The Effect of Community-Based Support Services on Clinical Efficacy and Health-Related Quality of Life in HIV/AIDS Patients in Resource-Limited Settings in Sub-Saharan Africa

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Abstract

Antiretroviral therapy (ART) for HIV/AIDS in developing countries has been rapidly scaled up through directed public and private resources. Data on the efficacy of ART in developing countries are limited, as are operational research studies to determine the effect of selected nonmedical supportive care services on health outcomes in patients receiving ART. We report here on an investigation of the delivery of medical care combined with community-based supportive services for patients with HIV/AIDS in four resource-limited settings in sub-Saharan Africa, carried out between 2005 and 2007. The clinical and health-related quality of life (HRQOL) efficacy of ART combined with community support services was studied in a cohort of 377 HIV-infected patients followed for 18 months, in community-based clinics through patient interviews, clinical evaluations, and questionnaires. Patients exposed to community-based supportive services experienced a more rapid and greater overall increase in CD4 cell counts than unexposed patients. They also had higher levels of adherence, attributed primarily to exposure to home-based care services. In addition, patients receiving home-based care and/or food support services showed greater improvements in selected health-related QOL indicators. This report discusses the feasibility of effective ART in a large number of patients in resource-limited settings and the added value of concomitant community-based supportive care services.

Introduction

With the growing efforts to scale up medical treatment programs for HIV/AIDS in resource-limited settings, there is a need for operational outcomes research studies to determine the effectiveness of nonmedical community support services on improving health in patients receiving antiretroviral therapy (ART). The World Health Organization (WHO) has recommended a public health approach to ART to improve care in resource-poor settings.1 The essential components of the public health approach include simplified, standardized, first- and second-line ART regimens; equitable access to care for all in need; simplified clinical decision making and standardized; simplified monitoring (e.g., using CD4 cell counts rather than HIV viral load measurements); decentralized, integrated...
delivery of care; and ART provided free at the point of delivery. However, there are limited operational outcomes research studies to determine which approaches are effective in the field, which are not, and why.2,4

Several challenges compromise efforts to deliver ART in resource-limited settings. These constraints include not only the lack of health care infrastructure but also poverty and other social conditions that undermine patients’ ability to access services, adhere to a strict ART regimen, and derive optimal therapeutic benefit.3 Overall health can be influenced by multiple factors, including a person’s psychological, behavioral, and social well-being, as well as access to adequate nutrition. Studies have demonstrated an association between increased level of social support and reduced risk for physical disease, mental illness, and mortality.5,6 In particular, a minimum care package of community support provided in rural Malawi, including home-based care, support to family caregivers, adherence counseling, and defaulting tracing has been associated with better ART outcomes.6 Home-based support for ART may also aid in preventing HIV; an integrated ART and prevention program in rural Uganda was associated with reduced sexual risk behaviors among HIV-positive patients.7 There is increasing recognition of the potential for religious organizations to establish formal psychosocial support programs for those on ART.8 Religious organizations could provide spiritual support and guidance, as well as make referrals for other care services. Social support includes real or perceived resources provided by others that enable a person to feel cared for, valued, and part of a network of communication and mutual obligation.

The Community-Based Treatment Support Program Model

The Community-Based Treatment Support Program (CBTSP) was a multicenter, prospective, observational cohort study of HIV-infected individuals receiving ART who were provided with community-based supportive services designed to assess key patient outcomes and their determinants in a resource-poor, sub-Saharan African setting. The CBTSP is supported by the Bristol-Myers Squibb Foundation (BMSF) SECURE THE FUTURE program. The CBTSP model emphasizes that people living with HIV/AIDS in resource-limited settings need both clinical services and community support services to effectively enhance their quality of life (QOL) and clinical outcomes. Instead of focusing solely on ART as a means of reducing mortality rates, this model stresses the value of supportive services such as nutrition support and home-based care (HBC) to help people living with HIV/AIDS manage their chronic HIV disease outside the clinic and in their homes and communities. The program leverages the strengths of government, private-sector, and community-based organizations to offer a continuum of care. This continuum is composed of disease management, psychosocial support, and patient self-management that occurs in the patient’s home and community between medical care appointments in the clinic. The standard package of community-based services across sites and countries includes home-based care, food security, psychosocial support (positive living, nutritional advice, and support groups), buddy programs, tools for drugs literacy, prevention educations, orphans care, referrals for counseling and testing, income-generating activities, and other services. The model is delivered as a partnership involving the government, the private sector, and nongovernmental organizations (NGOs). All care providers involved in this approach act as members of an integrated implementation team, whether serving clients in the clinic or in the community.

By late 2002, four communities and primary hospitals were identified by each of the health ministries and departments to pilot the CBTSP model: Bobonong Primary Hospital, Bobirwa Sub District, Botswana; Senkatana Clinic, Maseru, Lesotho; Katima Mulilo Hospital, Caprivi Region, Namibia; and Ladysmith Provincial Hospital at Uthukela District in Kwa Zulu-Natal, South Africa. At each of the facilities, it was agreed that the government would invest in the sites and sustain the implementation after a 3-year start-up phase.

Other ART scale-up programs have also reported clinical efficacy in similar resource-limited areas.3,9–15 There are few studies, however, that have examined the effect of community-based support services on clinical outcomes of ART.16,17

We report here the 12- and 18-month results of the CBTSP prospective Enhanced Patient Evaluation (EPE) observational cohort study of coordinated community-based services integrated with clinical care and ART for previously treatment-naive HIV-infected patients.

