WE BEGAN A JOURNEY
WE HAVE A DIRECTION
ARV TREATMENT MODEL IN RURAL UGANDA
INTRODUCTION AND BACKGROUND

The UGANDA CARES Initiative is a partnership of the Ministry of Health Uganda, Uganda Business Coalition on HIV/AIDS (UBC) and AIDS Healthcare Foundation (AHF)/Global Immunity. The name was derived from the World AIDS Day theme for the year 2001: “I CARE, DO YOU?” It was thus worked out as an anticipatory and positive answer to the question that the theme posed, thus the name “UGANDA CARES”.

In Uganda, the first AIDS cases were reported in 1981 at Kasensero village in the current Rakai District, formerly part of the greater old Masaka district. Choice and coincidence have it that the first treatment center of the UGANDA CARES Initiative got established in the same district believed to be the epicenter of the HIV/AIDS epidemic in the country. The Masaka Healthcare Centre is located at Masaka Regional Referral Hospital. Though currently limited in capacity, it brought one of the first rays of hope in providing ARV therapy in resource-constrained settings. It is just two decades since the HIV/AIDS epidemic started in Uganda. The epidemic is most prevalent in socio-economically disadvantaged communities, which make up the majority of the Ugandan population. It is estimated that just over 2 million Ugandan have been infected with HIV since the onset of the epidemic. Almost 1 million have died of AIDS, leaving 2 million orphans behind. It is believed that about 1.5 million people are currently living with HIV/AIDS. This has created great demand for medical care and support and further strained Uganda’s health delivery systems. The demand for ARV drugs and treatment for opportunistic infections rise everyday as more HIV-infected people progress towards advanced stages of HIV disease. It is estimated that about 10% of the HIV-infected population requires ARVs, but treating them with ARVs would decrease mortality by up to 80%.

Information disseminated by the Uganda AIDS Commission secretariat in June 2002 indicated a decline in national HIV prevalence rates from about 18.5% in 1995 to 6.1% in 2002. In spite of the decline in HIV prevalence, the challenge to provide care and ARVs for those already infected still exists. The majority of HIV/AIDS patients in Uganda cannot afford to pay for ARV drugs.

SUMMARY OF PROGRAM ACTIVITIES 2002

The year 2002 began with the continuing development of the key partnerships involved in the UGANDA CARES Initiative. This was at both the local and international levels. The main activity was the preparation for the clinic opening, which included renovations, refurbishing, staff training, consultative meetings, and procurement and acquisition of basic equipment and supplies to enable the clinic to become operational. These activities drew participation from UBC, AHF/Global Immunity, Masaka District Administration, Masaka Regional Referral Hospital, and all the other partners.

Under the UGANDA CARES Initiative, the Masaka Healthcare Center is operated as a collaboration between the key partners noted above as well as TASO Masaka, Kitovu Mobile Homecare Services, MRC, AID Child. The center is accredited by the Ministry of Health to provide ARV drugs.

The local partners and the Ministry of Health formed a steering committee to oversee and monitor the formative and ongoing stages of the initiative. The committee is chaired by the District Chairman, Mr. Vincent Sempijja, and Dr. Bernard Okongo, Medical Director of Masaka Healthcare Center, serves as secretary to this committee. The membership is comprised of representatives from all the local partners and officials of the Ministry of Health. Patient selection criteria were agreed upon and finalized by all the partners.

In the first two weeks of February 2002, patient selection and recruitment procedures began. The clinic was accredited as an ARV treatment center by the Ministry of Health in the first week of February after fulfilling the stipulated necessary requirements.

The first two patients to meet the selection criteria started treatment on 15 February 2002. Since then, patients meeting the criteria have progressively and cumulatively started on ARV therapy. The use of standardized criteria ensures that only patients referred by partners are seen at the clinic.

Three AHF HIV specialists were each sent for 4 weeks from AHF to train clinic staff and enhance the local capacity of the clinic. This was achieved by working together with the clinic staff in patient care and management. The Medical Director and Case Manager were recruited and have since been key in the day-to-day operation of the clinic and in providing patient care.

