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EVALUATION OF THE INTEGRATION OF ISONIAZID PROPHYLACTIC THERAPY (IPT) IN HIV/AIDS PREVENTION AND CONTROL PROGRAMS AT THE AIDS INFORMATION CENTER (AIC) UGANDA

FINAL REPORT

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EVALUATION TEAM MEMBERS

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OPERATIONAL DEFINITIONS

Screening for TB: This is a process of identifying patients with active TB from those who are HIV positive in the context of this report. The process involved administering a questionnaire, reviewing key symptoms of TB and examination for TB-related signs and, finally, performing specific laboratory tests, such as sputum examination for those likely to have tuberculosis.

PPD Test: This is a standard test also called a Mantoux or Tuberculin Skin Test (TST) which is used as an indirect indicator of exposure to the organisms that cause TB. In this test, 5IU of PPD (**Purified Protein derivative of Tuberculin**) are injected intradermally on the forearm, eliciting an immunological reaction which will manifest as an induration.

PPD Positive: If, after 48-72 hours, the induration elicited by the PPD test is measured and is equal to or more than 5mm in its widest diameter, this is interpreted as a positive PPD test. This means past exposure to TB.

PPD Negative: An induration of less than 5mm in diameter is considered negative.

INH Completion: According to the AIC program, an individual who receives the final dose of Isoniazid upon attending the fourth follow-up visit after seven months of treatment, is considered to have completed the IPT course.

ACRONYMS

AAFB	Acid Alcohol Fast Bacilli
AIC	AIDS Information Center
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV(s)	Antiretroviral(s)
BCG	Bacille Calmette Guerin
CBC	Complete Blood Count
CB-DOTS	Community Based Directly Observed Treatment
CDC	Centers for Disease Control and Prevention
CORPs	Community Resource Peoples
HC III	Health Center Grade III
HC IV	Health Center Grade IV
HCT	HIV Counseling and Testing
HIV	Human Immunodeficiency Virus
IEC	Information Education and Communication
INH	Isoniazid
IPT	Isoniazid Preventive Treatment/therapy
ITNs	Insecticide-Treated Nets
MEMS	Monitoring and Evaluation Management Services project
MoH	Ministry of Health
MU-CWRU	Makerere University Case Western Reserve University
N'TLP	National Tuberculosis and Leprosy Program
OIs	Opportunistic Infections
PMTCT	Prevention of Mother To Child Transmission
PPD	Purified Protein derivative of Tuberculin
PHAs	People with HIV/AIDS
QA	Quality Assurance
TASO	The AIDS Support Organization
TB	Tuberculosis
WHO	World Health Organization
USAID/U	United States Agency for International Development/ Uganda
VCT	Voluntary Counseling and Testing

EXECUTIVE SUMMARY

This is a report of a study designed and commissioned by the USAID/Uganda office to evaluate the integration of Isoniazid Prophylactic Therapy (IPT) in HIV/AIDS prevention and control programs at two centers—The AIDS Information Center (AIC) and the Makerere University – Case Western Reserve University (MU-CWRU) Research Collaboration. However, this report only presents findings from AIC due to the fact that the evaluation team was not permitted by MU-CWRU to review its IPT integration activities.

The purpose of this study was to determine the level of integration of IPT in HIV/AIDS prevention programs, evaluate the TB screening process, adherence and predictors for adherence, toxicity, monitoring of patients, quality, planning and any other program challenges.

The key evaluation questions of the study were:

1. What is the level of integration of IPT into HIV/AIDS and TB programs in general but specifically at AIC?
2. What are the challenges facing IPT integration into HIV/AIDS/TB programs?
3. What are the successes for IPT integration into HIV/AIDS/TB programs?
4. What are the factors that have to be considered if success is to be consolidated?

METHODOLOGY

Per the SOW (see Annex 1), the study was based on a descriptive cross-sectional survey and record review from the AIDS Information Center (AIC). In terms of sample size, HIV-positive clients who were enrolled and screened for TB from 2001 to 2006 and were currently attending the Center were included in the study. The evaluation team reviewed data in the AIC database for the unique individuals and interviewed service providers and managers at AIC, and some clients.

FINDINGS

- The integration of TB prevention programs into existing Voluntary Counseling and Testing (VCT) services has been scaled up to four branches – Kampala, Jinja, Mbale and Mbarara. The comprehensiveness of the services offered has improved with AIC offering VCT, IPT, malaria control, safe water, and family planning to HIV-positive clients.
- AIC's TB screening and follow-up protocols developed with partners including National Tuberculosis and Leprosy Program (NTLP) have been used to screen and follow up patients with increasing success. The AIC detection rate is 831 per 100,000 compared to the national average of 163 per 100,000.
- AIC's follow-up of clients for IPT has been limited to those undergoing treatment with no follow-up once treatment is completed. The benefits in the AIC-IPT project are based on the fact that IPT reduces the risk of tuberculosis by 67 percent in HIV-infected adults with a positive tuberculin test. These adults will be protected from active TB for two-three years (1).
- There are notable improving trends in IPT completion and drop out rates over the years 2001 to 2006.
- IPT is implemented with specialized full-time staff at AIC who screen clients for active or latent tuberculosis. The staff enrolls clients into the program and follows up with them at regular intervals.

CONCLUSIONS

- AIC has integrated TB prevention activities into its HIV Counseling and Testing (HCT) in the Kampala, Jinja, Mbale and Mbarara branches. At least 85 percent of all HIV-positive clients are screened for TB.
- AIC has offered IPT to 78.2 percent of clients found to have latent TB with an IPT completion rate of 78.1 percent. Currently, there is no long-term follow-up of clients who have completed IPT.
- AIC has integrated the diagnosis of active TB in all the branches that offer IPT but it is only the Kampala branch that offers treatment for active TB patients. The other branches refer their clients to other diagnostic and treatment units.
- AIC offers other basic care elements to clients on IPT and on TB treatment especially at the Kampala branch. However, there is minimal integration in the way these services are offered. The provision of services is carried out by different clinicians and not in an integrated manner.
- The program was challenged by periodic shortages of either Isoniazid, pyridoxine and PPD, or a combination of these, but managed to procure them to complete the program.
- IPT provision remains a domain of AIC and is a practice not well recognized by other health workers from the MoH headquarters to the lower level facilities.
- AIC has a database that helps the program effectively track and monitor IPT interventions.

RECOMMENDATIONS

- The AIC protocols used for TB screening are effective and should be adapted by interested agencies for TB screening programs across the country as part of a basic package of health care for HIV clients.
- Organizations or facilities planning to implement IPT should have reliable HCT services that offer same-day results for clients to be screened for IPT.
- A considerable investment is needed for facilities to capably implement IPT. They will need health workers who can be trained and devoted full-time to providing IPT services. They will need a system for procuring and properly storing PPD. And they will need medical officers in order to exclude active TB disease from the sputum-negative clients.
- AIC should endeavor to follow up and document details about all clients during and after IPT, particularly those who develop active TB. The Ministry of Health has developed a communication strategy and policy guidelines for TB/HIV collaborative activities that include IPT, but no guidelines for implementation. Therefore, an implementation strategy must be developed and supported to ensure effective scaling up of IPT.
- AIC should scale up IPT to its other branches.
- IPT-providing institutions should limit IPT services to facilities that have mechanisms for effective follow-up of their clients in their communities and have, or can ably integrate into, existing community support mechanisms.
- AIC and other organizations planning to implement IPT should consider mechanisms for long-term follow-up of clients who have completed the treatment phase
- In order to spread the importance of IPT, MoH-NTLIP should make information available throughout communities. In addition, health workers must be trained so they can knowledgeably inform clients about IPT.
- NTLIP should ensure that there are adequate supplies of Isoniazid (INH), they are packaged in blister packs for safe custody, and that IPT follow-up cards (similar to CB DOTS) are developed and supported to ensure a comprehensive follow-up of patients.

INTRODUCTION

The AIDS Information Center (AIC) was established in 1990 to provide VCT services and is currently the largest private VCT provider in Uganda. AIC has eight branches and 150 indirect sites, mostly in government health units. Through its network of branches and indirect sites, AIC tested about 240,000 clients in 2004. As part of a basic health care package for those that test HIV positive, AIC provides TB screening and IPT at four main branches – Kampala, Jinja, Mbale and Mbarara.

The USAID/Uganda office designed a study to evaluate the integration of Isoniazid Prophylactic Therapy (IPT) in HIV/AIDS prevention and control programs at two centers – The AIDS Information Center (AIC) and the Makerere University, Case Western University Research (MU-CWRU). The purpose of this study was to determine the level of integration of IPT in HIV/AIDS programs and evaluate the TB screening process, adherence and predictors for adherence, toxicity, monitoring of patients, quality planning and any other program challenges (see Annex 1 for the Scope of Work).

Makerere University, Case Western University Research has been collaborating in HIV/AIDS and tuberculosis research since the late 1980s. The MU-CWRU TB Clinic in Mulago provides IPT as part of their services and extends it to household contacts of TB patients. The HIV prevalence in household contacts under the care of the MU-CWRU TB clinic has been found to be 10¹ percent. Together, the AIC and MU-CWRU's Mulago clinic provide a large pool of HIV-positive clients and key entry points for integrating IPT.

PROGRAM THEORY

Opportunistic complications are primarily responsible for the morbidity and mortality associated with HIV disease.⁽¹⁾ These include TB, pneumonia, diarrhea diseases, meningitis, encephalitis, and wasting syndrome among many others. Tuberculosis (TB) is an early and serious complication of human immunodeficiency virus – type 1 (HIV) infection in the developing world, especially in Africa. Although HIV-infected patients with TB respond to effective anti-tuberculosis therapy, the course of their HIV disease is accelerated leading to increased morbidity and mortality compared to patients without TB. HIV infection is the greatest known risk factor for progression of primary tuberculosis infection and reactivation of latent tuberculosis infection. The development of active tuberculosis in HIV-infected individuals is associated with increased HIV replication, possibly mediated via enhanced cytokine expression (2), and shortened survival (3, 4). Tuberculosis is now the leading cause of death due to an identifiable infectious agent in patients with AIDS worldwide and accounts for approximately 40 percent of deaths worldwide. Dual infection has therefore, the potential to destabilize TB control efforts and catalyze the spread of drug resistant TB.

One of the greatest challenges in TB therapy is the development of an optimal regimen for treatment of latent TB infection in the HIV-1 infected population. Ideally, this treatment should confer long-term protection and its administration should be feasible from an operational standpoint other than research settings. Use of INH as a single drug is attractive but there are potential problems of non-adherence due to the long duration of therapy. Short-course Rifampicin containing preventive regimens have shown similar safety and efficacy compared to INH alone regimens (5, 6). However, because of the difficulty of reliably excluding active TB and therefore, the risk of generating drug resistance, WHO has been reluctant to recommend widespread use of Rifampicin-containing preventive therapy.