Methods

Setting and study population

Beginning in 2004, HIV medical care was provided to HIV-infected, treatment-naive adults at four treatment sites that were established by the CBTSP in collaboration with government, NGO, and local community organizations in Maseru, Lesotho; Ladysmith, Kwa Zulu Natal, South Africa; Katima-Mulilo, Namibia; and Bobonong, Botswana.

All HIV-infected adult patients who initiated ART beginning in August 2005 at these sites were invited to participate in the Enhanced Patients Evaluation (EPE) observational cohort study. Patients interested in participating received the details of the study from the health facility staff and written informed consent was obtained from these patients. The study was approved by local ethics committees in each country and by the Family Health International (FHI) Protection of Human Subjects Committee. Patients received no incentive or compensation for participation in the study. The recruitment pe-

<table>
<thead>
<tr>
<th>Data collection instruments</th>
<th>Timing</th>
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<tbody>
<tr>
<td>HRQOL</td>
<td>Baseline and 3, 6, 12, 18 months</td>
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<tr>
<td>Adherence monitoring record</td>
<td>3, 6, 12, 18 months</td>
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<td>Stigma and discrimination</td>
<td>Baseline and 6, 12, 18 months</td>
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<tr>
<td>Baseline survey instrument</td>
<td>Baseline</td>
</tr>
<tr>
<td>Exposure to intervention</td>
<td>Baseline and 6, 12, 18 months</td>
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<tr>
<td>programming checklist</td>
<td></td>
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<tr>
<td>and satisfaction assessment</td>
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</table>

HRQOL, health-related quality of life.
period lasted for a period of 12 months (August 2005 to July 2006). Enrolled patients were then followed up over time for the next 18 months. The study period ended in February 2007.

**Study objectives**

The objectives of the EPE study were to document changes over time in patients’ clinical outcome as measured by CD4 cell count, health-related quality of life (HRQOL), and adherence to ART and to correlate these changes with exposure to community support programs. HRQOL and psychosocial assessments were conducted during the regular medical visits in each facility, which also coincided with the period of follow-up of the cohort. The longitudinal cohort design allowed for the monitoring of key patient indicators over time and examined the temporal relationship between exposure to supportive care services and the aforementioned outcomes variables. Perceived stigma and discrimination were assessed and will be the subject of a separate article.

**The community-based services**

Development and implementation of integrated community-based services are essential components of the CBTSP model. Before the delivery of services to patients, community needs assessment, community mobilization, and local organizational capacity-building, including infrastructure support specific to each local participating community, were undertaken. In preparation for coordinated and integrated services delivery, CBTSP developed a community treatment support guidance manual and a training regimen given by teams of government, NGO, and local community-based organizations and volunteers.

The CBTSP was conceived and implemented as a community-based participatory action. In order to engage a broad base of community partners in the CBTSP, STF staff conducted outreach through local governments and NGO associations and conducted education and planning sessions that (1) acquainted potential partners with the goals of the program and the model of integrated care; (2) encouraged organizations to see how their services and reach could become part of the community response to HIV/AIDS—even if they had never before been directed specifically to people affected by HIV/AIDS; and (3) facilitated adaptations of the CBTSP model to the local settings and resources and specified how partners would collaborate to provide well coordinated referrals and continuum of care. In this process and to enhance the multisectoral partnership, STF staff also provided technical assistance to the overall partnership and program in each CBTSP community and to individual NGOs for a range of needs including project development and management, expenditure responsibility, monitoring and evaluation, good clinical practice, and communications.

Community mobilization was critical to transforming an environment in which HIV-infected and -affected people are ostracized and stigmatized by other community members into one that is nurturing and conducive to positive behavior change. Community mobilization encouraged community members to come forward for testing and treatment—especially in communities in which treatment is being offered to the general population for the first time. Several techniques were used to mobilize the people of the communities to access the services of the CBTSP including public service announcements through television and radio, community events, drama, door-to-door campaigns, and workshops for community stakeholders.

The community-based support services provided to program participants included community mobilization, prevention education and outreach, voluntary counseling and testing, home-based health care, tracing of defaulting patients, support groups, positive-living workshops, food security and nutritional support, financial and income-generating support, and buddy services. All services were provided by experienced and trained community workers and volunteers. HBC was coordinated by nonprofit organizations and provided by caregivers, volunteers, and paid professional staff. All providers attended an HBC training course that prepared them to serve as patient companions, to pick up medications, to run errands, and to assist with the care related to opportunistic infections, adherence to ART, and management of ART side effects. An NGO based in Botswana (Coping Centre for People Living With HIV/AIDS [CO-CEPWA]) conducted buddy training.

**Data collection procedures**

Standardized data-collection instruments were used to collect enhanced patient outcome data during baseline and scheduled follow-up visits (Table 1). These instruments were translated into the local languages and tested before use in the field. Trained research assistants consisting of people living with HIV/AIDS already benefiting from the program, trained and supervised by FHI, collected the enhanced patient data. In each site, a research nurse, local research organizations, and the FHI technical support team monitored and supervised the data-collection activities. The use of PLWHA for the data collection had the advantage of increasing open responses to the questions without reservation from respondents, who are also AIDS patients; however, in turn it slowed down the recruitment of the cohort and the data collection period because of periodic absence due to sickness sometimes during the period of the study implementation. The research nurse and the local research organizations ensured the day-to-day data quality, and carried out the data collection when the research assistant was absent; FHI reviewed the data every month. A secured room was identified in each of the clinics where the research assistant could interview patients confidentially.

