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## HIV Care & PMTCT in Resource-Limited Settings

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prepared by the Bordeaux Working Group

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Apondi R, Bunnell R, Awor A, Wamai N, Bikaako-Kajura W, Solberg P, Stall RD, Coutinho A, Mermin J. **Home-based antiretroviral care is associated with positive social outcomes in a prospective cohort in Uganda.** *Journal of Acquired Immune Deficiency Syndromes* 2007;44(1):71-6.

**Abstr.** BACKGROUND: Home-based antiretroviral therapy (ART) care in Africa has expanded; but social outcomes of home-based ART programs are unknown. METHODS: Social experiences of participants in an antiretroviral therapy program involving weekly home visits in Uganda were assessed through interviews at enrollment and after 3 months and analyzed using generalized estimating equations. RESULTS: Of 654 participants, 72% were women; median baseline CD4 cell-count was 123 cells/ $\mu$ L. At follow-up, participants were more likely to report community support (adjusted odds ratio [OR] 2.10, 95% confidence interval [CI]: 1.46 to 3.03,  $P < 0.001$ ), family support (OR 2.65, CI: 2.01 to 3.49,  $P < 0.001$ ), and relationship strengthening (OR 2.10, CI: 1.46 to 3.03,  $P = 0.001$ ) than at baseline; 84% attributed these experiences to antiretroviral therapy program participation. There was no change in incidence of negative experiences ( $P = 0.3$ ). Forty-six percent of women reported a history of partner abuse, but abuse rates 3 months before and after program initiation were low (1% vs. 2%, OR 3.20, CI: 0.94 to 10.9,  $P = 0.063$ ). Of five women who reported abuse associated with program participation, all had history of domestic violence. Of all participants reporting outcomes associated with antiretroviral therapy program participation at follow-up, 464 (79%) had only positive experiences, 35 (6%) had both positive and negative experiences, and  $<1\%$  had only negative experiences. CONCLUSIONS: Participation in a home-based antiretroviral therapy program was associated with multiple positive social outcomes.

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Friedland G, Khoo S, Jack C, Lalloo U. **Administration of efavirenz (600 mg/day) with rifampicin results in highly variable levels but excellent clinical outcomes in patients treated for tuberculosis and HIV.** *Journal of Antimicrobial Chemotherapy* 2006;58(6):1299-1302.

**Abstr.** Objectives: Pharmacokinetic interactions between rifampicin and antiretroviral therapy (ART), including efavirenz, are problematic and need to be better defined to determine proper dose and to be correlated with short-term and long-term clinical outcomes. Patients and methods: Consenting patients with smear-positive pulmonary TB and HIV received once daily didanosine + lamivudine + efavirenz (600 mg), with rifampicin-containing TB regimen by directly observed therapy and self-administration at TB therapy completion. Trough efavirenz levels were measured by HPLC at 1, 2, 4 and 6 months while on rifampicin and after discontinuation. HIV and TB outcomes were monitored. Results: Twenty African patients were enrolled [15 female, mean age 31 years, baseline weight 59.4 kg (range 45-97), viral load 5.75 log<sub>10</sub> copies/mL and CD4 230 cells/mm<sup>3</sup>]. Seventy-two efavirenz concentrations were available from 19 patients (58 on, 14 after rifampicin). The geometric mean efavirenz concentration was 1730 ng/mL (range 354-27 179) on and 1377 ng/mL (range 572-3975) off rifampicin ( $P = 0.55$ ). Inter-subject variability in efavirenz concentrations was greater on rifampicin (CV 157% versus 58% off) with relatively consistent intra-subject variation over time (median CV 24%). Over half of patients had efavirenz concentrations above or below the expected therapeutic range (1000-4000 ng/mL). Efavirenz levels were not predicted by weight or gender and were not associated with HIV clinical outcomes. Overall 80% of patients had non-detectable viral loads at 6 months and 65% at 21 months with a cumulative CD4 cell increase of 196 cells/mm<sup>3</sup>. Conclusions: In this longitudinal study, despite wide variability in plasma efavirenz concentrations during rifampicin administration, excellent clinical outcomes were obtained. In African patients treated for HIV and TB, our data support the routine use of efavirenz at 600 mg/day when receiving rifampicin.