Throughout the year, patients have been recruited, monitored, and followed. The treatment center operates an outpatient clinic two days per week. Patients who require hospitalization are admitted for further care at Masaka Regional Referral or Kitovu Hospitals. The treatment package involves counseling with an emphasis on ARV treatment information and the importance of adherence. CD4+ count is the primary monitoring parameter. Blood is drawn every three months and the specimens sent to the Joint Clinical Research Center (JCRC) laboratory in Kampala for processing.
Medications are purchased from Medical Access Limited in Kampala and other key pharmaceutical companies. A system of stock inventory ensures proper drug management and accountability. The accounting firm Acclaim Africa Limited provides accounting services for the program, including accounts payable and receivables, to ensure independence and transparency of overall financial management.

THE PROGRAM GOAL
The goal of UGANDA CARES Initiative is to improve and accelerate access to life-saving, holistic, easily accessible and acceptable AIDS care and support services to socio-economically disadvantaged persons living with HIV/AIDS in resource-constrained settings.

OBJECTIVES
1. Provide standard ARV treatment to socio-economically disadvantaged people living with advanced AIDS;
2. Demonstrate that ARVs can be delivered effectively in resource-constrained settings in the developing world;
3. Identify determinants for treatment success and to the quality and cost-effectiveness of using ARVs;
4. Utilize and strengthening existing healthcare infrastructure for rapid scale-up of ARVs provision in Uganda
5. Develop a replicable and scalable model of HIV/AIDS clinical care appropriate to the safe and effective provision of ARVs in resource-constrained settings.

ACHIEVEMENTS
The UGANDA CARES Initiative was formally launched at a reception on 27th March 2002 at the International Conference Center in Kampala by the Minister of State for Health (General Duties), the Honorable Captain Mike Mukula and the Director General of Health Services, Professor Francis Omaswa.

- The Ministry of Health and AHF HIV specialists provided successful medical training and capacity building.
- As of February 2003, 100 patients are receiving standard and continuous antiretroviral therapy. Patients include 80 adults and 20 children. Fifty six are female and 44 male.
- Over 80% of these patients have registered remarkable improvement in their health and are living healthy lives once more. Average CD4+ count at start of treatment was 51 cells/mm^3. One year later it is 310 cells/mm^3.
- Partners have established an operational monitoring and referral system for patients with the two NGOs, TASO Masaka and Kitovu Mobile Homecare Services.
- Partners have held three successful management meetings since the inception of the program.
- Masaka Healthcare Center collects and manages data on patient progress, treatment adherence, laboratory monitoring, and medications.
- Ninety-seven percent adherence rate has been achieved over one-year with clients receiving continued support, education, monitoring and follow-up by TASO Masaka, Kitovu Mobile Homecare Services and Masaka Regional Referral Hospital VCT Unit.
- The program has demonstrated over the last year that ARVs can be provided effectively in resource-constrained settings, substantial clinical improvement can be achieved, and high levels of adherence maintained.

AND CHALLENGES
- The main challenge is accessing resources to scale up the program and treat larger numbers of patients. This would involve replicating the model by opening up treatment centers in other districts. The successful treatment of patients in Masaka District has created a higher demand that the program cannot currently meet.
- Despite ARV treatment, to date eleven patients have died. These deaths were attributed to advanced HIV disease and co-morbid conditions and none of them to ARV treatment complications.

FIRST- AND SECOND-LINE REGIMEN
- Choice of First-Line Regimens: d4T/3TC/Nevirapine or d4T/3TC/Efavirenz; In pregnant women, Nevirapine-containing regimen is used as a substitute for efavirenz-containing regimen
- Choice of Second-Line Regimen: AZT/ddI/Lopinavir/ritonavir

