political will is needed at the country level to adopt and properly implement these new guidelines. Countries should invest more domestic resources in their implementation. Also, issues of supply chain management should be clearly addressed because this protocol calls for a major increase in ART enrollment and retention. Countries should identify treatment models to accommodate the huge number of patients now eligible for ART. Finally, to see the true gains of these new guidelines, we need to reinforce community approaches to HIV education and ART enrollment.

What are the critical elements and enablers for Treatment for All to be achieved in your country?

Supply chain management, human resources (an increase in the number of staff prepared to test and treat patients), and health system strengthening (through technical assistance, supportive supervision, and policy directives such as task shifting and decentralized care). Most importantly, all of these require strong political will and government backing.

What immediate challenges and outcomes (both short- and long-term) do you expect after the roll-out of Treatment for All?

Challenges will include stocking commodities (test kits and drugs) in every health setting throughout the country and funding ART services, including community initiatives and adherence support, since the number of HIV patients on lifelong ART will increase. As for outcomes, we'll be able to increase pediatric ART coverage, reinforce prevention, and most importantly, totally control the epidemic.

How will Treatment for All change the atmosphere of HIV/AIDS programs and HIV-affected communities moving forward?

I expect that clinicians' work will be simplified through the standardized strategy of initiating each HIV-positive patient on ART. With increased access, the number of patients under ART will increase. Communities will need to be more involved in HIV management. Workplace environments will change to allow more task sharing and shifting. Finally, we'll see marked improvement in pediatric treatment coverage.

Keys to Success: Promising Practices from EGPAF Programs in Implementing the 2015 WHO Guidelines

1

Roll-out of the Treatment for All paradigm will require the adoption of a comprehensive framework including implementation of enabling policies (e.g., task shifting to supportive cadres, decentralization, viral load monitoring and community-based models of care), health systems strengthening interventions, introduction of new technology and innovations, increased allocation of financial resources, and community-level involvement to drive demand and retention forward.

2

Cohesive political will, as well as comprehensive dialogue and strategy-setting between ministries of health, HIV program implementing partners, health facilities, and the communities and clients they serve will be essential components in successful adaptation and implementation of the revised guidelines

3

In the implementation of Option B+, EGPAF programs have noted a challenge in retaining women in lifelong ART, particularly when those women are asymptomatic. Strategies to mitigate this issue will need to be implemented early as we move into the Treatment for All era. Some successful strategies highlighted in this issue of Haba Na Haba have involved early adherence counseling among HIV-positive patients, use of community health workers to drive patients back into clinics for treatment and monitoring, and stronger monitoring and evaluation techniques using advanced technology (electronic databases and cellular technology) to better track defaulting patients.

Experiences in expanding ART to a greater number of individuals has also resulted in facility-level challenges, such as health worker workload constraints, limited space in facility to accommodate patients and stock outs of testing and treatment supplies. Program implementers should work with individual health facilities to bring in early solutions such as taskshifting, employment of trained lay/community health cadres, revision to facility flow and supply chain management.

A comprehensive HIV testing and treatment strategy that is differentiated to accommodate various client types (men, key populations, pregnant women, urban and rural residents, etc.) and ages (infants, children, adolescents, young adults, and adults), based on successful individual interventions, needs to be introduced and brought to scale.

Introducing stable asymptomatic patients who are diagnosed as HIV-positive to lifelong treatment will be a challenge and will require aggressive advance community sensitization and patient education. Community-based demand generation must be considered a fundamental element of any strategy for implementing these revised guidelines.

Pediatric and adolescent populations require their own approaches within the Treatment for All paradigm. Rigorous parent and community education, integration of testing with routine child and adolescent wellness clinic services, and pediatric and adolescent support groups are all methods shown to help reach these special populations.

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LEAD WRITER & TECHNICAL ADVISOR	MANAGING EDITOR	GRAPHIC DESIGNER	ASSISTANT EDITOR
Francesca Celletti	Alexandra Angel	Janet Kim	Katherine Stewart

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EGPAF HEADQUARTERS

1140 Connecticut Avenue NW, Suite 200
Washington, DC 20036

P +1 202 296 9165
F +1 202 296 9185

WWW.PEDAIDS.ORG