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Leroy V, Sakarovitch C, Viho I, Becquet R, Ekouevi DK, Bequet L, Rouet F, Dabis F, Timite-Konan M. **Acceptability of formula-feeding to prevent HIV postnatal transmission, Abidjan, Cote d'Ivoire: ANRS 1201/1202 Ditrane Plus Study.** *Journal of Acquired Immune Deficiency Syndromes* 2007;44(1):77-86.

**Abstr.** OBJECTIVE: To describe the maternal acceptability of formula-feeding proposed to reduce postnatal HIV transmission in Abidjan, Cote d'Ivoire. METHODS: Each consenting HIV-infected pregnant women, age > or =18 years, who received a perinatal antiretroviral prophylaxis was eligible. Two hierarchical infant-feeding options were proposed antenatally: exclusive formula-feeding or short-term exclusive breast-feeding. Formula-feeding was provided free up to age 9 months. Determinants of acceptability were analyzed using a logistic regression. Formula-feeding failure was defined as having breast-fed one's child at least once. RESULTS: Between March 2001 and March 2003, 580 women delivered: 97% expressed their infant-feeding choice before delivery; 53% chose formula-feeding. Significant prenatal determinants for refusing formula-feeding were: living with her partner, being Muslim, having a low educational level, being followed in one of the study sites, having not disclosed her HIV status, and having been included within the first 6 months of the project. Among the 295 mothers who formula-fed, the Kaplan-Meier probability of success of the formula-feeding option was 93.6% at Day 2 (95% confidence interval [CI]: 90.7% to 96.3%) and 84.2% at 12 months (95% CI: 79.9% to 88.5%): 46 of 295 (15.6%) women breast-fed at least once, of whom 41% temporarily practiced mixed-feeding at Day 2 because of social stigma or newborn poor health. CONCLUSIONS: In settings with general access to clean water, structured antenatal counseling, and sustained provision of free formula, slightly over half of HIV-infected women chose to artificially feed their newborn infant. Low mixed-feeding rates were observed. This social acceptability must be balanced with mother-child long-term health outcomes to guide safe recommendations on infant-feeding among HIV-infected women in African urban settings.

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Lockman S, Shapiro RL, Smeaton LM, Wester C, Thior I, Stevens L, Chand F, Makhema J, Moffat C, Asmelash A, Ndase P, Arimi P, van Widenfelt E, Mazhani L, Novitsky V, Lagakos S, Essex M. **Response to antiretroviral therapy after a single, peripartum dose of nevirapine.** *New England Journal of Medicine* 2007;356(2):135-47.

**Abstr.** BACKGROUND: A single dose of nevirapine during labor reduces perinatal transmission of human immunodeficiency virus type 1 (HIV-1) but often leads to viral nevirapine resistance mutations in mothers and infants. METHODS: We studied the response to nevirapine-based antiretroviral treatment among women and infants who had previously been randomly assigned to a single, peripartum dose of nevirapine or placebo in a trial in Botswana involving the prevention of the transmission of HIV-1 from mother to child. All women were treated with antenatal zidovudine. The primary end point for mothers and infants was virologic failure by the 6-month visit after initiation of antiretroviral treatment, estimated within groups by the Kaplan-Meier method. RESULTS: Of 218 women who started antiretroviral treatment, 112 had received a single dose of nevirapine and 106 had received placebo. By the 6-month visit after the initiation of antiretroviral treatment, 5.0% of the women who had received placebo had virologic failure, as compared with 18.4% of those who had received a single dose of nevirapine (P=0.002). Among 60 women starting antiretroviral treatment within 6 months after receiving placebo or a single dose of nevirapine, no women in the placebo group and 41.7% in the nevirapine group had virologic failure (P<0.001). In contrast, virologic failure rates did not differ significantly between the placebo group and the nevirapine group among 158 women starting antiretroviral treatment 6 months or more post partum (7.8% and 12.0%, respectively; P=0.39). Thirty infants also began antiretroviral treatment (15 in the placebo group and 15 in the nevirapine group). Virologic failure by the 6-month visit occurred in significantly more infants who had received a single dose of

nevirapine than in infants who had received placebo ( $P < 0.001$ ). Maternal and infant findings did not change qualitatively by 12 and 24 months after the initiation of antiretroviral treatment. **CONCLUSIONS:** Women who received a single dose of nevirapine to prevent perinatal transmission of HIV-1 had higher rates of virologic failure with subsequent nevirapine-based antiretroviral therapy than did women without previous exposure to nevirapine. However, this applied only when nevirapine-based antiretroviral therapy was initiated within 6 months after receipt of a single, peripartum dose of nevirapine. (ClinicalTrials.gov number, NCT00197587 [ClinicalTrials.gov]).