**Treatment outcome collected**

At baseline and every 3 months, HRQOL, treatment adherence and CD4 cell counts were assessed through questionnaires to patients and chart reviews. The study team piloted data-collection tools in each of the countries of concern before the data collection started. The QOL questionnaire was based on the validated WHO standardized questionnaire and consisted of 21 questions that assessed 9 dimensions of HRQOL, including overall health, general health perceptions, physical functioning, role functioning, pain, social functioning, mental health, energy, and cognitive functioning. In addition, the baseline survey also assessed sociodemographic characteristics of the patients.

Drugs included in the most common regimens varied slightly by country. In Lesotho, Swaziland, and Namibia the drugs used were stavudine, lamivudine, and efavirenz or
Table 2. Background Characteristics

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Botswana</th>
<th>Lesotho</th>
<th>Namibia</th>
<th>South Africa</th>
<th>Regional</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>M</td>
<td>F</td>
<td>All</td>
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<tr>
<td>Number</td>
<td></td>
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<td>Baseline 3 months</td>
<td>46</td>
<td>101</td>
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<td>6 months</td>
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<td></td>
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</tr>
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<td>15–24</td>
<td>0.0</td>
<td>9.0</td>
<td>6.2</td>
<td>11.1</td>
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<td>25–34</td>
<td>28.3</td>
<td>39.0</td>
<td>35.6</td>
<td>33.3</td>
<td>39.6</td>
</tr>
<tr>
<td>35–44</td>
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<td>35.0</td>
<td>34.2</td>
<td>40.0</td>
<td>34.0</td>
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<td>45+</td>
<td>39.1</td>
<td>17.0</td>
<td>24.0</td>
<td>15.6</td>
<td>17.9</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
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<td>Mean, years</td>
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<td>36.8</td>
<td>36.7</td>
<td>35.5</td>
<td>36.1</td>
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<td>Range: youngest, oldest</td>
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<td>20, 74</td>
<td>20, 75</td>
<td>16, 55</td>
<td>20, 60</td>
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<td>Education: % distribution</td>
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<td></td>
<td></td>
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<tr>
<td>Never attended school</td>
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<td>20.0</td>
<td>20.9</td>
<td>2.2</td>
<td>0.0</td>
</tr>
<tr>
<td>Primary school</td>
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<td>40.0</td>
<td>44.6</td>
<td>46.7</td>
<td>41.5</td>
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<tr>
<td>Secondary and above</td>
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<td>40.0</td>
<td>34.5</td>
<td>51.1</td>
<td>58.5</td>
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<tr>
<td>Total</td>
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<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
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<tr>
<td>Marital status</td>
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<td></td>
<td></td>
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<tr>
<td>Married</td>
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<td>16.8</td>
<td>19.7</td>
<td>52.3</td>
<td>40.6</td>
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<td>Cohabiting</td>
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<td>14.3</td>
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<td>Never married</td>
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<td>61.4</td>
<td>53.7</td>
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<td>20.8</td>
</tr>
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<td>5.0</td>
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<td>6.8</td>
<td>17.0</td>
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<td>Widowed</td>
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<td>6.9</td>
<td>7.5</td>
<td>20.5</td>
<td>21.7</td>
</tr>
<tr>
<td>Total</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
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</tr>
</tbody>
</table>

F, female; M, male.
nevirapine; in Botswana they were zidovudine, lamivudine, and efavirenz or nevirapine.

Health-related quality of life. HRQOL was analyzed at each scheduled visit on the basis of responses to 21 questions concerning perceived limitations over the previous 4 weeks in overall health, general health, physical functioning, role functioning, pain, social functioning, mental health, energy, and cognitive functioning.

- Physical functioning: Physical functioning among participants was assessed by four survey questions that asked about their degree of limitation in the performance of physical activities (e.g., walking, working, and dressing). The response scale of possible responses was 4 to 12, with 12 representing no limitations.
- Social functioning: Social functioning among participants was assessed through 1 survey question that evaluated their degree of limitation in participating in social activities (e.g., visiting with family and friends). The scale of possible responses scale was 1 to 6, with 6 representing no limitations.
- Cognitive functioning: Cognitive functioning (e.g., maintaining attention, reasoning, problem solving) was assessed by three questions, reported on a scale of 3 to 18.
- Emotional well-being: Three survey questions assessed the participant’s emotional well-being (e.g., feeling sad or happy), on a scale of 3 to 18.
FIG. 3. Changes by exposure to community services. (A) Change in overall health-related quality of life (HRQOL) by exposure to community services. (B) Changes in cognitive functioning by exposure to community services. (C) Changes in emotional well-being by exposure to community services.
• Energy and fatigue: Two survey items assessed energy and fatigue perceptions (e.g., having enough energy to do the things you want to do), on a scale of 4 to 12.
• General health: The general health of participants was assessed through 1 survey question, on a scale of 1 to 5.

Adherence to ART

Participant adherence to ART was assessed through patient self-reporting and pill counts. Good adherence was considered to be an adherence rate of 95% or more. If a patient was prescribed medication to be taken twice a day, 95% adherence was defined as missing no more than 3 doses per month. For adherence based on pill count, the following formula was used:

\[
\text{adherence} = \frac{\text{[pills dispensed} - \text{returned pills]}}{\text{number of days} \times 2 \text{ pills per day}} \times 100
\]

“Returned pills” represents the number of pills remaining in the bottle or pack during the visit. “Number of days” in the formula is the number of days between the dispensing date and the return date of the pill bottle or pack.

