GAIA Vaccine Foundation Plan 2009

Executive Summary

Access to HIV and TB care is one of the most significant problems facing women and men living with HIV in West Africa. With the approval of the Ministry of Health, GAIA Vaccine Foundation (GAIA VF) VF is addressing this problem by setting up the first village-based HIV care and treatment clinic in Mali. This project, to be called **Projet Espoir/ Project Hope**, will focus on (1) TB and HIV outreach (identification of new TB and HIV) cases in the surrounding village, (2) TB and HIV case management, and (3) development of protocols and procedures for TB/HIV care in the village-based clinic setting. The end goal of the program is to develop a model that can be replicated and sustained in other village-based clinic settings in West Africa.

The village-based model for HIV care and treatment is a novel program in Mali. No CSCOMs in the region currently provide HIV care. Despite being novel, the GAIA VF **Projet Espoir/ Project Hope** initiative is supported by the national and local HIV programs (the HCNLS – Haut Conseil National pour la Lutte contre le Sida, CSLS – Cellule Sectorielle de la Lutte contre le Sida and the DRS – Direction Régionale de la Santé) who have identified "decentralization" as the next objective for HIV care in Mali. GAIA VF shares the HCNLS and CSLS belief - that village CSCOMs (village infirmaries), which are at the bottom of the health care delivery pyramid in Mali, are ideal sites for improving access to HIV care for the general population.

Why is it that the Malian government has given GAIA VF the opportunity to develop a model for the rest of Mali and Africa? According to Dr. Alou Sylla, head of the CSLS, GAIA VF has a proven capacity to deliver on promises. GAIA VF has been promoting HIV prevention through collaborations with Malian agencies since 2002. GAIA VF established the first CSCOM-based MTCTP program in Bamako in 2005. GAIA VF built an HIV care center in the Sikoro CSCOM in 2008. GAIA developed two peer outreach programs and has successfully evaluated their impact on knowledge attitudes and practices in the population. GAIA VF proposed to provide village level HIV care and treatment in 2007.

Malian government officials are convinced that GAIA VF's plans are consistent with the national HIV and TB programs. Dr. Alou Sylla gave official permission for GAIA to begin distributing ARVs in February 2009. In September 2009, Bristol Meyers Squibb "Secure the Future" program joined forces with GAIA, providing $70,000 in grant support for Project Hope for the next twelve months. These collaborators and government authorities will work with GAIA VF to **establish, describe, evaluate and transfer** the **Projet Espoir/ Project Hope** model to the 750 other CSCOMS in Mali. This document is intended to serve as a road map for that will allow us to attain that objective. Provided we follow the plan as outlined here, GAIA VF will be able to put access to TB and HIV care "at the reach of the patient's hand" in Mali, over the next few years. Until a vaccine to prevent HIV transmission is developed, here is no better means of stopping the HIV epidemic than making prevention methods and treatment accessible to the individual at risk.

GAIA Mission and History

The Global Alliance to Immunize Against AIDS Vaccine Foundation (GAIA VF) is a Rhode Island-based non-profit organization working in Bamako, Mali and in Providence, Rhode Island since 2002. Our mission is to promote HIV prevention, while we work to promote the development of globally relevant, globally accessible HIV vaccine that can be distributed on a not-for-profit basis in the developing world. The foundation activities are centered on four themes: education, prevention, access to care and vaccines. Through our active, ongoing collaborations with West African physicians and support for HIV-related clinical activities in the region, we work to improve the health of West African children and their parents, while setting the stage for ethical HIV vaccine trials.

HIV Treatment is an important component of prevention, because patients who are informed about their HIV status, who are on treatment (with lower viral loads) and who are receiving psychosocial support are less likely to transmit HIV.[i] It is also well known that improving access to HIV care in the developing world is cost effective.[ii] Furthermore, access to HIV care is one of the most significant barriers to HIV prevention worldwide. The importance of access was emphasized during the most recent IAS World AIDS meeting; less than 15% of HIV infected women world wide have access to MTCTP, and less than a quarter of people living with HIV infection in Sub-saharan Africa have access to HIV care. Until universal access is a reality, it is unlikely that HIV prevention activities will make much headway.

