



## Acute HIV Study Provides Improved Clinical Care, Counseling and HIV/AIDS Related Referral to Patients at UNC Project-Kamuzu Central Hospital Sexually Transmitted Infections Clinic, in Lilongwe, Malawi

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### Introduction

The Centre for HIV AIDS Vaccine Immunology (CHAVI) is conducting an acute HIV study (CHAVI 001) run by a consortium of academic institutions including Duke University and The University of North Carolina at Chapel Hill among others. The study aims at investigating transmission of HIV-1, host responses, and genetic factors that determine transmission and viral set point. The study enrolls subjects with acute HIV infection and their sexual partners, as well as subjects with established HIV and HIV negative controls. The University North Carolina (UNC) Project in Lilongwe, Malawi is a participating site, based at UNC Project in the Kamuzu Central Hospital sexually transmitted infections (STI) clinic which the Project runs in collaboration with Ministry of Health.

Research studies are always faced with questions from participating communities or stakeholders regarding the "benefits" provided by the study. There are fears that some research is conducted only for academic curiosity and not to produce useful information or benefit the long term care of participating individuals or communities. Our research has helped inform clinical decisions for participants and improved the medical care provided while meeting study objectives.

During 30 months of study implementation, the Lilongwe site has observed several benefits associated with the study. The Ministry of Health provides space and some STI drugs while the project provides additional supplies and medications in the STI clinic. In addition, project personnel provide all clinical STI services. STI clinics in Malawi generally do not offer HIV routine HIV testing irrespective of the national policy. The reasons for not implementing this important policy decision include lack of capacity such as personnel, space and staff training. Since the CHAVI study relies on people who know their HIV status, strategies were instituted in the Lilongwe site and successfully increased the uptake of HIV testing in the clinic. Our clinic's experience has affirmed the fact that HIV testing is indeed an entry point to care and support, and the CHAVI study served as a catalyst for such improvement.

### Methods

In preparation for the CHAVI 001 study, improvements in staff and infrastructure were undertaken in 2005 to improve the quality of services. Additional personnel were deployed to the clinic and included 8 nurses, 2 clinicians, 4 HTC counselors, 2 community educators, 2 data officers, 2 receptionists and 2 clinic aides.

Existing rooms in the STI clinic were partitioned and renovated to increase space and privacy for clients. 8 patient consultation rooms and 3 counseling rooms were partitioned and renovated. Staff trainings in topics such as the syndromic management of sexually transmitted infections, HIV testing and counseling and couples counseling were conducted for all nurses and clinicians to provide them with the required clinical competencies and counseling skills. These improvements enabled the increase in uptake of HIV testing and counseling through the routine offer of HIV testing to all clients. Study specific training also facilitated the appropriate linkage and referral of clients to other reproductive health and HIV/AIDS related services.

Clients receive group health education/counseling regarding HIV/AIDS, acute HIV infection and other STIs before they are examined. Those who consent to HIV testing and enroll onto the study receive additional counseling on risk reduction, safe sex practices, as well as periodic routine physical examinations and immunological evaluations including CD4 cell count and HIV viral load testing. IRB approval was obtained from the Malawi National Health Sciences Research Committee and all collaborating institutions.

### Results – November 2006 to June 2009

- Total new STI clients seen in the clinic was 16,073.
- 2056 (12.8%) reported having already tested HIV positive.
- 10,364 (73.9%) of 14,017 eligible participants accepted HIV testing.
- HIV prevalence at the Lilongwe STI clinic was 26.92%.
- 3,311 (43.7%) of 7,573 HIV negative and an additional 79 clients with discordant HIV rapid test results have been screened for the study
- Cotrimoxazole preventive therapy (CPT) is initiated promptly for study participants with a CD4 count below 500.
- All 78 of 109 HIV-infected eligible participants have initiated CPT.
- Study participants are promptly referred for initiation of ART if their CD4 count decreases below the 250 threshold beyond the acute phase of infection.
- 36 of 38 participants eligible for ART treatment were referred; 2 were lost to follow-up. Treatment source documents verified that 25 of 29 who reported starting ART had initiated ART; 7 participants reported having not started ART treatment with no clear reason given other than "I am yet to go".

Table 1. Demographic characteristics of enrolled participants

	Male	Female	Total
Acute HIV infections	39	12	51
Established HIV Infections	21	37	58
HIV Negatives	7	5	12
Partners to Acute HIV Infections	-	-	18
Total	67	54	-

• Among participants with established HIV, 22 have been started on ART.

• Three participants in the acute HIV infection arm were started on ART.

- No participants had clinical symptoms at ART initiation and decisions to treat were based on CD4 count.
- In six acute HIV participants, nadir CD4 rebounded above the threshold for CPT or ART initiation.
- In a high HIV prevalence setting, only 2 of 12 negative participants seroconverted.
- 100% of clients who tested HIV positive and did not enroll on CHAVI were directly linked to care and follow up services at various AIDS service organizations and/or sexual reproductive health care for psychosocial needs as appropriate.
- Every client in the STI clinic receives the appropriate care and/or referral as indicated.
- Good client satisfaction with STI care received has been confirmed via comments submitted through a suggestion box located in the clinic.
- Following implementation of the clinic's strategic improvements, clinic attendance has almost doubled. (Gift Kamanga, abstract, IAC 2008)

Figure 1. Patient Group Education



### Discussion

The importance of HIV testing cannot be overemphasized. It is only after learning one's HIV status that individuals can access and benefit from counseling and treatment interventions. Since the STI clinic is located in a high HIV prevalence setting, the strategy to increase HIV testing with the launch of the CHAVI 001 study in November of 2006 has facilitated the linkage to HIV care for thousands of clients newly diagnosed with HIV.

Every client who tests HIV positive in the STI clinic is referred to the AIDS Treatment Centre of Excellence (Light House clinic) located adjacent to the STI clinic, or to other centers for further counseling and treatment. While the CHAVI study lacks the capacity to perform CD4 counts on all routine clients attending the clinic, CD4 cell counts are obtained free of charge to all the HIV-infected subjects who enroll on the study.

Notably, 100% of study participants who started CPT and ART would have been denied these interventions in other care settings as they did not meet WHO clinical criteria at the time of initiation.

As in many high HIV prevalence settings, Malawi has observed a high mortality among HIV patients following ART initiation. Mortality following ART initiation is likely due to the high prevalence of advanced immunosuppression at ART initiation in Sub-Saharan Africa, as well as concurrent opportunistic infections. Given the high mortality among patients starting ART with advanced immunosuppression, interventions which increase earlier HIV diagnosis and prompt linkage to HIV care are critical.

As described, identifying patients with acute HIV infection permits the earliest possible diagnosis and access to counseling and treatment measures such as CPT and ART. In addition, many CHAVI participants report behavior changes following their diagnosis, including a reduction in the number of sexual partners and episodes of unprotected sexual intercourse. Such positive behavior change during the period of acute HIV is of public health importance given evidence that transmission during acute HIV infection accounts for a significant number of new HIV infections, especially among discordant couples.

### Conclusion

- **The CHAVI 001 study has fostered practical strategies to improve the quality of clinical care, HIV-related counseling and referral to HIV care services.**
- **A motivated and determined clinical team can utilize study resources to achieve high quality study results and simultaneously improve the routine clinical care provided.**
- **Sustained efforts to improve clinical care facilitates retention on study.**
- **Efforts to increase HIV testing in a high risk STI clinic has resulted in earlier HIV diagnosis and prompt referral to HIV care among clinic clients.**