Data analysis

Data were analyzed using Epi Info v. 6 and SPSS for Windows version 13.0 (SPSS, Chicago, IL). Analysis was performed first within each country program and then pooled across country program sites. Bivariate data analysis was conducted using \( \chi^2 \) tests for categorical variables and unpaired \( t \) tests and analysis for variance (ANOVA) for continuous variables. Multivariate data analysis was conducted using stratified analysis and linear logistic regression.

Results

A total of 587 patients initiating ART were enrolled in the study. The study period was from August 2005 to February 2007. The observational cohort consisted of 163 males and 424 females who were receiving regular medical care, including ART, in CBTS clinics in 4 countries in sub-Saharan Africa. The distribution of patients by country was fairly equal: Botswana, 147; Lesotho, 151; Namibia, 143; and South Africa, 146. Table 2 presents the background characteristics of study participants by country of enrollment. The overall median age of participants was 35, with 36 for males and 35 for females; 54.2% of participants had completed a secondary school or higher level of education, and 51.3% were not currently married.

At 18 months, there had been 47 deaths (12%). There were 10 transfers to other clinics. Eighty-three patients were lost to follow-up. Eighty-three patients were lost to follow-up (14%) and there were 70 patients for whom there were incomplete data on exposure to intervention. As a result, 210 patients were excluded from analysis. The total number of patients included in the analysis sample was 377 (64% of all patients initially enrolled in the study).

Exposure to community support services

Exposure to community support services refers to patients who reported having received the services in the previous 3 months. At 12 months, 41% of the study participants reported having been exposed to community-based support. The mean number of different services accessed by the participants was 2. Approximately 61% of the participants had been exposed to HBC, and 40% had been exposed to food package support (Fig. 1). Financial and income-generating support were the least used. Roughly one third of the participants reported being exposed to psychological and counseling support. There was a decline in the exposure to each of the community-based support services between the 12- and 18-month evaluation. The most notable declines were seen in HBC and food package support.

Family support

Participants were surveyed regarding the types of family support they received at baseline and at 6, 12, and 18 months. Most participants (n = 347) reported receiving family support consisting of encouragement and psychological support (71%) and physical care (66.5%) at baseline (Fig. 2). They reported receiving somewhat less financial support (48.9%) and undefined “other support” (1.6%). Family support of each type was reported among all participants to have increased at 6 months (22% exposed) and to have been sustained or increased further at 12 months (n = 429 and 41% exposed) and 18 months (n = 377, 33% exposed). There was a significant difference between family support reported at 6 and 12 months (p = 0.025), but not between 12 months and 18 months.

Health-related quality of life

The overall HR-QOL score for all participants at baseline was 49.35 (n = 587), and at 18 months it had increased to 56.6 (n = 377). The participants who reported receiving food support and/or HBC experienced a significant improvement in overall HRQOL at 18 months (57.3 versus 56.0; p = 0.010) compared with those not receiving those services (Fig. 3).

HRQOL domains

HRQOL scores at baseline and 18 months were compared for each of the five individual domains and for overall health. There were improvements for all participants in overall QOL and in each of the individual domains (Table 3).

Physical functioning. The mean score for overall physical functioning of all participants at baseline was 9.7. At 18 months, the mean score was 10.9, an improvement of 1.2 points. Among participants who received food services and/or HBC services, the physical functioning score increased above baseline at 12 months and was sustained at 18 months. Among those participants not receiving these services, the mean physical functioning score increased by 1.6 points to 11.2 at 12 months; at 18 months, the mean physical functioning score decreased to 10.6. The difference in points between those receiving community services and those not receiving services was significant (p = 0.003).

Social functioning. Social functioning scores improved from a baseline score of 5 to 5.6 at 12 months and were sustained at 5.6 at 18 months among all participants regardless of their receipt of community support services.

Cognitive functioning. Scores on the three-question cognitive functioning domain (scale, 3–18) increased significantly
from baseline (13.45) for all participants at both 12- and 18-month assessment times. There was a slight, but not statistically significant, change from 16.1 at 12 months to 15.9 at 18 months for those not receiving community support services (Fig. 4).

Emotional well-being. Emotional well-being scores among all participants \( (n = 377) \) increased from the baseline of 13.4 to 15.1 at both 12- and 18-month measurements (15.1). Receipt of community services did not affect emotional well-being scores (Fig. 5).

Energy and fatigue. Energy and fatigue scores improved significantly \( (p < 0.05) \) from baseline in both the group receiving food and/or HBC support and those not receiving services at 12 months; the improvement was sustained at 18 months. The overall improvement of QOL may be explained by the combination of interventions. The questionnaires were self-administered and may not reflect an objective assessment of the physical and overall health and well-being of the patients. However, it does reflect functional improvement felt by the patients during the time of the interview.

General health. The general health score for all participants improved significantly from baseline to 18 months (2.3 versus 3.7; \( n = 377 \) ), representing a 59% change \( (p = 0.009) \).