Mali is not usually considered a "high prevalence country". Despite this perception, there are many PLWH/A and few HIV-infected individuals have access to HIV care. To place the epidemic in perspective, there are almost as many PLWH/A in Mali, a country that is less than two times the size of Texas, as there are in the continental USA. Between 170,000 to 400,000 people are living with HIV in Mali (including more than 70,000 women).

Despite the recent expansion of access to HIV medications in Mali (with support from the Global Fund), access to the lifesaving medications remains limited. The number of HIV care "dispensers" who are allowed to prescribe HIV medications is limited (less than 40) and concentrated in Bamako, the capital city. Experienced HIV providers are isolated in academic centers within Bamako, leaving large numbers of HIV infected individuals in the capital city and rural countryside without care. Furthermore, HIV care and risk reduction efforts are hampered by a severe lack of successful management models, vehicles for the exchange of expertise, defined standards of care, and effective treatment algorithms.

Treatment for HIV and TB in peri-urban Mali, West Africa is also constrained by extreme poverty. Even though treatment for TB and antiretrovirals is free or low cost, and even though Malians are aware of the importance of HIV and TB treatment, few have the funds to pay for the fees and transportation costs that would allow them to access to the centers where these life-saving medications are distributed. Currently, only 18,000 of the estimated 180,000 Malians living with HIV infection have access to HIV care, and less than a third of TB cases are detected and treated on an annual basis.

National AIDS agencies in Mali, such as the HCNLS and the CSLS, have recognized the access to care problem and recently launched a "decentralization" effort (December 2006), but decentralization has only reached the level of the "center of reference" (community hospital or CsRef) in some communities. In the next phase of the national decentralization effort, the plan is to reach the level of the community-based clinic, or CSCOM, that remains the primary care center for 90% of Mali's peri-urban and rural poor. GAIA VF has been asked to set up one of the first HIV care programs in a CSCOM, as a part of this effort.

GAIA VF History and Experience in Mali

In **2005**, GAIA VF established a clinic-based peer discussion group for women and a Mother-to-child HIV transmission prevention program (MTCTP) in Sikoro, a resource-limited village within Bamako. Women could be tested for HIV and then provided with ARVs and artificial milk to prevent transmission. Over the past four years over 5,000 women have been tested, and more than 120 HIV-positive women given medications to prevent HIV transmission to their babies. Thus far no HIV transmission has been recorded among women attending the MTCTP program.[iii]

In **December 2006**, when the Malian national agencies HCLS (Haut Conseil pour la Lutte contre le SIDA) and CSLS (Cellule Sectorielle pour la Lutte contre le Sida) launched their decentralization effort to improve access to HIV and TB care. In the next phase of decentralization, the CSLS wishes to make HIV care available at the community-based clinic, or CSCOM, a format for healthcare delivery that currently serves as the primary care center for 90% of Mali's suburban, rural and poor population. In keeping with this national objective, GAIA VF began providing HIV care at the Sikoro CSCOM in 2006, and received permission from the CSLS to open the first CSCOM-based HIV medication distribution center in February 2009. In addition, GAIA established a peer education and outreach program "Here Bolo" in 2006 that now provides HIV prevention information directly to the villagers through peer education; in 2008, more than 10,000 condoms were distributed and 8,000 individual contacts were made.[iv] We found that HIV and STD testing requests increased as a direct result of this intervention.[v] A pilot program that combined TB cased detection with the peer outreach program was successfully carried out in October-November. We recently integrated the TB Bolo program into our activities at the Hope Center Clinic.

Between **2006 and 2008**, GAIA raised funds for the construction of a new HIV care center, the Hope Center Clinic (Bloc Espoir). Construction was completed in June 2008. This care center is located within the walls of the CSCOM in Sikoro.

On **February 2, 2009** the Hope Center Clinic became the first-ever village-based clinic in Mali approved to provide full access to HIV medications, an HIV specialist, specialty pharmacist, a peer educator and nutritional assistance, all within the village CSCOM walls. Funding for the "Project Hope" initiative would support this effort and allow GAIA to establish the protocols and procedures that could be replicated in other such centers in Mali and West Africa.