People living in Sub-Saharan Africa are at high risk of developing TB and can benefit from preventive therapy. The optimal regimen and duration of treatment of latent tuberculosis infection remains uncertain

¹ From the SOW (Annex 1).

Simple, low cost but accurate strategies to exclude active TB in PPD+ve HIV-infected persons remains a challenge.

Although TB preventive therapy has been shown to be effective in clinical trials, the feasibility of providing it at National Program levels is hindered by logistical difficulties, such as lack of resources for implementing voluntary counseling and testing, as well as the cost of excluding active TB.

Standard practice for screening active TB in PPD-positive HIV-positive clients: Patients being considered for INH preventive therapy undergo a detailed medical evaluation. This includes a physical examination, TB diagnosis through blood and sputum, and a postero-anterior chest X-ray.

The patients' evaluation also includes assessing presenting symptoms, signs, HIV status and PPD skin testing. PPD-positive (PPD ≥ 5 mm induration after 48-72 hours), HIV-infected persons will be screened for active TB through a detailed medical evaluation including questioning about key symptoms of active TB, prior TB or anti-TB treatment, and exposure to persons with active TB. Their physical examination will include taking body temperature and weight, plus an assessment of their general appearance (wasting); their chest (consolidation, fibrosis, pleural effusion); and their abdomen (focal or generalized lymphadenopathy). All patients will have blood and sputum taken for TB diagnosis using serologic and immunologic diagnostics. A postero-anterior chest X-ray² will also be done. Persons with any symptoms or chest X-ray findings suggesting active tuberculosis will then have three sputum exams (smear and culture) for tubercle bacilli. Persons with pleural effusion or lymphadenopathy are evaluated for TB by thoracentesis and lymph node or pleural biopsy as clinically indicated.

It is usually from the above screening details that a cohort of PPD+, HIV-infected patients without active TB are identified.

The identified tuberculin skin test positive (PPD ≥ 5 mm) HIV-infected subjects receive treatment with nine months of self-administered Isoniazid. These subjects are followed-up *monthly* during preventive therapy and *quarterly* thereafter for incident tuberculosis, drug safety and mortality.

Follow-up Measurements: The total duration of follow-up varies according to the availability of resources. Initially CD cell counts as well as CBC and body weight should be taken. Serum chemistry and complete blood counts are monitored monthly during the treatment phase. CD4 cell count and CBC will be done at the completion of TB preventive therapy and then every six months. Body weight, Karnofsky performance score, and review for symptoms of TB and other opportunistic infections, as well as adverse drug experiences, are done at all follow-up visits. Repeat chest X-rays are performed annually or as clinically indicated during follow-up. Additional studies, such as liver function tests and AAFB smears and cultures, are performed as clinically indicated.

Compliance Assessment and Assurance: Long-term follow-up in TB preventive therapy trials exceeds 85 percent when utilizing a multidisciplinary team approach. This includes counselors, health educators, a urine INH metabolite testing program, routine questioning of all subjects about compliance, and an active home health visitor program that locates, motivates, and assists those who do not report within seven days of a scheduled clinic appointment.

Incident Tuberculosis: The primary outcome is the development of active tuberculosis. TB is suspected when subjects present with a persistent cough for more than three weeks, weight loss, night sweats, fever, chest pain or new focal peripheral or cervical lymphadenopathy. The evaluation of suspected cases of TB includes chest radiography, multiple AAFB smears and cultures and responses to specific therapy for TB. Cases are either classified as definite (in which TB organisms have been demonstrated), probable or possible TB, or unlikely to be TB.

² At AIC under the IPT program, a chest X-Ray is recommended for clients who have active TB symptoms with a negative sputum smear for AAFB.

METHODOLOGY AND STUDY DESIGN

STUDY DESIGN

The study design was a combined cross-sectional survey and retrospective data analysis covering AIC. Because MU-CWRU would not allow the team to review its integration activities, this report only highlights findings from AIC.

SAMPLE SIZE AND PROCEDURE

Population of interest: The population of interest in this study were the HIV-positive clients at AIC and service providers. All HIV-positive clients who were enrolled and screened for TB at AIC from 2001 to date and currently attending the center were included in this study. All clinicians during the study period were interviewed together with IPT program managers at AIC and the NTLIP manager.

STUDY SCOPE

The data reported in this evaluation is based on information from four AIC branches – Kampala, Mbale, Mbarara and Jinja. For the Kampala branch, data was collected from January 2001 to June 2006. For the rest of the branches, data was collected from the start of the IPT programs in those branches (January 2003). The study excludes data collected at the AIC indirect sites (AIC supported sites) and those from AIC outreaches. Therefore, the target population for this study was *self-selected individuals* who attend AIC clinics for HIV testing.

DATA COLLECTION AND DATA COLLECTION TOOLS

Before data collection, two meetings were held between the consultants and the Monitoring and Evaluation Management Services (MEMS) to interpret the evaluation questions in a similar way before proceeding to the development of research tools. An initial visit was made to both sites by the principal investigator, the co-investigator and the social scientists at AIC. The team specifically looked at the way data from clients at AIC was collected and managed. This gave the evaluation team insight into designing the necessary data collection tools and training of the research assistants. The tools were then pretested before the actual data collection. The team then carried out quantitative data collection, interviews and focus group discussions. The quantitative data collection tool is attached in Annex 2 and the qualitative data tool is in Annex 3.

The quantitative data and patient information was collected using the AIC database, which tracks subjects from the point they are screened for TB, through follow-up, and to the time they complete IPT.

The team collected qualitative data using structured questionnaires. Specific, different questionnaires were used to collect information from managers at AIC, from clinicians and counselors, and from clients who were on IPT during the study period. The team also conducted a focus group discussion with AIC staff who were involved in the IPT program. Other methods to gather information included:

- Observing the TB screening process carried out at AIC's Kampala branch.
- Analyzing records of HIV-positive clients who were eligible to receive IPT at AIC Mengo, Mbale and Mbarara branches between 2001 and 2006.
- Interviewing a sample of clients receiving IPT to identify factors which either facilitated or hindered adherence.

LIMITATIONS

This study was designed to look at the achievements of IPT at both AIC and a research setting such as MU-CWRU. MU-CWRU was not included in the study since the evaluation team was not granted clearance from MU-CWRU to carry out the study. It is believed this information would have been very useful in filling in gaps that could not be captured at AIC, specifically the period of maximum protection against TB when one takes IPT and the efficiency of active follow-up. This data would have enabled us to compare findings at AIC and MU-CWRU. This report therefore presents the findings from AIC only.

The matrix below summarizes the different evaluation questions, data sources and methods used in trying to answer the evaluation questions.

Table I. Evaluation Questions, Data Sources, and Data Methods

Evaluation question	Data source	Data method
1. What is the level of integration of IPT into HIV/AIDS and TB programs in general but specifically at AIC? Areas of focus include:		
<ul style="list-style-type: none"> • # screened for HIV • #HIV+ identified • # screened for TB • # on IPT • Methodology of IPT screening: algorithms, guidelines • Knowledge of IPT by clinicians • Follow-up of patients 	<ul style="list-style-type: none"> • Medical records and reports • Policy documents of MoH and others • Technical reports and standards of MoH • Program managers and service providers at the sites • Service beneficiaries • Clinics set up and flow of patients • Protocols used 	<ul style="list-style-type: none"> • Review of documents • Structured interviews • Focus group discussions • Review of patient records/ data base • Observations
2. What are the challenges facing IPT integration into HIV/AIDS/TB programs?		
<ul style="list-style-type: none"> • Process of initiating IPT • Human resources • Time required • QA • The process of case identification • Failure rates • Follow up • Toxicity • Adherence • Drop outs • Availability of INH • Percentage of IPT clients that developed TB 	<ul style="list-style-type: none"> • Medical records and reports • Policy documents of MoH and others • Technical reports and standards of MoH • Program managers and service providers of the sites • Patient interviews • Clinics set up and flow of patients • Protocols and standards 	<ul style="list-style-type: none"> • Review of documents • Structured interviews • Focus group discussions • Review of patient records • Observations
3. What are the successes for IPT integration into HIV/AIDS/TB programs?		
<ul style="list-style-type: none"> • Percentage on IPT • Adherence and dropout rates • Training activities • Materials developed • IEC materials 	<ul style="list-style-type: none"> • Medical records and reports • Program Reports • Policy documents of MoH and others • Technical reports and standards of MoH • Program managers and service providers of the sites • Patient interviews • Clinics set up and flow of patients • Protocols and standards 	<ul style="list-style-type: none"> • Review of documents • Structured interviews • Focus group discussions • Review of patient records • Observations

Evaluation question	Data source	Data method
<p>4. What are the factors that have to be considered if success is to be consolidated?</p> <ul style="list-style-type: none"> • Sustainability of funding • Human resource availability • Etc 	<ul style="list-style-type: none"> • Program managers and service providers of the sites • Patient interviews 	<ul style="list-style-type: none"> • Review of documents • Structured interviews • Focus group discussions

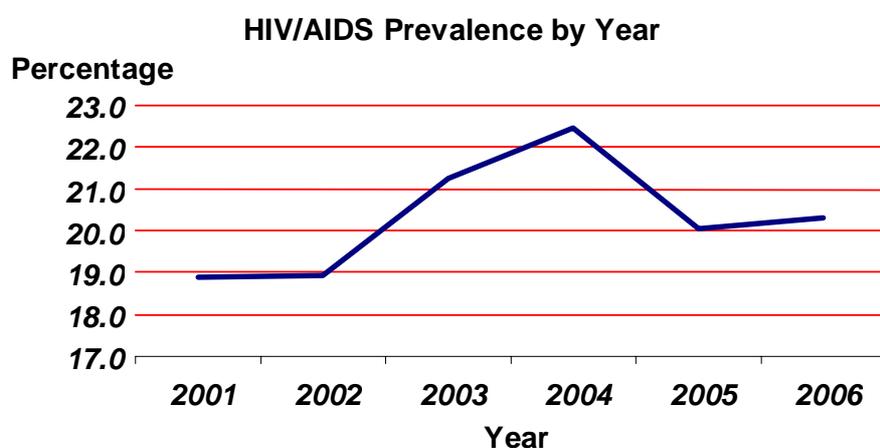
FINDINGS

Between January 2001 and June 2006, a total of 186,540 were reported to have been offered VCT from Mengo, Jinja, Mbale and Mbarara branches of AIC. It was also during this time that AIC had integrated TB services into VCT. The overall prevalence of HIV was 20.7% or 38,571 clients testing positive for HIV. This figure represents clients from the Kampala branch from 2001 to 2006, where integrated services started and it also includes results from Mbale, Mbarara, and Jinja from 2004 to and 2006 (see Table 2 below).