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Manosuthi W, Kiertiburanakul S, Phoorisri T, Sungkanuparph S. **Immune reconstitution inflammatory syndrome of tuberculosis among HIV-infected patients receiving antituberculous and antiretroviral therapy.** *Journal of Infection* 2006;53(6): 357-63.

**Notes:** Manusuthi et al in a retrospective study conducted in Thailand on 167 patients co-infected with HIV and TB, report on the incidence, risk factors and mortality rate of Tuberculosis Immune Reconstitution Inflammatory Syndrome (TB IRIS). The interest of this article lies in the fact that there is currently an increasing use of highly active antiretroviral therapy (HAART) in resource poor countries often with a high burden of TB, associated with late presentation of patients with advanced disease, which in the long run will result in large numbers of very immunocompromised patients receiving HAART and thus at risk of developing IRIS. However the determinants of IRIS occurrence in patients with TB remain unknown, with limited clinical data allowing creating clinical guidelines. The first reports describing TB associated IRIS were published in 1998 with frequencies varying between 29%-36% amongst the various studies however mostly retrospective in design<sup>1</sup>. IRIS results from the rapid reversal in immune function with an exaggerated inflammatory immune response to an opportunistic pathogen during immune restoration<sup>2</sup>. The difficulty of diagnosis results from the absence of a clear-cut definition, lack of diagnostic tools and clear guidelines for the clinical management as well as the need to exclude alternate diagnosis such as non TB related illnesses, drug toxicity or treatment failure (drug resistance, non compliance to TB treatment)<sup>3</sup>. Although most patients present short-lived minor clinical problems, this syndrome can also be associated with significant morbidity and the authors point out that physicians running ART programmes worldwide need to be aware of the occurrence of the determinants of IRIS. In the largest cohort study to date, the authors describe the baseline characteristics of patients with and without IRIS. IRIS occurred in 12.6% of coinfecting patients on ART and TB treatment with a median CD4 cell count of 36 (15-69) cells/mm<sup>3</sup>. There was an 8-fold higher risk of having IRIS in those with extrapulmonary TB ( $P < 0.0001$ ). However in this study the authors did not find that an increment of CD4 cell count was associated with IRIS as was shown in previous reports<sup>14</sup> Other findings in previous reports<sup>1</sup> have shown an association of IRIS with lower CD4 cell count, higher viral load (VL) before ART, greater reduction in VL<sup>6</sup> and higher increment of CD4 cell count as well as initiation of HAART during the first 2 months of TB treatment. In an article by Lawn and al<sup>1</sup> where 27 papers on IRIS were reviewed, median duration of TB treatment was 8 weeks (IQR: 5.5-11.5 weeks) with a nadir CD4 of 51 (IQR: 26-103 cells/microl). Lawn<sup>1</sup> also found that lymphadenopathy was the most frequent manifestation of IRIS (71%) followed by the development or deterioration of parenchymal lung disease (28%). Possible bias exist in reported cases in the literature whereby cases occurring soon after initiation of HAART are more readily attributed to IRIS than those occurring remotely<sup>1</sup>. The authors in this paper conclude that strategies should be devised to identify patients at risk of IRIS as well as to prevent IRIS in patients about to commence antiretroviral therapy, stressing the need to carefully screen for TB before commencing HAART<sup>7, 8</sup>. This raises the important issue of the optimal timing between antiretroviral and anti tuberculosis treatments and clinical trials are needed to help physicians better understand when to initiate HAART in severely immunocompromised patients in the context of TB and adequate guidelines resulting from prospective studies are needed to identify TB IRIS risk factors<sup>9</sup>.

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Nattrass N. **South Africa's "rollout" of highly active antiretroviral therapy - A critical assessment.** *Journal of Acquired Immune Deficiency Syndromes* 2006;43(5):618-623.