I. Project Framework

Project Overview	Indicators of Success	Monitoring & Evaluation
Strategic Area: HIV/TB case detection and care	(1) More HIV cases are detected (2) More TB cases diagnosed (3) More HIV/TB co-infected people will receive care. (4) Development of a set of protocols and procedures for HIV and TB care at other CSCOMS.	We have performed a baseline survey of HIV and TB (2008) with the local Department of Health (DRS). With the participation of the DRS, we will replicate this study in future years, using it to monitor the number of HIV,TB and dually infected patients identified and followed in our community annually.

Project Goal: To build an HIV/TB village-based clinic that is a model for Mali and West Africa		
Objectives: **HIV:** • Community Outreach • Detection • Access to Medication • Case Management • Adherence • Nutritional Support • Psychosocial support **Tuberculosis:** • Community Outreach • Detection • Access to Medication • Case Management • Adherence • Nutritional Support • Psychosocial support	**HIV:** (1) Our current patient load for HIV testing is 120. We expect a doubling of HIV cases to 240 in the first year and to 480 in the third year. We hope to reach all 800-1000 HIV-infected patients served by the CSCOM. (2) Using patient records, we can document the number of patients attending the clinic and track success in adherence and patient follow-up. (3) Since refills of medication will occur at the clinic, we can make reasonable estimates of adherence. Our HIV adherence educators will make contact with the families and provide support. **Tuberculosis:** (1) Less than 1-2 TB cases are detected per month at the CSCOM. We expect a doubling of TB cases to 4-6 per month in the first year and to 10 per month in the third year. We hope to improve the detection of TB to 70% of cases by the completion of the period of support. (2) We will track the TB cases with the assistance of the national TB program. (3) We will provide adherence assistance through the peer education program based at the Hope Clinic.	(1) Outcome measurements of success will include: • HIV and TB case detection rates • Number of HIV tests performed • Number of TB cases identified, • Number of TB and HIV patients followed at the CSCOM (2) Specific measurements of success in terms of HIV care will include: • Average CD4 T cell count, trends • Viral load trends (at 6 months and 12 months of follow-up), annual trends (3) Specific measurements of success in terms of TB care will include: • Sputum smear and culture results at midpoint and at completion of treatment • Chest X-Ray improvement at midpoint and completion of treatment • Number of TB cases completing treatment (4) The clinic's quality of support will be evaluated through a survey using a Likert scale. Our student-volunteers will conduct the survey in the summer 2009 and 2010. (5) An additional patient-based survey will be made to evaluate knowledge about TB among people attending the clinic.

II. General Approach

The CSCOM (Centre de Santé Communautaire) is the most basic unit of health care delivery in Mali –the most important means of reaching the average Malian at risk for HIV and TB. As described here, the **Hope Project** case management, outreach and home-based care program will address the problem of access to HIV and TB care by:

- Further development of existing TB/HIV peer educator programs "Here Bolo" and TB Bolo"
- Through peer outreach- education of at-risk individuals and referral for HIV and TB testing at the CSCOM.
- Reduction of the cost to the individual of TB and HIV screening and improving access to screening
- Reinforcement of staffing levels to levels appropriate for management of TB and HIV patients
- Training of CSCOM clinic staff in competent, compassionate HIV and TB care
- Material support for TB and HIV screening activities

Projet Espoir/ Hope Project Program activities will include the following:

- Peer education: Door-to-door HIV education and TB outreach program that will educate villagers about the availability of HIV and TB care and the need for such care;
- Free TB and HIV Testing and screening (tests provided by the national TB and HIV programs)
- Free TB and HIV care (medications provided by the national TB and HIV programs)
- Weekly nutritional support interventions for TB/HIV patients
- Clinic-based educational programs for patients about medication and medication adherence;
- HIV specialty clinic staffed by trained MD at CSCOM
- HIV specialty pharmacist and pharmacy at the CSCOM
- Medication Adherence plans (Year 2)
- Home delivery program (by Year 3) for antiretroviral therapy medications.