ELIGIBILITY FOR TREATMENT AND CARE
All patients recruited into the treatment program are accepted through established patient selection criteria. Both health and community considerations were included in developing the criteria. They are:
- Patients should be residents of Masaka District
- Patients be ambulatory
- Patients should come from a stable social network or family
- Patients should be ARV treatment naïve
- Adult patients should have a CD4+ count of 200 cells/mm^3 or less
- Pediatric patients should have CD4+ count of 25% of normal range per age or less
- Pediatric patients should have caretakers able to take responsibility for, consent to, and supervise their treatment
- Patients should not have an active major opportunistic infection
- Patients must be referred through TASO Masaka, Kitovu Mobile Homecare Services or Masaka Hospital VCT Unit
- Patients should have a known address/location for purposes of follow-up
- Patients must consent to treatment and be willing to comply with treatment schedules and follow-up procedures.
PATIENT MONITORING AND FOLLOW UP
A basic clinical examination is performed at every visit to the clinic, then the baseline CD4+ count and complete blood count is taken. Patients on ARVs are initially seen weekly for the first 4 weeks, then fortnightly for another 4 weeks, and then monthly if clinically stable and responding to the ARV regimen.

During follow up, the following indicators are recorded: CD4+ counts every quarter, body weight, blood pressure, patient’s level of activity, adherence to treatment, compliance with follow up, nutrition, and social, family, and reproductive health issues. Prophylaxis against Pneumocystis carinii pneumonia and toxoplasmosis is provided until the CD4+ count exceeds 200 cells/mm³.

INTERCURRENT ILLNESSES AND OPPORTUNISTIC INFECTIONS
We have observed a number of common illnesses among our clients. The table below gives a summary and the number of patients in which the illnesses was observed >

Eleven patients who have initiated ARV therapy have died, and all were attributed to advanced HIV disease and co-morbid conditions. The co-morbid conditions and the number of patients with them were >

THE PEDIATRIC COMPONENT
Treatment of children was initiated late last year with the recruitment of a local pediatric consultant. Since then the program has begun ARV therapy for 20 children. The partners also decided to treat children referred by AIDCHILD, an AIDS orphanage in Masaka. To date one child is under 3 years of age, two are from age 4 to 6, nine from age 7 to 12 and eight from 13 to 15. Five of the children are female and fifteen are male.

PATIENT ADHERENCE TO TREATMENT
The center has noted a high rate of adherence to treatment among its patients, more than 95%. This is attributed to:

- Highly motivated patients
- Symptomatic patients who, upon receiving ARV therapy, note the marked improvement in their health and thus understand the effects of therapy
- The availability of regular follow up by TASO and Kitovu Mobile.

RESPONSE TO TREATMENT
The following main health outcomes have been met:

- Average CD4+ count increase of 259 cells/mm³ after one-year treatment, from 51 to 310 cells/mm³
- Average weight gain of 11.3 kg for 76 patients treated beyond six months, from 45.3 to 56.6 kg
- Improvement in the activity status of the patients, based on the Karnofsky Performance Score, from an average score of 75 to 95 after 4 months of treatment
- Resolution of opportunistic infections in most patients after 6 weeks of treatment, except Kaposi’s sarcoma
- Average time to cessation of Pneumocystis carinii pneumonia and toxoplasmosis prophylaxis of 5 months.

THE MONITORING AND FOLLOW-UP PARAMETERS

<table>
<thead>
<tr>
<th>CLINICAL</th>
<th>IMMUNOLOGICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>BODY WEIGHT</td>
<td>CD4⁺ COUNT</td>
</tr>
<tr>
<td>PATIENT ACTIVITY</td>
<td>ADHERENCE</td>
</tr>
<tr>
<td>GENERAL CONDITION</td>
<td>CLINICAL PARAMETERS</td>
</tr>
<tr>
<td>PRESCRIPTION REFILLS</td>
<td>PATIENT ACTIVITY</td>
</tr>
<tr>
<td>SUPERVISION</td>
<td>VISITS</td>
</tr>
<tr>
<td>MISSED DOSAGES</td>
<td>CLINICAL ATTENDANCE</td>
</tr>
</tbody>
</table>

