Long-Term Experience Providing Antiretroviral Drugs in a Fee-for-Service HIV Clinic in Uganda

Evidence of Extended Virologic and CD4⁺ Cell Count Responses

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Objective: To describe the long-term experience of providing antiretroviral (ARV) therapy, including CD4⁺ cell count and virologic response, at St. Francis Hospital, Nsambya, Uganda.

Methods: The HIV clinic established in 1998 is a fee-for-service model where patients pay for ARVs. The care of patients who started ARVs from August 1, 1998 until October 31, 2000 was evaluated through December 31, 2002. Data were collected at the HIV clinic on standardized clinical forms. These patients had free CD4⁺ cell count and viral load testing performed at times determined by the physician. All persons who had ≥1 CD4⁺ cell count or viral load done ≥90 days after starting therapy were evaluated.

Results: Three hundred twenty-one patients (49% women, 66% ARV naive, median age = 38 years, median CD4⁺ cell count = 79 cells/mm^3, and median viral load = 249,489 copies/mL) attended the HIV clinic. Two hundred sixty-three (82%) patients returned at least once after the initial visit, of whom 54 (21%) had an interruption in therapy for >1 year. One hundred thirty-five patients were in care in 2002, 69 were known to have died (9 of whom died in 2002), and 68 were lost to follow-up. The probability of remaining alive and in care at 1 year was 0.56 (95% confidence interval [CI]: 0.50–0.61), 0.46 (95% CI: 0.41–0.51) at 2 years, 0.40 (95% CI: 0.34–0.45) at 3 years, and 0.35 (95% CI: 0.29–0.41) at 4 years. In an on-treatment analysis, the median CD4⁺ cell count increase during year 1 was +55 cells/mm^3, +112 cells/mm^3 during year 2, +142 cells/mm^3 during year 3, and +131 cells/mm^3 during year 4. The median log viral load change from baseline during year 1 was −1.4 copies/mL, −1.32 copies/mL during year 2, −1.9 copies/mL during year 3, and −1.51 copies/mL during year 4.

Conclusions: This fee-for-service HIV clinic providing ARV treatment has successfully operated and managed patients for more than 4 years. Those who survived and remained on therapy derived long-term virologic and immunologic responses to ARV drugs in a manner similar to that observed in industrialized countries. Strategies to reduce the financial burden and other barriers to uninterrupted care as well as incentives to increase such practice models should be further explored in the African context.

Key Words: antiretroviral therapy, Uganda, Africa

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HIV care and treatment that include antiretroviral (ARV) drugs in Africa are expanding at a rapid rate because of increased efforts by the international community,[1–4] price reductions for ARV drugs, and localized efforts by individual centers. Much attention is given to developing public sector projects to bring care to Africa; however, the demand by patients who pay for drugs in the private sector or at nongovernmental hospitals has in many ways led the way for access to drugs. In Uganda, treatment with ARV drugs began in the mid-1990s at a few treatment centers and expanded in 1998 due in part, to the Uganda Ministry of Health (MOH) and United Nations AIDS (UNAIDS) HIV Drug Access Initiative (DAI). The original report of the initial pilot period of the DAI in Uganda demonstrated that HIV programs that included ARV therapy could be successfully implemented and provided evidence of favorable virologic and immunologic responses out to 1 year.[5,6] Other published reports to date of the response to ARV drugs among patients treated in Africa have also described good responses for periods of 1 to 2 years.[7–12] This analysis reports the long-term experience and laboratory responses from a center that was part of the initial pilot DAI project in Uganda.

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METHODS

Background

St. Francis Hospital, Nsambya, is a nongovernmental tertiary care referral hospital located in Kampala, Uganda. The hospital is supported financially by a variety of donors and the Ugandan MOH, although some operating costs are recouped from patient fees. An HIV clinic was established to administer ARV drugs when the hospital joined the DAI in August 1998 and remains functional. The HIV clinic was integrated into an existing private medical clinic, which has evolved such that only HIV-infected persons accessing ARV drugs attend, with other patients shifting to a general medical clinic. Whereas medical clinic patients pay a small consultation fee for evaluation, patients at the HIV clinic pay no consultation fee to be seen by the care provider. The clinic operates 5 days per week, has registered more than 800 patients for ARV therapy since 1998, and is staffed with 2 to 3 physicians, a receptionist/data entry clerk, and a nurse. This program benefited from the organizational structure of the original DAI and the establishment of a local importer of ARV drugs. The support provided from the hospital to these clinicians to manage patients is considerable and includes administrative oversight of finances, dedicated clinic space, and salaries for the nurse and receptionist. Other services, such as phlebotomy and pharmacy, support the program through general integration with hospital services. The on-site pharmacy acquires ARV drugs from local suppliers, which the hospital sells to patients at a 3% to 5% markup to cover operating costs. Significant cost reductions for ARV drugs occurred in Uganda in December 2000, June 2001, and August 2002 as depicted in Table 1.