III. Similar programs

The HIV/AIDS epidemic has placed a large burden on public health facilities in developing countries that are already functioning with limited resources. This has shifted the burden of care to families and communities. A number of community/home-based care models and services have evolved in response to this need. For example, adherence intervention that included group education, personal adherence plans developed with trained counselors, a medicine companion, and weekly home delivery of antiretroviral therapy by trained lay field officers improved adherence and response to antiretroviral therapy in Uganda, in a resource-limited African setting.[vi] In a separate study, provision of home-based voluntary HIV testing and counseling to household members of people initiating ART was well accepted and resulted in the detection of a large number of previously undiagnosed HIV infections and HIV-discordant relationships.[vii] Home delivery of results revealed significantly higher demand to know HIV status than uptake figures from the past would have suggested.[viii] Several outreach programs that provide home-based care in Botswana have been developed with similar success.[ix]

In rural Swaziland, researchers have also found that community-based TB care was preferred to hospital care.[x,xi] In Tanzania, a collaboration between an HIV care NGO and state-based TB care agencies produced a successful home-based TB/HIV care program. TB case detection increased more than three fold. The study identified potential areas of collaboration and barriers – such as poorly trained staff - that need to be overcome so as to provide comprehensive services.[xii]

In summary, we believe that village based HIV/TB outreach and care plays a vital role in the care of people living with TB and HIV/AIDS. There is an urgent need for systematic research into the effectiveness of various partnership styles and strategies in West Africa. The Project Hope program is proposed as a valuable starting point for the development of improved HIV/AIDS and TB care networks and partnerships that are most likely to bridge the gap between National (Global Fund supported) HIV/TB care programs and local West African communities.[xiii]

IV. Collaborative Partnerships

GAIA Vaccine Foundation has been working in Mali since 2002. Initially GAIA Foundation-sponsored conferences on HIV/AIDS with the support of the Malian Ministry of Health, the Programme National de Lutte contre le SIDA (PNLS, now called the CSLS), UNAIDS Mali and Fondation Mérieux. This first conference in 2004 was followed by equally successful conferences held on January 2005, January 2006, and 2007. In 2005 GAIA began providing HIV care in the CSCOM context in collaboration with the local Department of Health (DRS) and the CSLS. In 2008, GAIA VF conducted a survey of Sikoro in collaboration with the Department of Health (DRS).[xiv] The objective of this study was to evaluate baseline levels of HIV knowledge and practices prior to a more extensive intervention. A random sample of 200 households from six sectors of Sikoro was selected to participate in an oral survey. Over a two-month period, trained interviewers of matched age and gender surveyed members of these households who gave their oral consent and recorded their knowledge of HIV, HIV transmission, and HIV prevention on a standardized form.

The Hope Center Clinic has recently been inspected by the national AIDS organization (CSLS) and the regional Department of Health (DRS). Our records and protocols have been audited and we are now approved as a “prescriptive center”. The final criteria for success in the long term will be the recognition of the Hope Center Clinic as a “model” for other clinics in Mali and the incorporation of the clinic into ‘Access to Prevention Funds’ and Global Fund operations. There is already strong interest from the Ministry of Health in scaling up the model we have developed for community level HIV care.

V. Projected Budget

	2009	2010	2011	TOTAL
Supplies				
HIV tests	5,000	5,000	5,000	15,000
Chest X rays (TB evaluation)	5,000	5,000	5,000	15,000
Clinical supplies (gloves, needles etc)	5,000	5,000	5,000	15,000
Office supplies (Charts, paper, copying)	3,000	3,000	3,000	9,000
Medication supplies (not supplied by DRS)	7,000	7,000	7,000	21,000
Equipment				
Laptop (data monitoring)	2,000	2,000	2,000	6,000
Portable incubator / coldchests	2,000	2,000	2,000	6,000
Software licenses	2,000	2,000	2,000	6,000
Travel				
RT Mali Providence Jan	2,000	2,000	2,000	6,000
RT Mali Providence June	2,000	2,000	2,000	6,000
RT Mali Providence September	2,000	2,000	2,000	6,000
RT Mali Providence December	2,000	2,000	2,000	6,000
Clinic Staff Salary (annual stipends)				
Nurse, Nurse midwife stipends	13,500	13,500	13,500	40,500
Office Rent	10,000	10,000	10,000	30,000
TOTAL	**$89,350**	**$89,350**	**$89,350**	**$268,050**

GAIA Fundraising revenue for most recent financial years (U.S. dollars):

2008: $120,000.

2009 to date: $ 90,000

A minimum of $90,000 per year is required to achieve the goals of the project outlined here.

Program evaluation would be possible with an additional funding of $10,000 to $20,000 per year.

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