### Relationship between CD4 cell counts and exposure to services

The CD4 cell counts improved from baseline among all study participants at 12 and 18 months (Fig. 4), comparing those participants receiving community-based services in the last 4-week period with those who did not. It was found that the median CD4 cell count improvement was significantly greater among those participants who received the community services \( (n = 207) \) than in those who did not \( (n = 170) \). Those receiving services improved by 252 cells/mm\(^3\), from a median baseline of 129 to 381 cells/mm\(^3\) at 18 months \( (p < 0.05) \). By comparison, those not receiving services improved by 204 cells/mm\(^3\), from a median of 126 cells/mm\(^3\) at baseline to 330 cells/mm\(^3\) at 18 months. The increase in CD4 cells/mm\(^3\) from baseline to 18 months among participants receiving services was 51 cells/mm\(^3\) greater than in those not receiving services \( (p = 0.016) \). Multiple regression analysis, which controlled for several possible confounding variables (age, gender, baseline CD4 count, secondary schooling, etc.), determined that receipt of community services was the significant factor associated with the increased CD4 cell count improvement \( (n = 416; \ p = 0.005) \). Those community-based services found to be most highly correlated with the CD4 cell improvement were HBC and food support.

The benefit of HBC and/or food support on the improvement in CD4 cell counts was greater when CD4 cell counts

<table>
<thead>
<tr>
<th>Domain</th>
<th>Physical</th>
<th>Social</th>
<th>Cognitive</th>
<th>Emotional</th>
<th>Energy</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline ( (n = 587) )</td>
<td>9.68</td>
<td>5.0</td>
<td>13.45</td>
<td>12.96</td>
<td>7.78</td>
<td>49.1</td>
</tr>
<tr>
<td>18 months ( (n = 377) )</td>
<td>10.9</td>
<td>5.6</td>
<td>15.5</td>
<td>14.8</td>
<td>9.4</td>
<td>56.4</td>
</tr>
<tr>
<td>Difference</td>
<td>1.22</td>
<td>0.6</td>
<td>2.05</td>
<td>1.84</td>
<td>1.62</td>
<td>7.3</td>
</tr>
<tr>
<td>( p ) Value</td>
<td>0.543</td>
<td>0.525</td>
<td>0.783</td>
<td>0.783</td>
<td>0.1002</td>
<td>0.002</td>
</tr>
</tbody>
</table>

HRQOL, health-related quality of life.

**Table 3. Participants’ HRQOL Scores at Baseline and 18 Months**

**FIG. 4.** Trend in CD4 count for all patients by exposure to community-based interventions (home-based care [HBC] + food).
were compared among patients with baseline CD4 counts less than 50 cells/mm³ (Fig. 5). In these patients with more advanced disease, those receiving selected community-based services had a median CD4 cell count greater than 56 cells at 12 months than the patients not exposed to those services. The importance of this higher CD4 count at 12 months is that those with higher CD4 counts at 12 months reached CD4 counts greater than 200 cells/mm³ sooner than those not receiving community support. CD4 cell counts below 200 cells/mm³ are associated with significant morbidity, including susceptibility to opportunistic infections.

Adherence

Adherence was assessed among participants by two methods: participant self-report and pill count. Participants reported higher level adherence rates than were estimated by pill count. For example, at 18 months, the self-reported adherence rate among all participants (n = 377) was 97.6%, whereas the rate estimated by pill count was 64.1% (p < 0.01).

Adherence level was affected by receipt of community-based support services. At 12 months, participants receiving HBC and/or food support services had a higher rate of adherence (n = 52; 67%) than those who did not receive those services (n = 133; 58.2%; p = 0.027), as presented in Fig. 6. When analyzed for the effect of being exposed only to HBC and food security compared with those not exposed to community support services, it was found that HBC was associated with an adherence rate of 68.8%; adherence among those receiving no community services was 57.8% (p = 0.035).

Multiple regression analysis of the effect of being exposed to HBC on adherence at 12 months—when controlled for other variables, including gender, age, education, baseline CD4 cell count, and HR QOL—showed that HBC had a significant, independent, positive effect on CD4 count (p = 0.049) (Table 4). The data show (Fig. 6) that at 12 months, a greater proportion of the patients with exposure to community services had 90% to 95% adherence rates compared with those patients with no exposure to community services. They also show (Fig. 6) on the low end of adherence rates that there was a greater proportion of patients among those with no exposure

<table>
<thead>
<tr>
<th>Factor</th>
<th>B</th>
<th>Standard error</th>
<th>p Value</th>
<th>Exp(B)</th>
<th>95.0% CI for Exp(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has received home-based care</td>
<td>0.591</td>
<td>0.301</td>
<td>0.049</td>
<td>1.806</td>
<td>1.002 – 3.257</td>
</tr>
<tr>
<td>Has received food support</td>
<td>-0.265</td>
<td>0.302</td>
<td>0.381</td>
<td>0.767</td>
<td>0.424 – 1.387</td>
</tr>
<tr>
<td>Control factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &gt; 35 years</td>
<td>-0.074</td>
<td>0.262</td>
<td>0.776</td>
<td>0.928</td>
<td>0.556 – 1.550</td>
</tr>
<tr>
<td>Female</td>
<td>-0.215</td>
<td>0.273</td>
<td>0.432</td>
<td>0.807</td>
<td>0.472 – 1.378</td>
</tr>
<tr>
<td>Secondary schooling</td>
<td>-0.160</td>
<td>0.262</td>
<td>0.542</td>
<td>0.852</td>
<td>0.510 – 1.424</td>
</tr>
<tr>
<td>Baseline CD4 count</td>
<td>0.001</td>
<td>0.001</td>
<td>0.519</td>
<td>1.001</td>
<td>0.998 – 1.004</td>
</tr>
<tr>
<td>HRQOL increased between baseline and 12 months</td>
<td>-0.253</td>
<td>0.278</td>
<td>0.363</td>
<td>0.777</td>
<td>0.450 – 1.340</td>
</tr>
<tr>
<td>Constant</td>
<td>0.726</td>
<td>0.439</td>
<td>0.098</td>
<td>2.067</td>
<td></td>
</tr>
</tbody>
</table>

Variable(s) entered on step 1: HBC, food, age, gender, education, baseline CD4 cell count, changes in overall QOL.