On-Treatment Analysis of Long-Term Virologic and Immunologic Responses

All patients who were enrolled at St. Francis Hospital, Nsambya, from August 1, 1998 through October 31, 2000 were provided free viral load (Amplicor HIV-1 Monitor Assay, version 1.5; Roche Diagnostics, Branchburg, NJ) and $CD4^+$ cell count (FACScan; Becton Dickinson, San Jose, CA) tests by the Uganda Virus Research Institute/US Centers for Disease Control–Uganda (UVRI/CDC) collaboration. These patients are the basis for this analysis, and we report follow-up results through December 31, 2002. Clinical data, including ARV drug regimens, were collected at the HIV clinic and entered into a database (Epi Info 6.0) using unique identifiers for each patient. Prescription-filling data were entered into a separate database (Epi Info 6.0) as patients filled ARV drug prescriptions at the pharmacy. The pharmacy refill information was used to supplement the clinical database to record times when patients were refilling prescriptions and thus could be considered to be taking ARVs, although patients may purchase ARV drugs from other sources. As viral load and $CD4^+$ cell counts were completed at the UVRI, results were entered into a database (dBase IV; dBase, Vestal, NY) at the UVRI/CDC laboratory and returned to the physicians in real time. These 3 databases were merged into 1 data set (Stata, version 7.0; College Station, TX) and are the source of the information for this report.

Drug therapy was characterized as highly active antiretroviral therapy (HAART) if regimens included 2 nucleoside reverse transcriptase inhibitors (NRTIs) plus (1) abacavir, (2) a nonnucleoside reverse transcriptase inhibitor (NNRTI), and/or (3) a protease inhibitor. Therapy was characterized as 2 NRTI if the regimen included 2 NRTIs with or without hydroxyurea. For analysis of immunologic and virologic responses, we conducted an on-treatment analysis of patients who had at least 1 follow-up visit and a laboratory test for $CD4^+$ cell count or viral load ≥90 days after starting therapy. Our primary analysis was only of those laboratory values that were obtained before an interruption in visits (medical visit or pharmacy refill) of more than 1 year, which allowed us to exclude values for patients who had likely stopped therapy and restarted at a later date. Response to therapy was analyzed in time intervals of 3 to 12 months, 13 to 24 months, 25 to 36 months, and 37 to 48 months since starting ARV therapy. Viral load and $CD4^+$ cell count were assessed as the last value in the interval and the best value in the interval. For viral load, we calculated the absolute log change from baseline and also categorized viral load values as <400, 400 to 999, 1000 to 9999, 10,000 to 99,999, and ≥100,000 copies/mL. For $CD4^+$ cell count, we calculated the absolute change from baseline and characterized the response for those with a baseline $CD4^+$ cell count <50 cells/mm^3 and ≥50 cells/mm^3 as described in Table 2.

TABLE 1. Prices in US Dollars for a 30-Day Supply of Some Typical Combinations of ARV Drugs Available in Uganda*

Date	Brand Name† NNRTI-Based HAART§	Non-Brand Name‡ NNRTI-Based HAART§	Brand Name[2] Protease Inhibitor–Based HAART§
August 1998	NA	NA	$479–$556
February 2000	$440–$533	NA	$531–$650
December 2000	$113–$411	$185–$190	$163–$540
June 2001	$69–$188	$50–$60	$107–$529
August 2002	$69–$121	$35–$50	$76–$379

*Prices reflect the cost for typical 3-drug HAART combinations available in Uganda at the time periods noted.

†Brand name drugs are those available from the large multinational pharmaceutic companies who were the innovators of the drugs.