OBSERVED CONDITIONS

<table>
<thead>
<tr>
<th>NO. OF PATIENTS</th>
<th>ORAL THRUSH</th>
<th>MALARIA</th>
<th>UPPER RESPIRATORY</th>
<th>GASTRIC/DIGESTIVE DISORDERS</th>
<th>PERIPHERAL NEUROPATHY</th>
<th>SEBORRHEIC DERMATITIS</th>
<th>ABDOMINAL CONDITIONS</th>
<th>CONJUNCTIVITIS</th>
<th>DIARRHEA</th>
<th>GENITAL HERPES</th>
<th>HERPES SIMPLEX</th>
<th>HYPERTENSION</th>
<th>ARBITRARY/BULLS</th>
<th>HERPES ZOSTER</th>
<th>TOXOPLASMOSIS</th>
<th>PNEUMONIA</th>
<th>CRYPTOCOCCAL MENINGITIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO. OF PATIENTS</td>
<td>43</td>
<td>42</td>
<td>38</td>
<td>27</td>
<td>23</td>
<td>12</td>
<td>9</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>6</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

MEDICATION MISSED

<table>
<thead>
<tr>
<th>NO. OF PATIENTS</th>
<th>FOR 76 PATIENTS</th>
<th>ADHERENCE HAS BEEN ASSESSED BY PILL-COUNTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO. OF PATIENTS</td>
<td>74</td>
<td>MISSED 1-2 DAYS 2</td>
</tr>
<tr>
<td>NO. OF PATIENTS</td>
<td>0</td>
<td>MISSED 3-4 DAYS 0</td>
</tr>
<tr>
<td>NO. OF PATIENTS</td>
<td>0</td>
<td>MISSED MORE THAN 7 DAYS 0</td>
</tr>
</tbody>
</table>
UGANDA CARES Medical Staff
Dr. Bernardo Okongo, Medical Director
Dr. Monica Kizito, Pediatric Consultant
Sal. Hope Ketete, Case Manager

UGANDA CARES PARTNERS
Uganda Business Coalition on HIV/AIDS
Dr. Dickson Opul
Dr. Lydia Musgrovera
Mama Angelina Wapakhabulo
Ms. Rosanabe Namuyomba

AIDS Information Center
Dr. Emmanuel Hithina
Kitovu Mobile Homecare Services
Dr. Carla Simmons

Masaka Regional Referral Hospital
Dr. Nathan Kenya-Mugisha

The AIDS Support Organization (TASO)
Dr. Alex Coutinho

We gratefully acknowledge
the support and commitment of:
The President of Uganda
His Excellency Yoweri Museveni

The First Lady of Uganda
Mama Janet Museveni

Minister of Health
Honorable Brig. Jim Musvezi
Minister of State for Health (General Duties)
Honorable Capt. Mike Mukula, MP
Minister of State for Health (Primary Health Care)
Honorable Wabudeya Beatrice
The Ugandan Ministry of Health
Professor Francis Owissa
Dr. Elizabeth Madraa
Dr. Alex Opiyo

Masaka District Administration Chairman
Mr. Vincent Sempijja

Joint Clinical Research Center
Dr. Peter N. Muyebvvi

Medical Research Council Masaka
Dr. Anatoli Kamali
AID Child
Nathaniel Dunigan

AIDS Healthcare Foundation
Michael Weinstein
Charles Farthing, MD
Mary Adair, PA-C
Paul DenOuden, MD
Henry Masters III, MD

Special thanks to
The Patients at the Masaka Healthcare Center and Their Families
The People of Masaka
Elton John AIDS Foundation
Lara Freeman

For further information or to make a contribution
please contact

AHF Global Immunity
Keizersgracht 518
1017 EK Amsterdam
The Netherlands
www.ahfghi.org
+31 20 330 7063 Phone
+31 20 330 7062 Fax

Henry E. Chang
Executive Director
henryc@ahfghi.org

Anton Kerr
Director of Operations
antonk@ahfghi.org

Concept + Design / K Birnhollz Creative / www.kbirnhollz.com
DTP / Bire Grafische Vormgeving
Print production / Fokker Printing & More
Photo credits / Lara Freeman / Henry E. Chang