**Abstr.** The number of people on highly active antiretroviral therapy (HAART) in South Africa has risen from < 2000 in October 2003, to almost 200,000 by the end of 2005. Yet South Africa's performance in terms of HAART coverage is poor both in comparison with other countries and the targets set by the government's own Operational Plan. The public-sector HAART "rollout" has been uneven across South Africa's nine provinces and the role of external assistance from NGOs and funding agencies such as the Global Fund and PEPFAR has been substantial. The National Treasury seems to have allocated sufficient funding to the Department of Health for a larger HAART rollout, but the Health Minister has not mobilized it accordingly. Failure to invest sufficiently in human resources-especially nurses-is likely to constrain the growth of HAART coverage.

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Pozniak AL, Gallant JE, DeJesus E, Arribas JR, Gazzard B, Campo RE, Chen SS, McColl D, Enejosa J, Toole JJ, Cheng AK. **Tenofovir disoproxil fumarate, emtricitabine, and efavirenz versus fixed-dose zidovudine/lamivudine and efavirenz in anti retroviral-naive patients - Virologic, immunologic, and morphologic changes - A 96-week analysis.** *Journal of Acquired Immune Deficiency Syndromes* 2006;43(5):535-540.

**Abstr.** Background: in antiretroviral-naive patients, tenofovir disoproxil fumarate (TDF), emtricitabine (FTC), and efavirenz (EFV) demonstrated superior outcomes compared with fixed-dose zidovudine (ZDV)/lamivudine (3TC) and EFV through 48 weeks. Results through a 96-week extension phase are presented. Methods: In this randomized, open-label, noninferiority trial, 517 anti retroviral-naive HIV-infected patients received TDF, FTC, and EFV (TDF + FTC + EFV) or ZDV/3TC and EFV (ZDV/3TC + EFV). The primary

endpoint was the proportion of patients with an HIV RNA level < 400 copies/mL in patients without baseline nonnucleoside resistance. Results: Through week 96, significantly more patients receiving TDF + FTC + EFV achieved and maintained an HIV RNA level < 400 copies/mL (75% receiving TDF + FTC + EFV vs. 62% receiving ZDV/3TC + EFV; P = 0.004). There was a trend toward greater virologic suppression to < 50 copies/mL in the TDF + FTC + EFV group (67% vs. 61%; P = 0.16). The TDF + FTC + EFV group demonstrated a significantly greater increase in CD4 count (270 vs. 237 cells/mm<sup>3</sup>; P = 0.036). No patient developed the K65R mutation. Limb fat at week 96 was significantly greater in the TDF + FTC + EFV group versus the ZDV/3TC + EFV group (7.7 vs. 5.5 kg; P < 0.001). Conclusion: Over 96 weeks, the combination of TDF, FTC, and EFV was superior to fixed-dose ZDV/3TC + EFV for achieving and maintaining an HIV RNA level < 400 copies/mL and an increase in CD4 cells.

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Rey D, Krebs M, Partisani M, Hess G, Cheneau C, Priester M, Bernard Henry C, de Mautort E, Lang JM. **Virologic response of zidovudine, lamivudine, and tenofovir disoproxil fumarate combination in anti retroviral-naive HIV-1-infected patients.** Journal of Acquired Immune Deficiency Syndromes 2006; 43(5):530-534.