‡Non-brand name drugs refer to products produced by pharmaceutic companies that produce multisource products. Most non-brand name drugs available in Uganda are those from companies in India. During the time period of this analysis, St. Francis Hospital stocked only brand name drugs, but patients could purchase non-brand name drugs from other nearby centers.

§HAART considered to be 2 NRTIs and 1 NNRTI or 1 protease inhibitor for this analysis.

NA indicates not available.

RESULTS

There were 321 patients who had at least 1 visit for ARV drugs from August 1, 1998 through October 31, 2000 (93 were enrolled in 1998, 97 in 1999, and 131 in 2000; Table 3). Initial therapy was HAART for 141 (44%) of 321 patients, 2 NRTI for 118 (37%), none/unknown for 59 (18%), 1 NRTI for 2 (<1%), and 2 protease inhibitors alone for 1 (<1%). The median time from enrollment date until last date recorded was 512 days (interquartile range [IQR]: 55–1064). Fifty-eight (18%) of 321 patients did not return after the initial visit,

TABLE 2. Characterization of $CD4^+$ Cell Count Response in Relation to Baseline $CD4^+$ Cell Count

$CD4^+$ Cell Count Response to ARV Therapy	Current $CD4^+$ Cell Count in Relation to Baseline $CD4^+$ Cell Count	
	Baseline $CD4^+$ Cell Count <50 Cells/mm^3	**Baseline $CD4^+$ Cell Count ≥ 50 Cells/mm^3**
Optimal	Increased $CD4^+$ cell count to ≥ 200 cells/mm^3	$CD4^+$ cell count ≥ 200 cells/mm^3 and $\geq 30\%$ increase from baseline
Desirable	Increased $CD4^+$ cell count to between 50 and 200 cells/mm^3 and $\geq 30\%$ increase from baseline	$CD4^+$ cell count $\geq$baseline, ≥ 200 cells/mm^3, but increase ($<30\%$ from baseline)
Acceptable	Increased $CD4^+$ cell count to between 50 and 200 cells/mm^3 but $<30\%$ increase from baseline	$CD4^+$ cell count between 50 and 200 cells/mm^3 and stable ($\pm 30\%$ change from baseline)
		$CD4^+$ cell count between 50 and 200 cells/mm^3 and $>30\%$ increase
Less desirable		Decreased $CD4^+$ cell count to $\leq 30\%$ from baseline but still ≥ 50 cells/mm^3
Undesirable	$CD4^+$ cell count <50 cells/mm^3	Decreased $CD4^+$ cell count to any value <50 cells/mm^3

68 (21%) were lost to follow-up before 2002, and 69 (21%) are known to have died (6 died in 1998, 21 in 1999, 23 in 2000, 10 in 2001, and 9 in 2002). Fifty-four patients had an interruption in visits of more than 1 year but returned for care as follows: 2 in 1999, 7 in 2000, 27 in 2001, and 18 in 2002. The number of patients who had at least 1 visit (baseline or follow-up) was 93 in 1998, 164 in 1999, 237 in 2000, 166 in 2001, and 135 in 2002. Considering those who had a visit in 2002 as being in care (including those who returned for care after an interruption in visits of more than 1 year), the probability of being in care at 1 year was 0.69 (95% confidence interval [CI]: 0.63–0.74), 0.60 (95% CI: 0.54–0.65) at 2 years, 0.55 (95% CI: 0.49–0.61) at 3 years, and 0.54 (95% CI: 0.48–0.60) at 4 years. In a less conservative analysis considering only patients who returned for at least 1 follow-up visit, which potentially indicates a more definitive commitment to therapy, the probability of being in care at 1 year was 0.80 (95% CI: 0.75–0.85), 0.70 (95% CI: 0.63–0.75) at 2 years, 0.64 (95% CI: 0.57–0.70) at 3 years, and 0.63 (95% CI: 0.56–0.70) at 4 years. The combined effects of being lost to follow-up and death for all patients resulted in a probability of being alive and in care at 1 year of 0.56 (95% CI: 0.50–0.61), 0.46 (95% CI: 0.41–0.51) at 2 years, 0.40 (95% CI: 0.34–0.45) at 3 years, and 0.35 (95% CI: 0.29–0.41) at 4 years.