Table 2. HIV prevalence among clients screened for HIV at AIC – Kampala, Mbale, Mbarara and Jinja.

Year	Number screened for HIV	HIV positives	Prevalence
2001	18,078	3,412	18.9%
2002	19,932	3,771	18.9%
2003	29,572	6,291	21.3%
2004	49,404	11,096	22.5%
2005	47,521	9,526	20.0%
2006	22,033	4,475	20.3%
TOTAL	186,540	38,571	20.7%

Figure I. Trend in HIV prevalence among clients seeking VCT at AIC.



The prevalence of HIV among clients screened at AIC progressively increased from 18.9% in 2001 to 22.5%. From 2004, the prevalence started falling from 22.5% to 20.3% in 2006. The average HIV prevalence was 20.7%. The highest prevalence of HIV in 2004 (22.5 %) can be partly explained by the 2004 ART country-wide drive where most individuals who had never tested for HIV came forward because free ARVs had become available. But it is high mainly because clients who attend the clinic at AIC are a self-selected population who believe they have a higher than usual risk of having HIV either because their partner passed away, they have been engaged in risky sexual behavior or have had symptoms suggesting a chronic, unexplained illness. These patients often go to AIC privately because they fear stigma. The rate therefore is not an indicator of the HIV prevalence of the people in the neighborhood of AIC branches. For the Kampala branch, clients come from within Kampala and neighboring districts.

LEVEL OF IPT INTEGRATION INTO HIV/AIDS/TB PREVENTION PROGRAMS AT AIC

SCREENING FOR TB

There is evidence that TB activities have been integrated into VCT services at AIC from the planning level to implementing integrated HIV and TB activities. In group counseling, which is offered to all clients who come for testing, the dangers posed by tuberculosis are discussed together with what AIC can offer in terms of treatment and referral and the prevention to those who are HIV positive and are found with latent TB.

AIC has designed protocols that help identify both latent and active TB in HIV-positive patients. These protocols and screening procedures were developed in 2001 with input from CDC and NTLIP and are regularly revised to support changes in reporting and procedures. Information gathered from AIC indicates that the counseling and clinical staff at AIC are all knowledgeable of these protocols. AIC provides same-day results for HIV testing and those who test positive for HIV are then to be screened for active or latent TB using the AIC protocol (see Annex 2).

These clients are initially reviewed by a medical counselor who introduces the topic of TB and available options and does preliminary evaluation for possible presence of active TB. The feasibility of IPT is also explored since some clients can be excluded at this level (e.g., those who are pregnant, those who are likely not to comply, and those whose follow-up may seem problematic) or clients exclude themselves from continuing.

The clients are then sent to the clinician who is a medical officer and has the responsibility of excluding active TB disease from the client or confirming latent TB. This is a full-time job for these clinicians and they are not involved in any other clinical activities at AIC other than screening clients for IPT and following up with them. The clinicians carry out a detailed history and clinical examination to exclude active TB, whether pulmonary or extra pulmonary as per AIC protocol (see Annex 2). Those clients who present with the symptoms of TB are first screened for TB, and only when it is excluded are they considered for a PPD. Then the medical officers order for a PPD which is administered to all the clients who accept the test and active TB has been excluded through history, clinical examination, and relevant laboratory tests. Results are read after 48-72 hours; a reading of equal or greater than 5mm is considered positive. Eligible clients are then started on a regimen of 300mg of IPT daily and 50mg of pyridoxine for nine months. To help clients cope and to prevent default, clinicians and IPT treatment supporters follow up with adherence counseling to willing clients in their communities. Clients are given a two-month supply of drugs. Then, every two months, the clinician reviews for any toxicity, evaluates for active TB symptoms, discusses any developments, and provides a new supply of drugs. On subsequent visits, clinicians use a protocol developed by AIC (see Annex 3). Clients who attend the fourth IPT follow-up after seven months of treatment and receive INH for the last two months are considered to have completed treatment. There are no pro-active mechanisms of ensuring adherence to IPT at AIC, which would have included making unscheduled visits to count tablets, measuring levels of drug metabolites in urine, etc. Basically, adherence is dependent on what the client reports. This is not an effective adherence mechanism.

For those found with active TB, initially AIC Kampala used to refer them to the various TB treatment units nearest to the clients' area of residence. However, AIC is now providing TB treatment for the uncomplicated TB cases at its Kampala branch. It refers those who are either too sick and need hospitalization or have other complications or prefer to have their treatment elsewhere to other branches. The other branches, however, do still refer TB patients to other TB diagnostic and treatment units.

AIC also provides other basic care services including management of STIs, prevention of other OIs with Septrin, and management of OIs, and nutritional and psychosocial support. A different set of clinicians not attached to the IPT /TB clinic provides these services including Septrin for prophylaxis. This means that clients eligible for ART are referred for treatment to nearby ART sites. However, AIC provides CD4 cell count to their clients at a lower than average user fee of 10,000 shillings and 5,000 shillings per test for the Kampala and upcountry branches respectively.

EVALUATION OF THE TB SCREENING PROCESSES AMONG PATIENTS TESTING HIV POSITIVE

At AIC, TB is an incidental finding meaning that clients come to AIC for their HIV specific needs. When they arrive at AIC, those who tested HIV-positive are counseled for TB screening. It is therefore difficult to convince an individual who is not ill to test for HIV. After testing for HIV and found to be HIV positive, it is equally difficult for an individual to accept the double tragedy of possibly having latent or active TB until proven otherwise. Below are the findings of the screening processes at AIC.

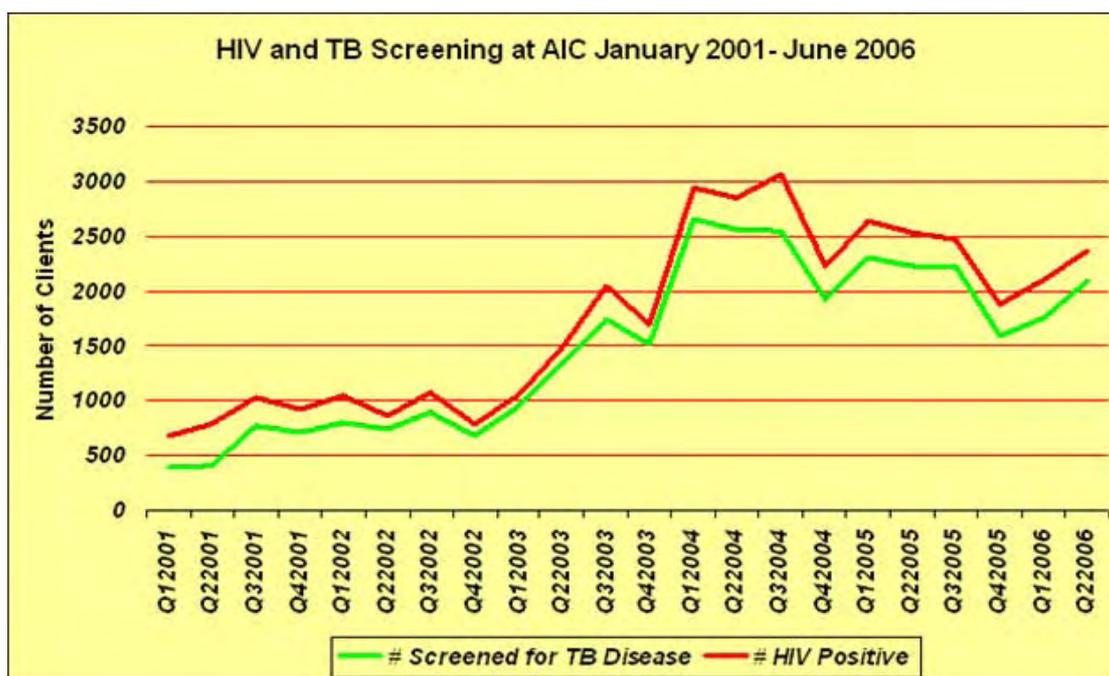
Table 3. Patients screened for HIV and TB between 2001 and 2006

Year	HIV positives	Number screened for TB	PPD positive N	Active TB disease N (%)	Percentage of HIV+ clients screened for TB
2001	3,412	2,302	495	161 (7.0)	67%
2002	3,771	3,135	427	173 (5.5)	83%
2003	6,291	5,551	492	247 (4.4)	88%
2004	11,096	9,676	781	405 (4.2)	87%
2005	9,526	8,338	492	359 (4.3)	88%
2006	4,475	3,837	190	180 (4.7)	86%
TOTAL	38,571	32,839	2,877	1,525 (4.6)	85%

The percentage of HIV positive clients screened for TB increased from 67% in 2001 to 88% in 2003 and has stabilized at 85-88%. This is the level of integration of HIV/TB services at AIC at the screening level.

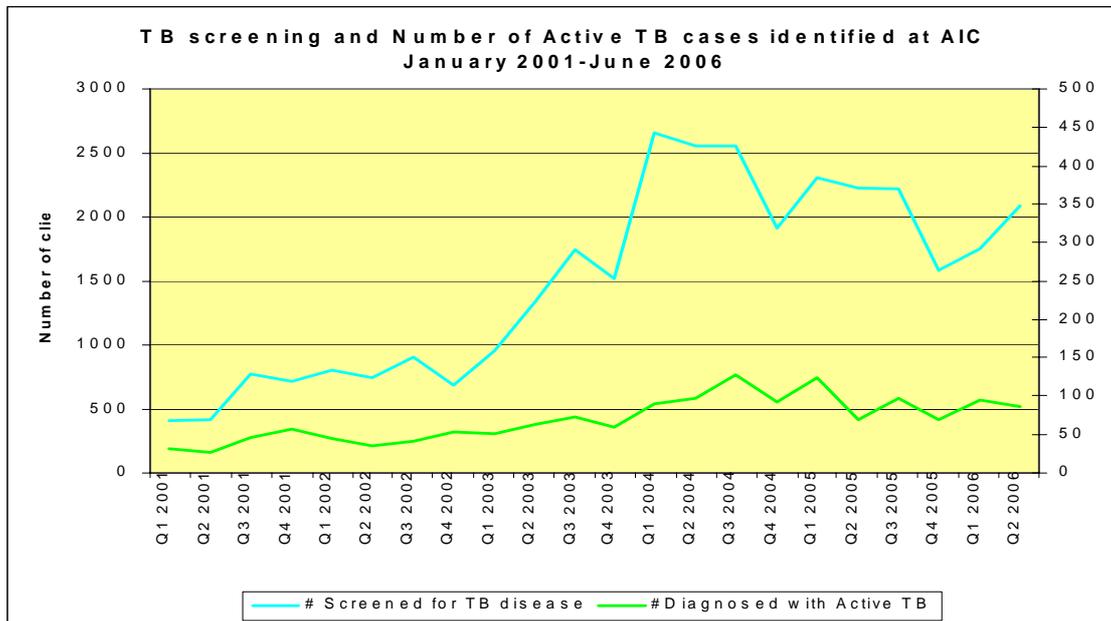
The main reason why those screened for HIV and found to be HIV-positive were not screened for TB was because most individuals are lost between HIV testing and referral for TB screening. It is generally two days between HIV testing and understanding the risk and need for TB services. In trying to understand and cope with the news of being HIV-positive, clients are also supposed to absorb the possibility of having TB and the need to be screened. For many, this is too short a time to assimilate all this information. They cannot cope and are lost at this stage. These clients do not want to continue to the TB screening to receive more bad news.