**Abstr.** Background: High rates of virologic failure have been reported in antiretroviral-naive patients receiving triple-nucleoside reverse transcriptase inhibitor (NRTI) combinations containing tenofovir disoproxil fumarate (TDF) with lamivudine (3TC) and didanosine or 3TC and abacavir (ABC). A regimen of once-daily zidovudine (ZDV), 3TC, ABC, and TDF showed an acceptable virologic success rate, however. Methods: This was a pilot prospective cohort study. Treatment-naive subjects were offered a fixed-dose combination of ZDV/3TC (300 mg/150 mg) twice daily and 300 mg of TDF once daily. Results: Fifty-one patients were enrolled between April 2002 and March 2005. At baseline, the median CD4 count was 230 cells/mu L (range: 23-425 cells/mu L), 20 (39%) of 51 subjects had CD4 counts of < 200 cells/mu L, the median HIV-1 viral load was 4.89 log (3.14 to > 5.87 log), and 24 (47%) of 51 subjects had a viral load > 5 log. The median follow-up was 12 months (range: 1 week to 38 months). On-treatment analysis showed a median HIV RNA load decrease of -1.7 log after 1 to 2 weeks of treatment and -2.41 log after 1 month, and 34 (89%) of 38 subjects had a viral load < 50 copies/mL at month 6, 21 (78%) of 27 at month 12, and 13 (81%) of 16 after 18 months (intent-to-treat results were 34 [72%] of 47 subjects, 21 [56%] of 36 subjects, and 13 [50%] of 25 subjects at months 6, 12, and 18, respectively). The median CD4 count increase at month 18 was 142 cells/mu L. Nine (17.6%) of 51 treatment interruptions for adverse effects were seen. Six viral failures occurred, including 2 with K65R mutations (alone or associated with Y115F and M184V). Conclusion: The combination of ZDV/3TC + TDF in treatment-naive HIV-infected subjects induces a rapid and sustained HIV-1 RNA decrease and is associated with a good immunologic response. No severe adverse events occurred. This triple-NRTI combination needs to be evaluated further.

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Rouet F, Fassinou P, Inwoley A, Anaky MF, Kouakoussui A, Rouzioux C, Blanche S, Msellati P. **Long-term survival and immuno-virological response of African HIV-1-infected children to highly active antiretroviral therapy regimens.** AIDS 2006; 20(18):2315-9.

**Abstr.** BACKGROUND: In Africa, facing the scaling-up of HAART, there is an urgent need to monitor accurately the long-term benefits of these lifelong treatments. METHODS: Survival and immuno-virological response were assessed for 78 children in the ANRS 1244/1278 Children's cohort (Abidjan, Cote d'Ivoire) who were enrolled from October 2000 for treatment with HAART and followed to September 2004. Initial HAART consisted of two nucleoside reverse transcriptase inhibitors with either nelfinavir (NFV) or efavirenz (EFV). For the comparison of immunological and virological responses, CD4 cell counts

and HIV-1 RNA viral load were assessed by performing time-point specific and longitudinal data analysis. RESULTS: At baseline, the median CD4 cell percentage was 7.5% and the median HIV-1 RNA viral load was 5.37 log<sub>10</sub> copies/ml. The survival probability was high (0.86 at month 42; 95% confidence interval, 0.77-0.92) with no difference according to whether the HAART regimen contained NFV or EFV. At 36 and 42 months of follow-up, an immune recovery was observed with median CD4 cell percentages reaching 23.1% and 24.8%, respectively, with no difference according to the HAART regimen (longitudinal data analysis). At the same time points, a sustained viral suppression was also obtained, with undetectable viral load achieving in 46.5% and 45.0%, respectively, regardless of whether the HAART regimen. CONCLUSION: This study demonstrates the durability of both clinical and biological response to HAART in African children.

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Saghayam S, Kumarasamy N, Cecelia AJ, Solomon S, Mayer K, Wanke C. **Weight and body shape changes in a treatment-naive population after 6 months of nevirapine-based generic highly active antiretroviral therapy in South India.** Clinical Infectious Diseases 2007;44(2):295-300.

**Abstr.** BACKGROUND: The nutritional and body shape response after the initiation of highly active antiretroviral therapy (HAART) in resource-limited environments has not been documented. In this environment, nutritional compromise is a common complication of human immunodeficiency virus (HIV) infection. METHODS: We conducted a prospective study of 190 HIV-infected patients who initiated a nevirapine-based HAART regimen. CD4+ T cell count, body weight, body mass index, anthropometry, and bioelectrical impedance data were collected prior to initiation of therapy and after 6 months of therapy. RESULTS: The mean age of participants was 35 years, 85% of participants were male, and 59% received stavudine as 1 of the nucleosides in their initial HAART regimen. The members of the cohort were malnourished before the initiation of therapy and had a mean body mass index of 20.1 (calculated as weight in kilograms divided by the square of height in meters). Overall, body weight increased a mean of 2.8 kg (range, -12.5 to 22.5 kg), and CD4+ T cell counts increased by a mean of 140 cells/mm<sup>3</sup>. Patients were stratified into those who lost weight (loss of >1 kg, 22%; n=41), those whose weight remained stable (19%; n=37), and those who gained weight (gain of >1 kg, 59%; n=112). Patients in all groups retained body shape symmetry and experienced no change in waist-to-hip ratio or regional body shape by anthropometry. CONCLUSIONS: The group that lost weight and the group whose weight remained stable experienced significant CD4+ T cell count increases at 6 months. Although the majority of HIV-infected patients who received nevirapine-based HAART gained weight, there were participants who lost weight despite initiating their first HAART therapy.