There was a shift in the numbers of patients on HAART over time such that the percentage of patient visits on HAART in 1998 was 32%, 63% in 1999, 76% in 2000, 93% in 2001, and 100% in 2002 (χ^2 for trend, $P < 0.001$). Of those on

TABLE 3. Baseline Characteristics for Patients Who Had an Initial Visit for ARV Therapy Between August 1, 1998 and October 31, 2000

Baseline	All Patients Who Had an Initial Visit	Patients With at Lease 1 Follow-Up Visit	Patients With ≥ 1 Laboratory Test After 90 Days*
n	321	263	159
Sex (n)†			
Male	162 (51%)	136 (52%)	77 (48%)
Female	158 (49%)	127 (48%)	82 (52%)
Age (y)			
Median	38	38	37
Range	3–76	3–76	3–76
Children <13 years old (n)	4 (1%)	4 (2%)	3 (2%)
ARV naive (n)	211 (66%)	175 (67%)	106 (67%)
$CD4^+$ cell count (cells/mm^3)			
Median	79	82	99‡
IQR	12–205	13–197	27–221
Viral load (copies/mL)			
Median	249,489	232,008	235,038§
IQR	57,693–690,296	59,778–689,715	51,343–689,715

*Included in the viral load and/or $CD4^+$ cell count analysis.
†Sex was not recorded for 1 client who came for only 1 visit in 1999.
‡A total of 116 patients had a $CD4^+$ cell count at baseline from which changes could be calculated.
§A total of 117 patients had a viral load at baseline from which changes could be calculated.

HAART, the percentage of visits for those prescribed an NNRTI in 1998 was 6%, 19% in 1999, 38% in 2000, 71% in 2001, and 58% in 2002 (χ^2 for trend, $P < 0.001$).

On-Treatment Analysis of CD4+ Cell Count and Viral Load Response

Included in the on-treatment analysis of laboratory response are the 159 patients who had at least 1 laboratory test ≥90 days after starting therapy (see Table 3). Considering only the time before an interruption of more than 1 year (where applicable), the observations used for analysis of response, there was a median of 243 days (IQR: 17–940 days) from enrollment until the last date before the interruption. When considering the last value in the interval before the interruption (282 $CD4^+$ cell counts and 259 viral load values), the median $CD4^+$ cell count increase in relation to the baseline value during year 1 was +55 cells/mm^3, +112 cells/mm^{3}during year 2, +142 cells/mm^3 during year 3, and +131 cells/mm^3 during year 4 (Fig. 1). Likewise, the median log viral load change from baseline during year 1 was −1.4 copies/mL, −1.32 copies/mL during year 2, −1.9 copies/mL during year 3, and −1.51 copies/mL during year 4. Trends were slightly better if considering the best value in the interval (see Fig. 1). An analysis that included an additional 22 $CD4^+$ cell count and 24 viral load values after an interruption in therapy yielded similar results: the median $CD4^+$ cell count increase in relation to the baseline value during year 1 was +55 cells/mm^3, +114 cells/mm^3 during year 2, +123 cells/mm^3 during year 3, and +120 cells/mm^3 during year 4, and the median log viral load change from baseline during year 1 was −1.4 copies/mL, −1.30 copies/mL during year 2, −1.88 copies/mL during year 3, and −1.25 copies/mL during year 4.

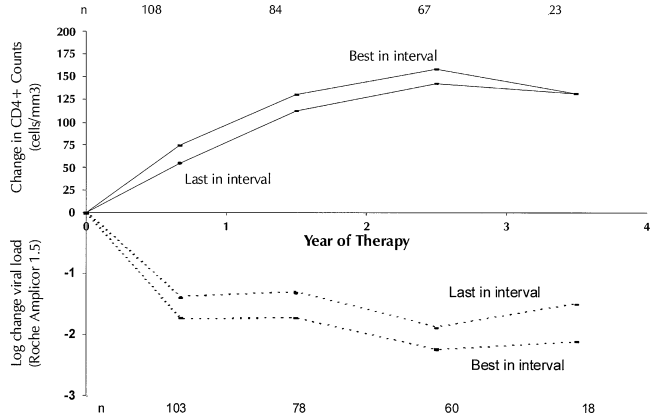

FIGURE 1. On-treatment analysis of change in $CD4^+$ cell count and viral load from baseline. Last in interval refers to the last value for either $CD4^+$ cell count or viral load if more than 1 was available. Best in interval is the best value in the interval. At baseline, a $CD4^+$ cell count was available for 116 patients and a viral load level was available for 117 patients. For persons who had an interruption in therapy of >1 year, only data before the interruption in therapy were included, which allowed us to exclude values for patients who had likely stopped therapy and restarted at a later date. The number of persons with observations available during each interval is indicated at the top for $CD4^+$ cell count and at the bottom for viral load. The positive side of the y-axis shows the absolute increase in CD4 cell count from baseline and the negative side of the y-axis shows the log change in viral load from baseline.