Figure 2. HIV and TB screening trends at AIC



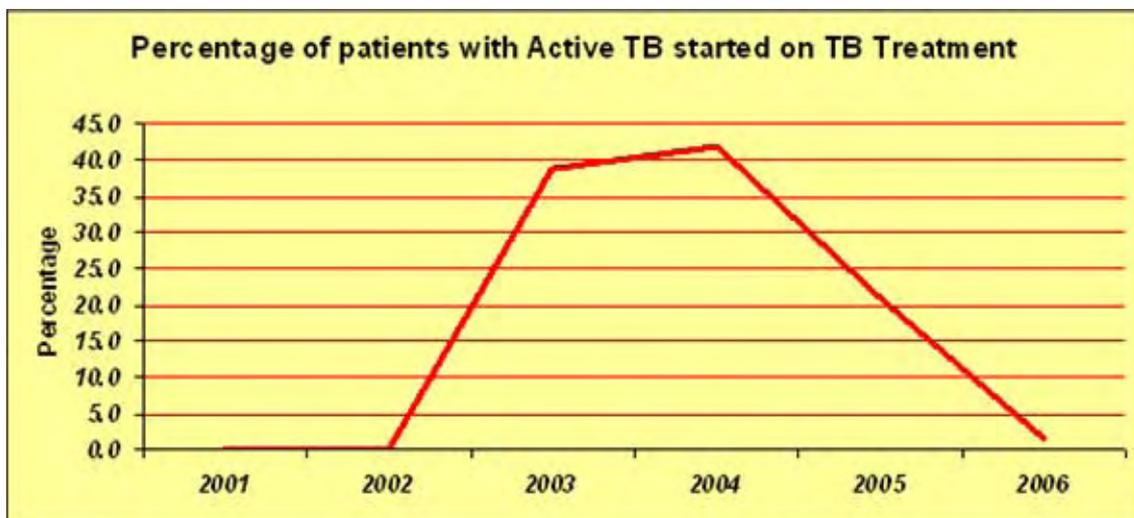
The figure further demonstrates how AIC has integrated TB services in HIV counseling and testing by looking for active TB in those who are HIV positive.

Figure 3. Trend of clients screened for TB and active TB cases identified at AIC



As indicated from Table 3 and Figure 3 above, the number of TB cases closely follows the number of clients screened for TB. The prevalence of active TB disease was highest in 2001(7.0%). The average prevalence of active TB disease among HIV+ clients at AIC is 4.6%.

Figure 4. Patients with active TB who were started on treatment



According to available data, no patients with active TB were put on treatment at AIC in 2001 and 2002. In 2004, the highest percentage of TB patients was started on treatment (42%), followed by 2003 (38.9%) and 2005 (20.9%) respectively. Only 1.7% in 2006 were put on treatment by the end of June 2006. The percentage of number of active TB cases identified at AIC and treated for TB dropped significantly in 2006 largely because most of those clients were recruited into another study between AIC and MU-CWRU.³ Figure 4 is significant as it shows the performance of AIC in integrating a whole range of TB services in VCT.

³ The details and impact could not be verified with the MU-CWRU team.

In 2001 and 2002, the emphasis was in screening for latent and active TB, treat for latent TB, and refer active disease. However, according to AIC, the referrals were found not to be very effective and there was no feedback mechanism to know whether these referrals were taking place. Recognizing that TB poses a serious public health problem and is the number one killer of HIV/AIDS patients, AIC, with support from NTLP, initiated treatment of HIV patients with TB at its Kampala branch in 2003. This figure increases markedly in 2004. With the exception of the Kampala branch, others have not started treatment of TB; they diagnose and refer their patients. It is important to note that plans are underway to start TB treatment at AIC Mbarara, Mbale and Jinja branches.

Table 4. TB case detection rate at AIC

Year	Number screened for HIV	Active TB disease	Case Detection Rate per 100,000
2001	18,078	161	891
2002	19,932	173	868
2003	29,572	247	835
2004	49,404	405	820
2004	47,521	359	755
2006	22,033	180	817
Average			831

The national case detection rate is 52% of the expected 300-330 per 100,000 population. This implies national programs are on average detecting 163 (156-171) TB patients per 100,000. At AIC, the detection rate is 831 TB patients per 100,000, more than 400% higher than the national average case detection rate. The screening process at AIC involves:

Step one: Preliminary screening includes administering a questionnaire to all those who are HIV-positive to determine whether they are eligible for IPT. Key factors include any condition that makes IPT contraindicated, such as pregnancy, breast feeding, and history of tuberculosis. In this stage, clients are also assessed for their ability to comply with IPT by distance between AIC and the clients' home (clients must be within a 20km radius from AIC). At this stage, clients who are not eligible for IPT are dropped. Those not dropped proceed to step two.

Step two: All clients are examined for symptoms and signs of active TB. Those suspected of having active TB are further examined by sputum AAFB, and a chest x-ray. Those found not to have active TB are then counseled about IPT and a PPD test is administered. Those found to have active TB are treated with anti-TB medication or referred for further treatment.

Step three: Based on results of PPDs, those clients with a positive PPD test who do not have active TB are started on IPT.

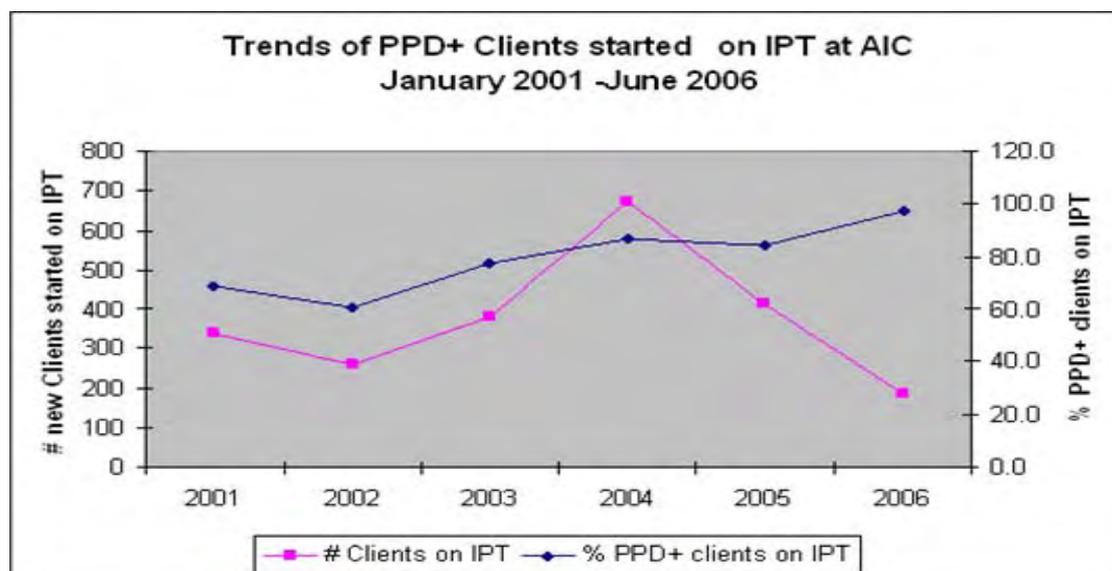
Table 5. Percentage of clients identified with latent TB and started on IPT at AIC

Year	HIV+ve Clients	Number Screened for TB	PPD+ve clients	Number of new Clients on IPT	Percentage of PPD +ve clients started on IPT
2001	3,412	2,302	495	339	68.5%
2002	3,771	3,135	427	260	60.9%
2003	6,291	5,551	492	381	77.4%
2004	11,096	9,676	781	674	86.3%
2005	9,526	8,338	492	413	83.9%
2006	4,475	3,837	190	184	96.8%
TOTAL	38,571	32,839	2,877	2,251	78.2%

There is a significant leap in percentages of clients started on IPT between 2005(83.9%) and 2006(96.8%) due to the persistent and repeated lack of Isoniazid in 2005. The recruitment of eligible candidates for

IPT suffered because many were on waiting lists for a long time and eventually left the program. At AIC, 78.2% of the PPD+ clients were started on IPT.

Figure 5. Trend of PPD+ clients started on IPT at AIC



The percentage of PPD+ clients started on IPT has increased progressively over the five-year period from 68.5% in 2001 to 96.8% in 2006. It is important to note, however, that from the peak of 2004, the number of clients started on IPT has consistently dropped.