HBC, home-based care; QOL, quality of life; HRQOL, health-related quality of life.

![FIG. 5. Median CD4 cell count for patients with less than 50 CD4 cells/mm³ at baseline by exposure to community services.](image-url)
to community services with adherence less than 70% than among those with exposure to community services.

In analyzing the association between CD4 counts and adherence at different times, there appears to be no discernable pattern characterizing the relationship between CD4 counts and adherence rates. Trends lines indicate no relationship between CD4 count and adherence at different time periods, except at 18 and 12 months.

In analyzing over time the relationship between adherence and CD4 counts among those exposed to HBC and food support versus those not exposed, a significant difference between the 2 groups is not demonstrated. As shown in Table 5, the same tendency is observed when comparing over time the change in CD4 counts among those who had been exposed to HBC and food support, but did not adhere and those who had not been exposed and did not adhere.

**Discussion**

The results of our study support the benefit of integrated, community-based supportive services and medical care for HIV-infected patients on both improved clinical outcomes and HRQOL indicators. They testify to the feasibility of providing decentralized, effective ART for a large number of patients in resource-limited settings and the added value of concomitant community-based supportive care services.

**Table 5.** Comparison of Median CD4 Cell Counts among Exposed who Adhere and Nonexposed who Adhere, and Exposed Adherent and Nonexposed Nonadherent

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Exposed to HBC &amp; food</th>
<th>Not exposed to HBC &amp; food</th>
<th>Rank sum p Value</th>
<th>Exposed to HBC &amp; food</th>
<th>Not exposed to HBC &amp; food</th>
<th>Rank sum p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline CD4</td>
<td>99</td>
<td>145.5</td>
<td></td>
<td>100</td>
<td>127</td>
<td></td>
</tr>
<tr>
<td>6 month CD4</td>
<td>245</td>
<td>242</td>
<td></td>
<td>170</td>
<td>238</td>
<td></td>
</tr>
<tr>
<td>Change in CD4</td>
<td>157</td>
<td>120.5</td>
<td>0.136</td>
<td>108.5</td>
<td>112</td>
<td>0.908</td>
</tr>
<tr>
<td>6 month CD4</td>
<td>199</td>
<td>263</td>
<td></td>
<td>218.5</td>
<td>243</td>
<td></td>
</tr>
<tr>
<td>12 month CD4</td>
<td>324</td>
<td>335.5</td>
<td></td>
<td>290</td>
<td>319</td>
<td></td>
</tr>
<tr>
<td>Change in CD4</td>
<td>56</td>
<td>67</td>
<td>0.998</td>
<td>96</td>
<td>48</td>
<td>0.248</td>
</tr>
<tr>
<td>12 month CD4</td>
<td>359</td>
<td>329.5</td>
<td></td>
<td>326</td>
<td>336.5</td>
<td></td>
</tr>
<tr>
<td>18 month CD4</td>
<td>419</td>
<td>361</td>
<td></td>
<td>422</td>
<td>356</td>
<td></td>
</tr>
<tr>
<td>Change in CD4</td>
<td>42</td>
<td>65</td>
<td>0.909</td>
<td>21</td>
<td>17</td>
<td>0.112</td>
</tr>
<tr>
<td>Baseline CD4</td>
<td>131</td>
<td>137</td>
<td></td>
<td>113</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>12 month CD4</td>
<td>324</td>
<td>335.5</td>
<td></td>
<td>290</td>
<td>319</td>
<td></td>
</tr>
<tr>
<td>Change in CD4</td>
<td>158</td>
<td>202.5</td>
<td>0.297</td>
<td>169</td>
<td>190</td>
<td>0.298</td>
</tr>
<tr>
<td>Baseline CD4</td>
<td>116</td>
<td>132</td>
<td></td>
<td>124</td>
<td>129.5</td>
<td></td>
</tr>
<tr>
<td>18 month CD4</td>
<td>361</td>
<td>395</td>
<td></td>
<td>320</td>
<td>394</td>
<td></td>
</tr>
<tr>
<td>Change in CD4</td>
<td>224</td>
<td>266</td>
<td>0.301</td>
<td>171</td>
<td>260.5</td>
<td>0.473</td>
</tr>
</tbody>
</table>

HBC, home-based care.
Patients receiving medical care, including ART, who were exposed to concomitant community-based support services, when compared with patients not exposed to those services, reached higher CD4 cell counts and reached them more rapidly (particularly among patients with a baseline CD4 cell count less than 50), demonstrated improved HRQOL indicators, and achieved higher levels of treatment adherence at 12 and 18 months.

Participation in the scaled-up community-based services program was offered to all patients receiving medical care, including ART, for HIV infection at each of the four community treatment sites. Participation was entirely voluntary. Approximately 61% of the participants received HBC and 40% received food package support. Most participants also reported having received family support and encouragement, which increased during the course of the study and with which participants expressed general satisfaction. Roughly one third of the participants reported having been exposed to psychological and counseling support services. Financial and income-generating support services were found to be the least used. HBC and food package support were found to have the most effect on improved clinical and HRQOL indicators.