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Szyld EG, Warley EM, Freimanis L, Gonin R, Cahn PE, Calvet GA, Duarte G, Melo VH, Read JS. **Maternal antiretroviral drugs during pregnancy and infant low birth weight and preterm birth.** AIDS 2006;20(18):2345-53.

**Abstr.** OBJECTIVE: To determine the relationship between maternal antiretroviral regimens during pregnancy and adverse infant outcomes [low birth weight (LBW) and preterm birth]. The a priori hypothesis was that protease inhibitor (PI)-containing regimens are associated with an increased risk of LBW and preterm birth. DESIGN: Prospective cohort study of HIV-1-infected women and their infants (NISDI Perinatal Study). METHODS: Data were analysed from 681 women receiving at least one antiretroviral drug [in order of increasing complexity: one or two nucleoside reverse transcriptase inhibitors (1-2 NRTI), two NRTI plus one non-nucleoside reverse transcriptase inhibitor (NNRTI) (HAART/NNRTI), or two NRTI plus one PI (HAART/PI)] for at least 28 days during pregnancy, and who delivered live born, singleton infants with

known birth weight and gestational age by 1 March 2005. Multivariable logistic regression modeling was used to assess the relationship of maternal ART with LBW and with preterm birth, adjusting for covariates. RESULTS: The incidence of LBW and preterm birth, respectively, was 9.6% and 7.4% (1-2 NRTI), 7.4% and 5.8% (HAART/NNRTI), and 16.7% and 10.6% (HAART/PI). There was no statistically significant increased risk of LBW [adjusted odds ratio (AOR), 1.5; 95% confidence interval (95% CI), 0.7-3.2] or preterm birth (AOR, 1.1; 95% CI, 0.5-2.8) among women who received HAART/PI compared with women receiving 1-2 NRTI. CONCLUSIONS: Among a population of HIV-1-infected women in Latin America and the Caribbean, maternal receipt of PI-containing ART regimens during pregnancy was not associated with a statistically significant increase in risk of LBW or preterm birth.

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**Free Full Text:** <http://www.who.int/hiv/pub/casestudies/Botswana2006.pdf>

Zachariah R, Teck R, Buhendwa L, Fitzerland M, Labana S, Chinji C, Humblet P, Harries AD. **Community support is associated with better antiretroviral treatment outcomes in a resource-limited rural district in Malawi.** Transactions of the Royal Society of Tropical Medicine and Hygiene 2007;101(1):79-84.

**Abstr.** A study was carried in a rural district in Malawi among HIV-positive individuals placed on antiretroviral treatment (ART) in order to verify if community support influences ART outcomes. Standardized ART outcomes in areas of the district with and without community support were compared. Between April 2003 (when ART was started) and December 2004 a total of 1634 individuals had been placed on ART. Eight hundred and ninety-five (55%) individuals were offered community support; white 739 received no such support. For all patients placed on ART with and without community support, those who were alive and continuing ART were 96 and 76%, respectively (P<0.001); death was 3.5 and 15.5% (P<0.001); loss to follow-up was 0.1 and 5.2% (P<0.001); and stopped ART was 0.8 and 3.3% (P<0.001). The relative risks (with 95% CI) for alive and on ART [1.26 (1.21-1.32)], death [0.22 (0.15-0.33)], Loss to follow-up [0.02 (0-0.12)] and stopped ART [0.23 (0.08-0.54)] were at (significantly better in those offered community support (P < 0.001). Community support is associated with a considerably lower death rate and better overall ART outcomes. The community might be an unrecognized and largely 'unexploited resource' that could play an important contributory role in countries desperately trying to scale up ART with limited resources.

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