CHALLENGES OF IPT INTEGRATION INTO HIV/AIDS/TB PREVENTION PROGRAMS

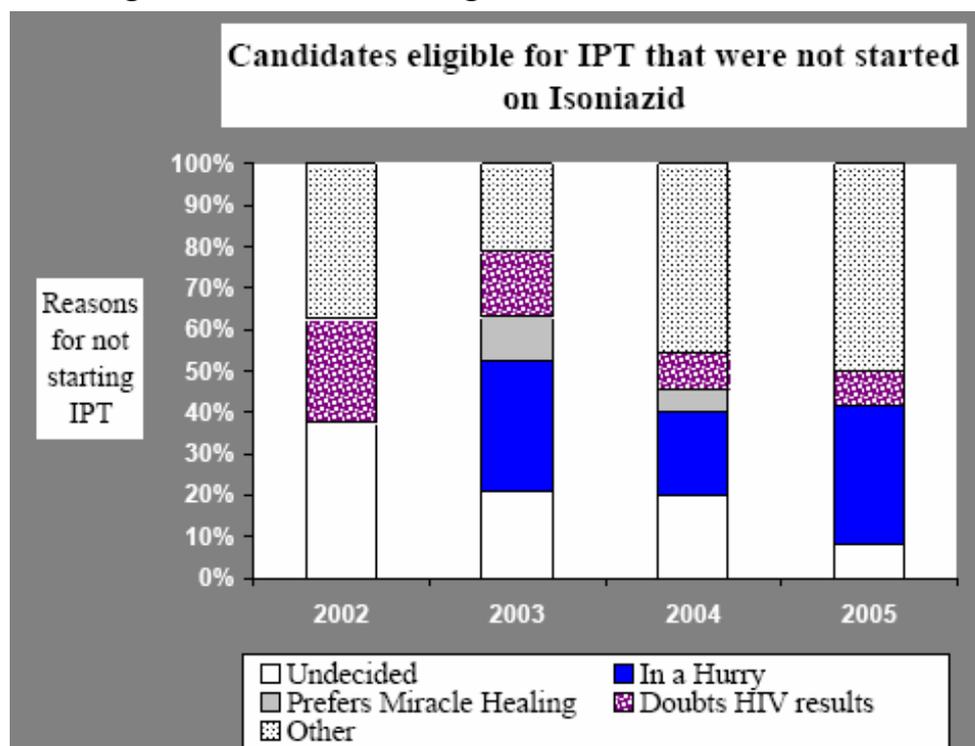
- *Integrating TB prevention into HIV systems is the first challenge.* The concern is adding more work to an already overburdened system. At AIC, clinicians are on board and each understands IPT. The clients interviewed were however not adequately knowledgeable of IPT; most of them thought that IPT was treatment for TB.
- *Screening for TB is the second challenge.* The preliminary screening at AIC is simple, involving a one-page tool with 11 questions for clients (Annex 2). Patients are then examined and based on the results, either placed into the active TB group or the inactive TB group. Those without active are then counseled and administered the PPD dose to identify latent TB. Overall AIC screened 32,839 clients for TB and 11,497 were administered a PPD. Of this number, 2,877 (25%) were PPD positive, and thus eligible for IPT, while 2,744 (23.9%) did not return. This implies that at AIC, 21 clients must be screened to identify one client with active TB, and 15 clients must be screened to identify one client eligible for IPT (see Tables 5 and 6). The key challenge is that many clients have to be screened to identify those who will be started on IPT.

Table 6. PPD tests administered at AIC

Year	PPD+	PPD-	Did Not return	Total
2001	495 (29.0%)	822 (48.1%)	391 (22.9%)	1,708
2002	427 (28.5%)	747 (49.8%)	326 (21.7%)	1,500
2003	492 (25.0%)	1,022 (52.0%)	452 (23.0%)	1,966
2004	781 (25.8%)	1,501 (49.5%)	748 (24.7%)	3,030
2005	492 (21.6%)	1,240 (54.5%)	545 (23.9%)	2,277
2006	190 (18.7%)	544 (53.5%)	282 (27.8%)	1,016
	2,877 (25.0%)	5,876 (51.1%)	2,744 (23.9%)	11,497

- *Challenges associated with administering a PPD test.* An important step in diagnosing latent TB is through the use of a PPD test, but this presents some logistical challenges. For AIC, PPD is procured by AIC and stored in a cold chain system. There are no provisions at NTLP to procure PPD and support a cold chain system for its storage. Nurses and medical officers must be adequately trained in the administration and interpretation of PPDs. From the technical point of view, there are still concerns expressed by TB experts and immunologists about the interpretation of a positive PPD in a country like Uganda that has high Bacille Calmette Guerin (BCG) coverage as well as high rates of tuberculosis. Many question if the PPD positives are correctly attributed to each. This same concern was also expressed by the NTLP technical staff. The question is: are PPD+ clients actually latent TB cases and in need of IPT?
- *Advantages of the PPD test in IPT Programs.* The PPD process at AIC is important in eliminating possible defaulters of IPT treatment. If an individual does not return within 48-72 hours for the reading of the PPD test, it is taken as an indicator of this individual having a high possibility of dropping out on treatment. Also, PPD reading is another counseling opportunity for the patients who tested positive, making issues clearer particularly for clients who are not coping well. For those clients who need to be convinced that they should be treated over a nine-month period for a disease they do not have but could get, this provides an opportunity to convince them with hard proof that they have a more than usual risk of developing TB.
- *Initiating IPT is another challenge.* Some clients have been identified as eligible for IPT according to the screening algorithm at AIC but declined to start IPT. Even after the rigorous process and all the support and counseling from AIC, not all eligible clients are started on IPT. Figure 6 below shows the various reasons given for eligible clients not starting IPT.

Figure 6. Reasons those eligible for IPT not started on IPT



The figure also shows that 2002 recorded the highest number of eligible IPT clients who declined starting IPT. However, through effective counseling, the number of clients that declined from starting IPT was reduced and June 2006 recorded the lowest number of clients who declined starting IPT. At AIC, IPT is provided by a specialized team of counsellors and doctors who spend valuable time with their clients, though many clients question the value of IPT and give reasons why they should not take the drug. This is mainly due to the public's lack of awareness of IPT and thus the critical lack of demand for IPT services.

- *Human resource constraints.* Staff requirements for IPT are specific in terms of time investment for IPT and technical skills of the health worker. Staff who implement IPT must be trained in administration of PPD, counseling for HIV/TB/IPT, and overall must spend 60 to 80 percent of their time on IPT activities. Due to the high number of patients to be screened and identified for IPT treatment, AIC has full-time medical counselors who can devote ample time to their TB/IPT patients. Providing this service to clients is challenging for health facilities whose health workers are already overstretched with the treatment and services they provide to a large population. ***This is a cornerstone challenge to integrating IPT into HIV/AIDS/TB prevention and control programs.***
- *Follow-up of IPT clients at AIC:* Once the clients are started on IPT, they should be reviewed every two months for compliance, side effects and development of TB (see AIC's follow-up protocol in Annex 3). If there is no communication from a client after a week, a "TB treatment supporter" makes a visit. This is a special cadre of staff recruited by AIC to offer treatment support and visit consenting clients in their homes. Even with the consenting clients, follow-up has been very challenging. Some treatment supporters have gotten lost, or have more than one person with the same name as the client's in a community. Sometimes treatment supporters are chased away or their clients hide from them. Many communities lack an address system (e.g., plot numbers) while other places, such as slums, have no address. Some clients fear being stigmatized by their community and will travel long distances for treatment. Many do not want their partners to know about their treatment and are reluctant to allow treatment supporters to reach them in their homes. Interestingly, without active follow-up at AIC, the drop-out rates are decreasing. (See Table 7 and Figure 7.) Funds are necessary for treatment supporters to follow up clients. The program manager pointed out that when the funding for follow-up visits came to an end in July 2006, so did the client visits. Clients would have to come in to the clinic for IPT follow-up.
- *Follow-up after IPT treatment.* Clients who complete IPT are awarded a certificate of completion. They are offered counseling for PTC and told to come back if they develop symptoms of active TB. The relevance of IPT is to protect clients who have latent TB from developing active TB both during and after IPT treatment. At AIC, there is passive follow-up during treatment with an assumption that this protection will continue. It is a challenge to determine how long after completion of IPT will this protection cover the client. AIC has not followed-up patients beyond completion of IPT. AIC also does not provide ART services, or manage the referral of clients to specific ART centers. This would ensure that some of their clients stay longer and can be evaluated on the outcomes of IPT after several years.
- *Adherence support mechanisms and measurements.* At AIC when clients are starting IPT, they receive adherence related counseling from their doctors and medical counselors about the importance of taking their drugs as prescribed by the clinicians. This includes taking IPT together with Pyridoxine. Clients are advised to report to AIC if they have any side effects while taking their drugs. On subsequent follow-up visits, medical counselors continue adherence counseling. Clients are asked if they missed taking their drugs and if so, how many days they missed and the reasons why, and the remaining pills are then counted. Though adherence at AIC is carried out by the clinicians and counselors, much depends on what the patient reports.

AIC does not actively monitor adherence, for instance supporting unscheduled visits, carrying out random pill counts, using treatment supporters to directly observe IPT tablet swallowing, and supporting urine sample collection in testing for metabolites of Isoniazid. Clients interviewed reported that they are committed to taking their drugs though some said that they occasionally forget. When asked what factors may prevent them from taking their drugs, most said that it is the long duration of taking pills (nine months) followed by the negative attitude or rejection of the treatment by health workers at facilities in which clients receive other services. Some reported that they were told to stop the medication by health workers because IPT does not help them or that they were wrongly being treated for TB which they did not have. One client said that "the health workers I met at Mulago were hostile to me when I told them that I was taking Isoniazid to prevent TB."

Another reason for not taking the medication was related to the interval of follow-up of two months and an issue with the storage of drugs. Clients interviewed noted that by the end of two months, the

color of the last INH tablets changed to a brownish yellow. Clients were not comfortable taking these because they believed the tablets had expired. Clients were also concerned about the availability of INH. Only AIC provides INH and yet AIC does not provide all the other HIV care and treatment services. This forces clients to go to other places as well as AIC for other interventions. One client said, "I had to stop my drugs when I was imprisoned. There was no place to get these tablets."

- *Drop-out rate:* Drop-out has not been tracked but was found high at the beginning of the project and then had significantly decreased by 2006. Overall, the drop-out rate was found to be 8.0%. This is quite significant considering that this was implemented as a specific intervention project with all the support. Looking at the various reasons documented for dropping out, the unknown reasons and others form the significant majority. There should have been mechanisms during the project to review these and characterize them. There is also a significant number of clients who refused treatment – 52 (11.5%) out of 463. This could indicate that clients were not convinced they would benefit from IPT or they may have been advised by others to stop IPT. Qualitative information from AIC indicates that many of these patients who were being treated for other problems at other facilities were told by those health workers to stop the IPT.

Table 7. Reasons for Drop-Out

Year	Diseased	Terminal Aids	Side effects	Active TB	Transport	Moved	Late ⁴	Unknown	Refused	Others	Total
2001	8	8	3	1	2	6	0	12	13	6	59 (13%)
2002	4	5	4	3	1	14	8	51	15	14	128 (27%)
2003	1	8	3	6	0	16	5	57	8	11	115 (24%)
2004	5	3	5	3	1	29	8	18	12	19	103 (22%)
2005	3	1	7	3	2	6	6	8	4	18	58 (12%)
2006	0	0	0	0	0	0	2	0	0	5	7 (1%)
Total	21 (4%)	25 (5%)	22 (5%)	25 (5%)	6 (1%)	71 (15%)	29 (6%)	146 (31%)	52 (11%)	73 (16%)	470 (100%)

Table 7 shows that 27% of drop-outs occurred in 2002, 24% in 2003, and only 1% in 2006.