In this study, median CD4 cell counts, a primary indicator of HIV disease management, had improved significantly from baseline to 12 and 18 months among all participants. However, among those participants receiving community-based food and HBC services, the median CD4 cell count improvement was significantly greater than for those who did not receive those services. The benefit of HBC and food support on the improvement in CD4 cell counts was found to be greater in patients with baseline CD4 counts less than 50 cells/mm³. In this group of patients with more advanced disease, patients receiving selected community-based services had a 56-cell–greater median CD4 cell count at 12 months than did the patients not exposed to those services. Also significant is that patients with less than 50 cells/mm³ at baseline who received HBC and food support improved clinically, reaching a CD4 cell count of 200 cells/mm³ more rapidly than those who did not receive those services.

These results are important for two reasons. First, they indicate that the efficacy of ART among patients receiving medical care in resource-limited, community-based health centers is comparable to the efficacy of ART in patients in developed countries. Second, they testify to the positive clinical enhancement effect that community-based support services can have when provided to patients receiving medical care for HIV/AIDS.

HRQOL in all participants receiving ART improved over the course of the 18-month study period. The mean overall HRQOL improved from baseline in all study participants, despite the finding of relatively high mean baseline values. When compared at 18 months, participants exposed to community-based services fared better than did those not exposed to support services.

Changes in some individual health domains could be correlated with exposure to community-based services. General health, social functioning, emotional well-being, and energy and fatigue scores improved in both groups at 12 and 18 months compared to baseline. On the other hand, physical functioning and cognitive functioning scores improved from baseline in both exposed and nonexposed groups at 12 months; however, at 18 months, these measures declined in the nonexposed group, whereas the improvement was sustained in the exposed group. At this time we have no explanation for the differential effect of community service exposure on some QOL measures, but not others.

The improvement in all of the assessed domains of HRQOL may be explained by the significant improvement seen in the clinical health indicator (CD4 cell count) of these patients. In addition, participants expressed satisfaction with family support and the community support services they received, which may have contributed to their perceptions of improved HRQOL.

Adherence with prescribed ART medication regimens is an essential factor in the durable suppression of HIV replication and the achievement and maintenance of improved clinical outcomes. High-level adherence (≥95% of all doses) is associated with reduced likelihood of drug resistance in HIV. Lower levels of adherence are correlated with loss of viral control and the emergence of drug-resistant mutations; there is no evidence that the risk of HIV drug resistance is any greater in resource-limited settings than in developed countries.

Although we did not investigate the markers for the development of drug resistance, we assessed the level of treatment adherence among participants using both self-reporting and pill count. Estimates of the rate of adherence were considerably lower based on pharmacy record analysis compared with estimates based on self-reporting. The average rate of adherence estimates by patient self-reporting from 3 months to 18 months was 96.3% (range, 95.2–97.6%); average adherence by pill count over the same period was 65.4% (range, 68.3–64.1%). Self-reported adherence is subject to desirability biases and overestimated by patients. This may explain the difference noted in this study. Adherence rates by self-reporting increased from 3 to 18 months, whereas rates based on pill count decreased. The adherence rate at 18 months by pill count data was 64.1%. There were no demographic characteristics that could be identified as determinants of higher or lower adherence rates. Exposure to community-based services, however, was significantly correlated with improved rates of adherence.

Adherence to ART in developed countries has been estimated to be 70% of patients (range, 53–93%) at the greater than 95% level, depending on the assessment method and the study population. Clinical studies have shown that similar high levels of adherence can also be reached in resource-limited settings. Adherence, often by patient self-reporting of recent missed doses, has been highly correlated with treatment efficacy. In a study of scaled-up study of 1308 patients in Malawi, self-reporting was found to be the best predictor of undetectable HIV viral load compared with pill count and a visual analogue scale. The pill count approach carries a number of strength and pitfalls. Patients may have saved their unused pills for later use or tossed them before returning the bottle because of social desirability or other reasons. An alternative to clinic-based pill counts are home-based pill counts, but these are labor intensive and usually reserved for research studies. The possibility of “pill dumping,” often observed during scheduled clinic-based pill counts is minimized by the unscheduled nature of the home visit. However, regardless of where the count actually takes place, information on timing of dosage and patterns of missed dosages is not
captured. Furthermore, anecdotally, some patients may have shared their medication with other patients who fear coming to health centers because of stigma issues.

A self-reported adherence rate of 88% was reported in a patient population with HIV in five treatment centers in Uganda. In a study of HIV patients in Soweto, South Africa, high-level adherence (>95%), measured by patient self-report, was observed in 88% of patients and was correlated with viral suppression and increased CD4 cell counts. The mean adherence, by pill count, was found to be 87.2% in a population of indigent African HIV-infected patients and was found to be a predictor of virologic control. Surprisingly, there appears to be no discernible pattern characterizing the relationship between CD4 counts and adherence rates. The question as to the reason why CD4 counts did not parallel adherence can be due to but not limited to the following: dichotomy between pill count approach adherence measurement and self reports; and stage of CD4 counts on which patients have started treatment. Several key factors have been associated with adherence in resource-limited settings. These include simplification of dosing and ART regimens, access to free medications, peer-driven treatment support and education programs, and decreased feelings of stigmatization, and a program of HBC.