The characterization of $CD4^+$ cell count response demonstrated that the last response observed was in the acceptable, desirable, or optimal category for more than two thirds of patients in any year (Table 4). The percentage of persons who attained a viral load <400 copies/mL in any 1-year period since starting therapy ranged from 50% to 65% (Fig. 2). Those with a viral load less than 1000 copies/mL ranged from 56% to 71%, and those with a viral load less than 10,000 copies/mL exceeded 70% in all time periods. Those with a viral load >10,000 copies/mL ranged from 22% to 29%. In a separate analysis of virologic response done by calendar time, regardless of whether it was before or after an interruption in therapy, the number of patients who attained a viral load <400 copies/mL in 1998 was 0 (0%) of 7, 33 (41%) of 81 in 1999, 58 (49%) of 118 in 2000, 80 (58%) of 137 in 2001, and 74 (64%) of 116 in 2002.

DISCUSSION

This model of care developed at St. Francis Hospital, Nsambya, of an HIV clinic integrated into the general functioning of a hospital outpatient clinic system has operated and managed patients for more than 4 years. A major challenge to patient care has been the many patients who became lost to follow-up either immediately after the initial visit or later during follow-up and the many patients known to have died. This combined to result in a net probability of remaining alive and in care that was modest by years 3 and 4. Regardless, in an on-treatment analysis, those who survived

TABLE 4. Categoric $CD4^+$ Cell Count Response

	Months			
	3–12	**13–24**	**25–36**	**37–48**
Baseline $CD4^+$ cell count Response*	Last in interval [n (%)]			
	N (%)	N (%)	N (%)	N (%)
<50 cells/mm^3				
Optimal	7 (18)	11 (38)	11 (44)	3 (50)
Desirable	20 (51)	13 (45)	11 (44)	2 (33)
Acceptable	0 (0)	0 (0)	0 (0)	0 (0)
Undesirable	12 (31)	5 (17)	3 (12)	1 (17)
	N (%)	N (%)	N (%)	N (%)
≥50 cells/mm^3				
Optimal	23 (33)	27 (49)	22 (52)	10 (59)
Desirable	15 (22)	7 (13)	6 (14)	1 (6)
Acceptable	17 (25)	9 (16)	8 (19)	3 (18)
Less desirable	9 (13)	6 (11)	5 (12)	2 (12)
Undesirable	5 (7)	5 (9)	1 (2)	1 (6)

*See Table 2 for definitions of response. A total of 116 patients had a $CD4^+$ cell count at baseline from which a response could be calculated.

†The last value in the interval if more than 1 was available. The best value in the interval was within +7% of the best value for all categories (data not shown).

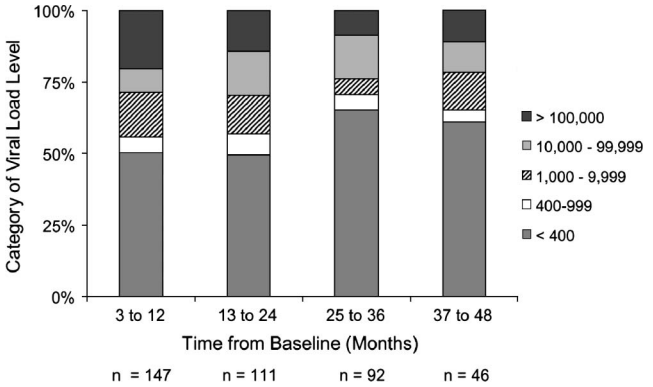

FIGURE 2. Percentage of viral load level by time from baseline. The last value in the interval if more than 1 was available. The best value in the interval was within +10% of the best value for all categories (data not shown). There are more observations for this analysis of viral load than for the log change in viral load (see Fig. 1), because a baseline value is not needed for this analysis. Viral load values are presented as copies/mL.