Figure 7. Reasons for dropping out of the AIC IPT program

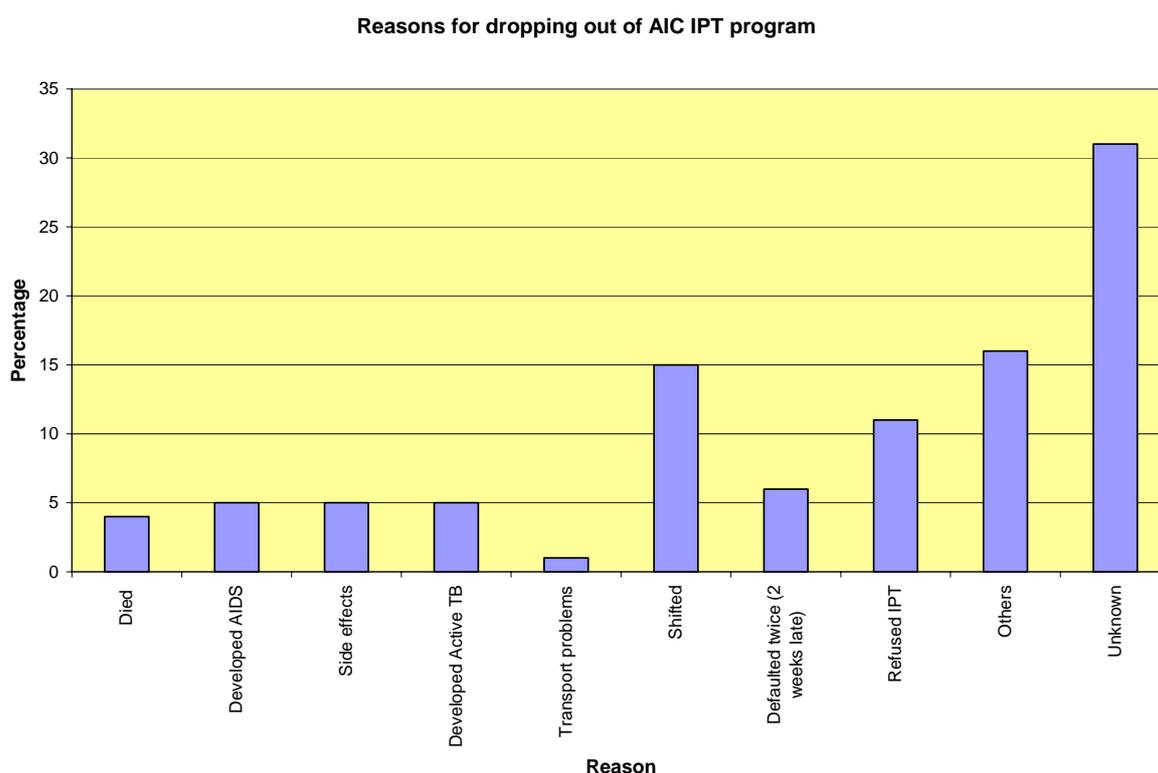
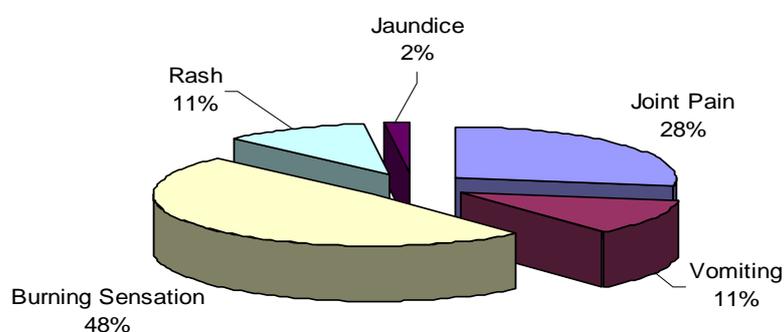


Figure 8. Reported Isoniazid side effects for the period 2001-2006



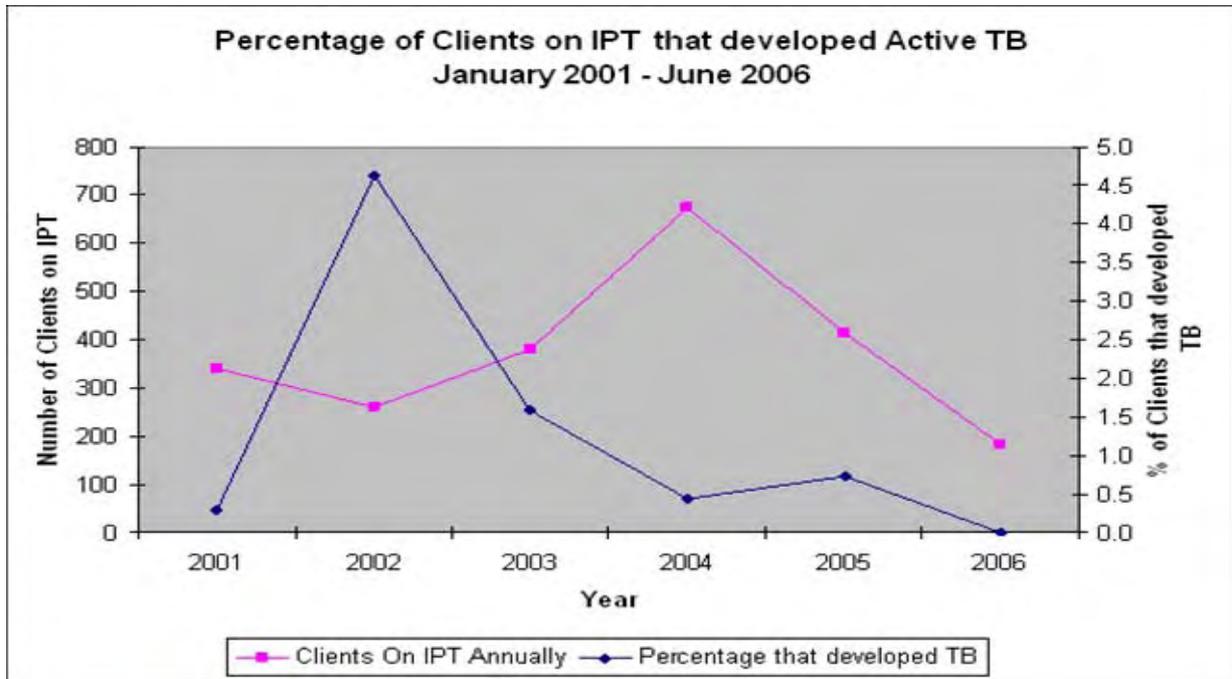
- *Development of side effects.* The delineation between side effects of IPT and other drugs taken by the patients was difficult to ascertain because HIV-positive patients are often on a number of medications concurrently.

The review found that burning sensation (48%) was the most common side effect reported by patients on IPT. This was followed by joint pain (28%), vomiting (11%), and rash (11%), while jaundice (2%) was the least reported side effect. Although burning sensation is a common complaint among HIV-positive patients, the frequent lack of pyridoxine contributed to the increased frequency in burning sensations. Looking at Figure 7 above, side effects contributed to 5% of the drop outs. For 252 clients on IPT, side effects were significant enough to warrant their discontinuing IPT.

- *Development of active TB.* Overall, 25 patients on INH developed active TB and monotherapy was stopped. This was detected by AIC during the course of active treatment. What is not reported are those clients who developed TB after the period of active follow-up. AIC needs to put in place mechanisms for following up their clients at least on a quarterly basis for an agreed period of time. The development of active TB could imply that INH failed to protect these individuals from developing TB. But it may also

indicate that these individuals already had TB which was not detected by the existing screening methods. The second reason is more important in that this may contribute to the development of Multi-drug-resistant Tuberculosis (MDR).

Figure 9. Development of TB while on IPT



Clients who developed TB while on IPT ranged between 1.2% in 2003 to 0.0% in 2005. The year 2002 recorded the highest proportion.

SUCCESS AND FACTORS TO BE CONSIDERED FOR CONSOLIDATION

- The screening methods at AIC are effective in capturing latent and active TB. The protocol is cost effective in diagnosing latent TB because the screening identifies both latent and active TB in HIV-positive clients, which means appropriate treatment can be started immediately. The IPT intervention has not been tested in a lower level public health facility (HC III or IV).
- Increasing numbers of PPD+ clients started on IPT is a successful achievement at AIC. As more are identified, more can be treated.

Figure 10. Trend of clients identified to be PPD+ and number started on IPT

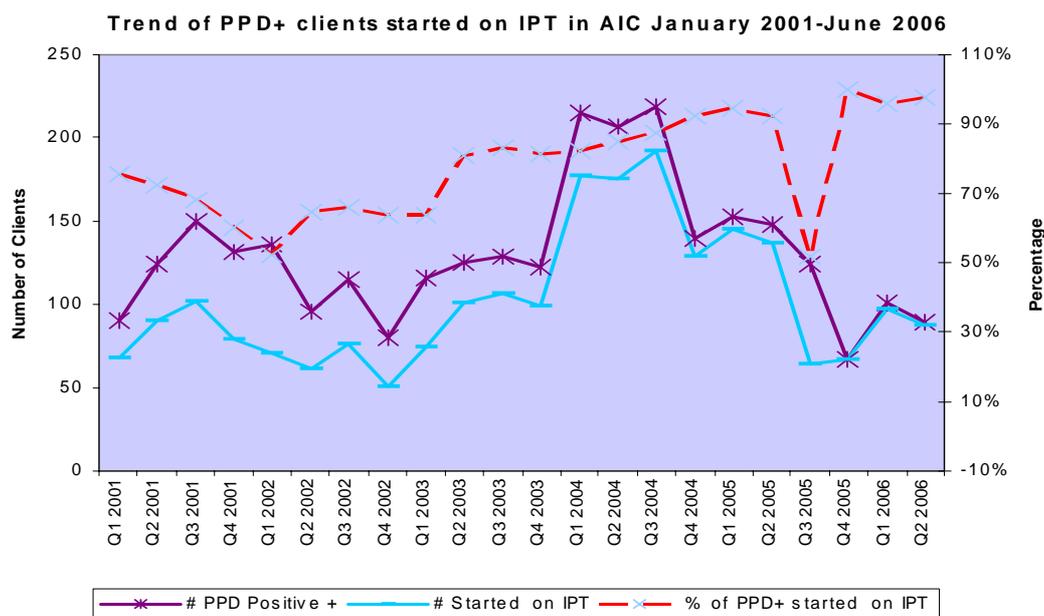


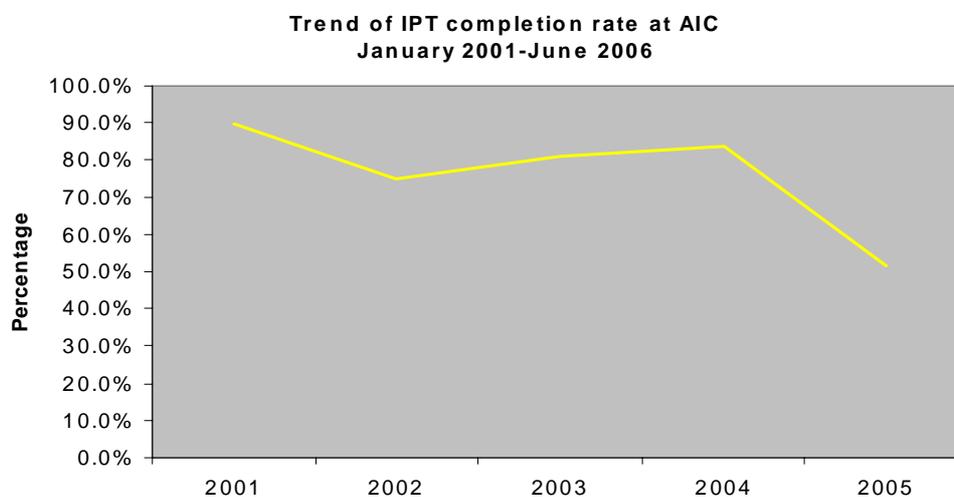
Figure 10 shows increasing performance with an increasing percentage of PPD+ clients being started on IPT reaching almost 100% in 2005. This means that over time AIC had worked on the issues which were hindering all their eligible clients from starting on IPT.