Adherence to ART regimens is a critical component of treatment success. Common structural barriers to adherence include the high cost of antiretrovirals, lack of transportation, long distances to health facilities, and long wait times. Moreover, fear of disclosure, stigma, and lack of social support have been shown to play a significant role in low adherence—particularly in sub-Saharan Africa. Community-based care and support ART programs, more than programs based in health facilities, have the capacity to mitigate such social barriers in addressing the psychosocial needs of ART patients and their families.

HBC and food support have been shown here to be both the most widely used and the most influential community-based support service in improving the health and well-being of participants receiving ART. They have emerged as key factors in addressing the HIV/AIDS epidemic in Africa and other developing countries. Many participants preferred to receive care at home in a familiar and supportive environment. In addition to providing patient care, HBC provided an opportunity to educate families and communities about HIV/AIDS prevention and care. These opportunities are rare in resource-limited and hard-to-reach communities. In this study, we observed that HBC workers were instrumental in encouraging family and community members to come forward and seek voluntary counseling and testing and, if appropriate, access to ART. Furthermore, we observed that as the health of participants improved, they were no longer bedridden, and they depended less upon HBC (as well as food package support). Thus the role of the HBC worker changed to one of helping participants achieve a more fulfilling life, as well as assisting with medication adherence, the management of side effects, and finding or returning to work and social activities.

Limitations

There are several potential limitations to the study. Community-based services were broad and were offered to all participants. We did not assess the degree of participation in each of the various services or assess the effectiveness of delivery. Consequently, we were unable to correlate the degree of participation in community services with outcomes. Given the relatively small number of participants in each of the treatment sites, it is possible that small differences in study sites and populations that we were unable to detect might have had some effect on the study results. The non-randomized nature of the study may have resulted in the creation of a “control group” that was different from the study group in some respect that may have affected interpretation of the results. For example, those participants who did not receive community-based services may have chosen not to because they did not need those services. In addition, we did not assess the possible role of changing participant needs for different services over time.

An additional potential limitation of this study was the relatively high rate of participants who were lost to follow-up. However, loss to follow-up was taken into account in the design at the level of 20%, and the patients lost to follow-up registered here do not significantly affect the magnitude of changes and the level of power desired for the analysis.

Conclusions

We have shown that HBC and other community services, including food support, have a positive effect on HIV patients’ overall health, QOL, treatment adherence, and clinical outcomes in a resource-limited setting. We are aware of no other scaled-up ART medical program that has studied as broad a range of community-based support services to participants. The CBTSP model has demonstrated the positive effect of combining clinical HIV/AIDS care (including ART) with the provision of community-based support services in four resource-limited settings in sub-Saharan Africa.

The findings from this study suggest a significant positive association between CD4 counts, overall HRQOL, and ART adherence and overall community support. The association is still strong even when age, education, gender, and baseline CD4 counts are taken into account. This implies the added value of community support beyond just focusing on medical care. CBTSP support may have enabled communities to reach their own people, within the boundaries of the communities’ values and cultural norms, resulting directly in better health outcomes among patients exposed to community support. We believe that this study has demonstrated that there is a need for increased operational research on the essential community-based services that support patient outcomes in coordination with medical care for HIV infection. Further study is also needed to determine the cost effectiveness of different modalities of care and the broader effects of combined HIV clinical and community support services on HIV awareness, education, prevention, and community stigma. Finally, the evidence that HBC and food support tend to augment and sustain the numerous benefits of ART for HIV/AIDS patients in resource-constrained settings calls attention to the need for more precise and detailed information so that HBC and food support can be replicated effectively to manage the HIV/AIDS crisis.

Acknowledgments

In all of the settings mentioned, there is a partnership between community, state structures, and private enterprise (SECURE THE FUTURE). SECURE THE FUTURE is a program launched by Bristol-Myers Squibb Company (BMS).
and Bristol-Myers Squibb Foundation (BMSF) to support the development and evaluation of cost-effective, sustainable, and replicable models for providing care and support to people living with HIV/AIDS in Africa.

We would like to acknowledge the contribution of the clinicians, community service providers, governmental representatives, and NGOs for their hard work and support, the BMSF, and the following individuals associated with the local research organizations who participated in the data collection for this study: Lesotho (University of Lesotho): Dr. Lucy Makoe, Dr. M. Makoa, Mrs. Dikokole Maqutu, Ms. Siphiwe Nzima Nseke; Botswana (Matshelo Community Development Association [MCDA]): Ms. Pedzisani Mlothabhane, Ms. Tinaye Mmusi, Mr. Tshologanyo Kaisara, Mr. Keabetswe Ramatheketh; Namibia (Social Impact Assessment and Policy Analysis Corporation [SIAPAC]): Dr. David Cownie, Mr. Randolph Mouton, Mr. Eric Afrikaner, Mr. Ricky Kavura; South Africa (Project Support Group [PSG]): Ms. Louise Henderson, Mr. M. Sesing, Mr. K. Hlatshwayo.

Author Disclosure Statement

P.M. reports that she is an employee of BMS and is a Program Director for SECURE THE FUTURE. A.T. reports that he is an employee of SECURE THE FUTURE. P.D., B.M., and A.S. report that they are employees of BMS. S.W. reports that he was an employee of BMS at the time of the study and now works for a nonprofit organization supported in part by BMS and the BMSF. I.K., J.B., G.E., W.O., P.N., N.M., E.A., J.B., A.H., T.M., A.K., J.M., N.Z., N.S., and R.S. report no conflicts of interest.

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