and remained on therapy derived long-term virologic and immunologic responses to ARV drugs, despite many having accessed therapy at an advanced stage of illness. These results extend earlier 1-year response findings[5] at one of the centers that started with the Uganda/UNAIDS DAI in 1998 and demonstrate that the long-term laboratory responses to ARV drugs among patients in Africa can be realized in a manner similar to that in clinical practices in industrialized countries.[13,14]

There are unique challenges to be addressed to provide AIDS care and keep patients in care in a fee-for-service model. First, the decision to operate the HIV clinic in an integrated manner, as opposed to a parallel self-supported or donor-supported entity, was made to safeguard the clinic against default should clinic income or donor support waiver. Second, patients pay for care out-of-pocket, which drives decisions about which drugs are preferred, the frequency and types of laboratory monitoring, and the frequency of medical visits. Shortly after prices of ARV drugs declined in December 2000, most patients were switched to HAART regimens, and NNRTI-based HAART was preferred because there were more substantial price reductions for those drugs. Likewise, a shift in the preferred NRTI combination occurred (data not shown), because companies offered price decreases at different times. Of interest was the observation that many patients had an interruption in therapy for more than 1 year and later returned. Although we did not record the reason for returning for care, the dates returning coincide with the price reductions of late 2000 and mid-2001, suggesting that affordability of medications was of high importance to patients. Of note, many of these patients were considered to be lost to follow-up or as having stopped therapy in our earlier report,[5] highlighting the dynamic nature of observational clinical data and underscoring the importance of a functioning HIV clinic to which they could return. Third, whereas the use of counselors and other support staff may be a major part of a program in public sector programs,[15] it is often harder to provide these services in the private sector. If not provided from a parallel source, the funds to hire support staff would need to be recouped through higher prices for services or drugs. Fourth, because of cultural and privacy concerns, some patients in a fee-for-service setting may not want to meet with staff other than the doctor. These latter 2 challenges combine to result in the need for the doctors to spend a great deal of time with many patients or being unable to spend sufficient time with each patient.

Our evaluation of laboratory response was limited by the frequent occurrence of patients experiencing interruptions in therapy for more than 1 year, resulting in diminishing numbers of data points over time. Our strategy of presenting an on-treatment analysis would be expected to bias the findings in a positive manner, because those who survive and remain on therapy are presumably those doing the best. Most of the analysis was done during a time period when patients were receiving HAART and is an aggregate of all patients, which provides an accurate representation of what occurred for the entire cohort. Restricting the analysis to only those who initially started on HAART may have yielded better outcomes; however, the management by the physicians reflected their best judgment at the time for individual patients, considering the constraints of available drugs and costs. Lastly, we do not know the status of the patients who did not return after the initial visit or those later lost to follow-up, although it is plausible that some of these patients may have accessed ARV drugs from other centers or private physicians in Uganda. Regardless, the number of deaths reported is likely not complete.

The results of the evaluation of this fee-for-service model in Uganda for access to ARV therapy highlight the constraints of keeping patients in care and the high mortality among patients accessing ARV therapy at an advanced stage of HIV disease. Nevertheless, it is encouraging to find that those who manage to stay on therapy can derive demonstrable long-term benefits in Africa in a manner that would be expected in industrialized countries. Many persons would be unable to access care from a fee-for-service clinic, and public sector models are increasing; however, incentives to support fee-for-service practice models to enable those patients who access ARVs in this manner, which would enhance retention in care, should be further explored in the African context. A simplified and standardized approach to ARV therapy has been suggested and is being adopted in many public sector programs.[16] Such an approach may be attainable in the private sector as well now that ARV prices have declined. Where patients are paying for care out-of-pocket, however, any future cost reductions would be expected to influence practice, because the market typically demands the lowest priced quality products available. The challenge of reducing the burden on those with sufficient income to afford treatment in the private sector requires adequate access to trained providers, stabilization of costs for drugs and laboratory monitoring at a level that is manageable to clients, as well as an increase in the support services available. We need not wait until all foreseeable obstacles have been overcome; as is increasingly called for[17] and with adequate resources, we can continue to implement and expand effective programs and bring treatment to people living in the countries with the worst HIV epidemics in the world.

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