Table 8. Annual completion and drop-out trends

Year	New Clients	Number(%) of Drop-Outs	Average Number of Clients expected to complete IPT	Average number of Clients on IPT	Number (%) of clients that completed IPT
2001	339	59 (17.4%)	68	339	61 (89.7%)
2002	260	119 (24.8%)	304	479	218 (71.7%)
2003	381	119 (22.8%)	202	523	175 (86.6%)
2004	674	103 (11.4%)	385	903	340 (88.3%)
2005	413	58 (6.6%)	576	873	311 (54.0%)
2006	184	5	68	688	92
	2,251	93 (16.6%)			1,197 (78.1)

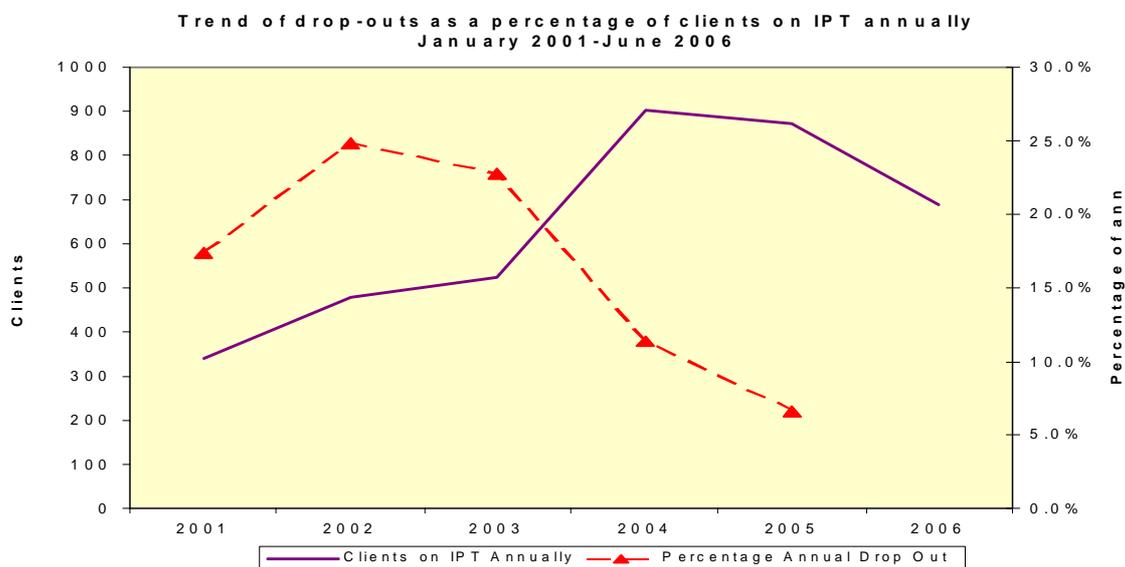
All figures annual

Figure 11. Trend of Completion rates at AIC



- AIC has success in achieving an average completion rate of 63.4%. The completion rate trend has however been decreasing from the highest of 89.7% of 2001 to 48.4% in 2005. Analysis for 2006, though only for the first six months, shows the lowest number of new clients started on IPT (see Figure 11 above). The reduction in the number of new clients for IPT has been largely due to the fact that the program had gone into the close-out phase and funding was expected to close in 2006. It has, however, received new funding offers and the trend highlighted above is expected to change.

Figure 12. Annual drop-out trends and clients on IPT



The drop-out rates have decreased over time, with the highest in 2002 (24.8%) but have decreased to 6.6% in 2005. AIC has been able to scale up services in three branches – Jinja, Mbale, and Mbarara. They have established a database that tracks IPT activities at all the branches. The database is kept up to date and provides information on each client as an individual. AIC has also developed tools and algorithms to screen and follow up IPT clients. As a result, AIC has significantly achieved integration of HIV counseling and testing services with TB services through identification and treatment of latent TB and active TB. The Kampala branch has scaled up to include treatment for clients with TB.

CONCLUSIONS

- AIC has been able to integrate TB activities into its HCT activities beginning with the Kampala branch and later with Jinja, Mbale and Mbarara branches. Screening for TB in all the HIV+ patients has been improving over time. On average, 85 percent of all HIV-positive clients are screened for TB. Fifteen percent of the clients are not screened for TB because they are lost along the way in AIC. The screening has however not been piloted in a lower level health facility due to staff requirements, time constraints, diagnostic demands, referral, attitude of health workers, and impact on other service delivery systems.
- AIC has offered IPT to 78.2% of the clients found to have latent TB and has progressively improved to a high of 96% of eligible clients started on IPT in 2006. The completion rate at AIC is 78.1% with the lowest in 2005 at 54.0%. The average drop-out rate is 16.6%. These are the key achievements of the AIC-IPT program. There is no information on long term follow-up of clients who have completed IPT.
- AIC has been able to integrate the diagnosis in all the branches that offer IPT. For active TB diagnosis and treatment, only AIC's Kampala branch offers treatment. The other branches refer their clients to other diagnostic and treatment units.
- AIC has been able to start offering other basic care elements to clients on IPT and on TB treatment, especially at the Kampala branch. However, there is minimal integration in the way these services are offered.
- Providing IPT is a specialized activity with a highly trained staff of medical counselors and medical officers who screen and identify clients for IPT, and follow up with them. IPT is labor intensive and requires full-time commitment on the part of the health workers. Health workers require funding for visits to follow-up clients.
- The provision of IPT at AIC has been affordable and running smoothly during the period in which there was specific funding for this activity from AIC partners. Funds were used to support the health workers attached to this project, for follow-up activities and procurement of diagnostics, especially PPD. The program was challenged by periodic shortages of Isoniazid, pyridoxine and PPD, or a combination of these. The program was, however, able to timely procure these medications.
- The understanding, use and benefits of IPT are well articulated by service providers at AIC but this does not seem to be the case with other health workers outside AIC, where AIC clients receive other services. IPT provision remains a domain of AIC and a practice not well recognized by other health workers from the MoH headquarters to the lower level facilities.
- AIC has been able to set up a database that helps the program effectively track and monitor IPT interventions.

RECOMMENDATIONS

- The AIC protocols used for TB screening are effective and should be adapted by interested agencies for TB screening programs across the country as part of a basic package of health care for HIV clients. The scale-up of the positive aspects of the AIC-IPT program needs to be restructured with a focus on district hospitals and lower level health facilities (HC IV). This design should then be piloted and studied for possible replication in the rest of the country.
- Organizations or facilities planning to implement IPT should have reliable HCT services that offer same-day results for clients to be screened for IPT.
- A considerable investment is needed for facilities to capably implement IPT. They will need health workers who can be trained and devoted full-time to providing IPT services. They will need a system for procuring and properly storing PPD. And they will need medical officers in order to exclude active TB disease from the sputum-negative clients.
- AIC should endeavor to follow up and document details about all clients during and after IPT, particularly those who develop active TB. The Ministry of Health has developed a communication strategy and policy guidelines for TB/HIV collaborative activities that include IPT, but no guidelines for implementation. Therefore, an implementation strategy must be developed and supported to ensure that the community, especially HIV-positive individuals, are aware of IPT services and that these services become part of the comprehensive care package. Increased awareness and demand will also lead to HIV program implementers considering and offering IPT as part of their package of services.
- AIC should scale-up IPT in its other main branches. AIC must strengthen its delivery of an integrated package of services to IPT clients and review of client flow systems in the facilities to ensure that fewer individuals are lost and thus not screened for TB, within the system.
- Institutions that provide IPT services should limit it to facilities that have mechanisms for effective follow-up of their clients in their communities and have, or can ably integrate into, existing community support mechanisms. The challenges treatment supporters have faced in implementing the program can be minimized by making best use of existing CORPS (Community Owned Resource Persons), or CB-DOTS supervisors in the community. They are known by the community and can effectively follow up with the clients. The principle should be integration of IPT into existing systems. IPT provision would be appropriate to organizations like TASO, Nsambya home care that has developed community follow-up mechanisms and has a specific high-risk population that they regularly follow up. The follow-up should also involve an efficient database, such as AIC's, that can track individual clients. Therefore, IPT should be tailored for lower level public health facilities and piloted before replicating in the rest of the country.
- AIC and other organizations planning to implement IPT should consider mechanisms for long-term follow-up of clients who have completed the treatment phase. This will help in the early detection of incidental TB that develops among patients. Providing clients with an array of services in one place would improve client follow-up.
- In order to spread the importance of IPT, MoH-NTLP should make information available throughout communities. In addition, health workers must be trained so they can knowledgeably inform clients about IPT.
- NTLP should ensure that there are adequate supplies of Isoniazid (INH), that they are packaged in blister packs for safe custody, and that IPT follow-up cards (similar to CB DOTS) are developed and supported to ensure a comprehensive follow-up of patients.

BEST PRACTICES AT AIC

- The AIC data system which is able to track individuals as unique clients, is an important tool that other organizations can emulate in implementing not only IPT programs but also other HIV interventions and health activities.

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ANNEX I: SCOPE OF WORK

EMERGENCY PLAN FUNDED TARGETED EVALUATIONS STUDY BACKGROUND SHEET

Country: Uganda

Program Area: TB/HIV program collaboration

Activity Budget: \$ 10,000

Mechanism/Prime Partner:

Project description: *(Not to exceed 100 words)*

The MU-CWRU Research Collaboration, with support from USAID/Uganda mission has designed a study to evaluate the integration of Isoniazid Prophylactic Therapy (IPT) in HIV/AIDS prevention and control programs at two centers – The AIDS Information Center (AIC) Clinic in Kisenyi-Mengo and the MU-CWRU Research Collaboration TB clinic in Mulago. The MU-CWRU Research collaboration is requesting funds to conduct a study to determine the level of integration of IPT in HIV/AIDS programs in Uganda, evaluate the TB screening process, adherence and predictors for adherence, toxicity, monitoring of patients, quality planning and any other program challenges.

Evaluation question:

(Explain what the study intends to examine, its programmatic importance, and anticipated outcomes).

The purpose of this study is to determine the level of integration of IPT in HIV/AIDS prevention and control programs in Uganda. The study intends to evaluate the TB screening process among patients testing HIV positive at the two centers – AIC and MU-CWRU. The study will document how cases with latent tuberculosis are identified and how active TB is excluded.

The study will determine the challenges of integrating IPT in HIV/AIDS programs. Special focus will be on human resource implications, case identification, quality assurance, failure rates, case follow-up, toxicity, adherence to Isoniazid and predictors for adherence.

HIV/AIDS is by far the most important of all predisposing factors to the development of TB. Patients infected with HIV and PPD-reactive, have a 60 percent lifetime risk of developing TB compared to 10 percent for PPD-positive and HIV-negative. IPT has been found to be safe and effective for prevention of active TB among those who are PPD-reactive. WHO recommends that IPT should be promoted as an intervention for those living with HIV rather than as a primary strategy to control the public health burden of TB. Despite the recommendations, IPT has not been incorporated in the Uganda National TB control program and few programs dealing with TB and HIV diagnosis, prevention and control in Uganda have integrated IPT. Secondly, long-term benefits (after 3-5 years of IPT) have not been demonstrated. Best practices in integrating IPT in HIV/AIDS programs are largely unknown.

The Emergency Plan envisions a comprehensive, holistic, interdisciplinary approach to HIV care. Through this plan Uganda is scaling up its response to Voluntary Counseling and Testing (VCT), Prevention of Mother to child Transmission (PMTCT) and provision of ARVs. AIC is the largest provider of VCT in Uganda with over 240,000 clients tested in 2004. One of the services provided under Palliative Care is IPT. MU-CWRU TB Clinic in Mulago provides IPT as part of their services and to household contacts of TB patients. These centers therefore provide a large pool of HIV positive clients and key entry points for integrating IPT. The HIV prevalence in household contacts under the MU-CWRU TB clinic has been found to be 10 percent.

A study at these two centers will provide an insight in the feasibility of implementing IPT in program settings. The study will identify challenges and document best practices and the minimum requirements

for integrating quality IPT services in HIV/AIDS programs. The results from the study will inform the scale-up of quality IPT in other HIV/AIDS programs in the country.

Currently there is no standard algorithm for the evaluation of TB in HIV positive clients in Uganda. The results of the study will feed into the construction of a standard algorithm that can be used nationally by the Ministry of Health, National TB control Program and other organizations implementing HIV/AIDS programs.

The study will provide insight into whether IPT should be integrated in TB/HIV programs and how this can be done.

The results of the study will be disseminated to MoH and other HIV/AIDS organizations to help them effectively integrate quality IPT services in their HIV/AIDS programs.

Some of the anticipated outcomes include:

- A description of the algorithms being used to screen HIV infected patients for latent and active TB.
- Challenges in integrating IPT in HIV/AIDS prevention and control programs.
- The human resource implications of integrating IPT in HIV/AIDS programs
- Uptake and failure rates of Isoniazid preventive therapy among HIV infected patients.
- Adherence rates of Isoniazid preventive therapy among HIV infected patients.
- Long-term benefits of IPT in preventing active TB
- Predictors of poor adherence to Isoniazid preventive therapy among HIV-infected patients.
- Side effects of IPT and some of the related factors for toxicity.

Methodology:

(Describe methods including comparison groups, study period, and instruments).

The study will be a descriptive cross-sectional survey and record review carried out at two centers - the AIDS Information center (AIC) and the MU-CWRU TB Research clinic in Mulago. AIC was established in 1990 to provide VCT services and is currently the largest private VCT provider in Uganda. AIC tested 240,000 clients in the year 2004. It has eight branches and 150 indirect sites mostly in Government health units. As part of a basic health care package for those that test HIV-positive, AIC provides TB screening and IPT to HIV-positive clients at its clinic in Mengo. In the first quarter of 2005, 122 clients were enrolled in IPT. MU-CWRU TB Research clinic in Mulago was established over 15 years ago. It is a collaboration between Makerere University and Case Western Reserve University. It carries out several studies on TB and HIV. One of the studies is called the Kawempe community study which enrolls household contacts of index cases and offers them IPT. Only HIV positive contacts will be included in the comparison.

This study will therefore evaluate the integration of IPT in the two HIV/AIDS programs (both the process and the outcomes). Permission will be sought from the two institutions to utilize the data collected.

Because this is an operational study, there will be no need for submitting the proposal to the National Council of Science and Technology.

Sample size calculation

For the AIDS Information center, all HIV-positive clients that were enrolled and screened for TB from 2001 to date and currently attending the center will be enrolled in this study.

For the MU-CWRU TB clinic, all HIV-positive household contacts of TB patients who were offered IPT from 2001 to date and currently attending the clinic will be enrolled. HIV prevalence among household

contacts of TB patients is 10 percent. At both centers, records of HIV-positive clients enrolled and screened for TB since 2001 will be reviewed.

Study Period:

3 months

Data collection:

- The program manager of the IPT program in both centers will be interviewed regarding the algorithms and standard operating procedures used.
- Observations of the TB screening process will be carried out in both settings.
- Records of HIV-positive clients that were eligible to receive Isoniazid preventive therapy at the AIDS information Center and MU-CWRU TB clinic in the years 2001-2004 will be reviewed.
- A sample of the patients currently receiving Isoniazid preventive therapy will be interviewed to identify the factors which either facilitate or hinder adherence.
- Key informant interviews with sources within the Ministry of Health will also be conducted.

Population of interest:

(Describe populations to be studied and strategies for achieving appropriate sample size).

- HIV-positive clients eligible to receive Isoniazid preventive therapy at the AIDS Information Center and MU-CWRU TB clinic in the years 2001-2004.
- Consenting patients currently receiving Isoniazid preventive therapy will be interviewed to find out the reasons for adhering and not adhering.
- Program managers and counselors at the two centers.
- Ministry of Health officials in the TB and HIV control programs.

Budget justification:

(Explain the study costs, including incentives for clients)

Budget

This study will involve the hiring of a principal investigator from the MU-CWRU Research Collaboration Center at 100 percent time for three months. This investigator will be supported by a social science researcher and statistician both of whom will be hired at 30 percent for the two months. Other costs include travel and administrative costs and costs associated with disseminating the study findings. The total budget for this study will not exceed \$10,000.

Primary Expect Outcome:

(Describe what you expect to better understand because of the study).

The primary expected outcome is to understand the challenges faced in integrating IPT into HIV/AIDS prevention, care and treatment programs and to explore the desirability and feasibility of scaling up this approach to a national level.

Other outcomes include:

- The algorithm being used at the AIDS information center and TB research clinic to screen for TB among HIV positive clients.
- The feasibility of providing Isoniazid preventive therapy in an HIV/AIDS program setting.
- Uptake of TB preventive therapy in a program setting.
- Predicators of adherence/compliance to Isoniazid preventive therapy.
- Toxicity of IPT in HIV/AIDS program setting

ANNEX 2: TB SCREENING TOOL

TB PREVENTION PROGRAMME ENTRY FORM

AIC no. _____

Date _____

Section 1: Counselor Code _____ HIV test date _____ Clientid No. _____ Client Status 1[] New 2[] Old 3[] Referral 4[] returnee. Full name: _____ If Referred, from where? _____ Date of birth (dd/mm/yyyy) _____ If Returnee; 1[] PPD Neg 2[] PPD Pos 3[] Incomplete 4[] Other _____ Type of screening 1 [] Active and Latent TB 2[] Active TB only Sex 1[] Male 2[] Female Age _____	
a. Have you ever received treatment for TB? 1[] Yes 2[] No 3[] Don't know b. Have you ever had a seizure/fit/ or convulsion? 1[] Yes 2[] No 3[] Don't know c. Are you pregnant? 1[] Yes 2[] No 3[] Not applicable 4[] Don't know d. Are you currently breast-feeding? 1[] Yes 2[] No 3[] Not applicable e. Do you stay far and will not be able to return for follow-up? 1[] Yes 2[] No f. Do you drink alcohol? 1[] Yes 2[] No If yes, Are you willing to stop taking alcohol? 1[] Yes 2[] No	
Section 2: Clinician's Examination Clinician Code _____ Do you currently have a cough? 1[] Yes 2[] No For how long? _____ (Days) Have you coughed blood in the past 3 months? 1[] Yes 2[] No Do you have a fever? 1[] Yes 2[] No For how long? _____ (Days) Have you had unintentional weight loss in the past 3 months? 1[] Yes 2[] No In the past 3 months, have you had night sweats for more than 5 days, defined as sweating that soaks bed sheets? 1[] Yes 2[] No Does patient have abnormal lymph nodes? 1[] Yes 2[] No If yes: 1[] Enlarged 2[] Fluctuant 3[] Matted Does patient have yellow eyes? 1[] Yes 2[] No Patient too ill for IPT? 1[] Yes 2[] No Remarks on exam _____ Laboratory Requests: (FILL LOCATOR CARD IF APPROPRIATE) Sputum: 1[] Yes 2[] No Chest X-ray: 1[] Yes 2[] No PPD placed: 1[] Yes Referred for Sputum Induction 1[] Yes 2[] No Referred for lymph node biopsy?: 1[] Yes 2[] No 2[] No	
Section 3: Laboratory Results Sputum 1: AFB1: 1[] Pos 2[] Neg 3[] Not done Gram stain _____ Sputum 2: AFB2: 1[] Pos 2[] Neg 3[] Not done Sputum 3: AFB3: 1[] Pos 2[] Neg 3[] Not done Final Sputum Result: 1[] Pos 2[] Neg 3[] Incomplete Chest X-ray (No. _____) X-ray Result: 1[] Consistent with TB 2[] Normal 3[] Abnormal, not consistent with TB 4[] Not done Abnormality _____ Already/Put on Antibiotics for pneumonia? 1[] Yes 2[] No Improved with Antibiotics? 1[] Yes 2[] No 3[] No return PPD maximum diameter _____ mm (99=No return) Biopsy Result: _____ If PPD ≥ 5mm, no pregnancy, not breastfeeding no alcohol abuse, then. Would you consider taking medicine to prevent TB? 1[] Yes 2[] No If no, why not? 1[] Undecided 2[] In a hurry 4[] Prefers miracle healing 5[] Doubts HIV results 6. Other: _____	
Section 4: Final Client Status: 1[] Smear-pos. TB 2[] Smear-neg. TB 3[] Extra-pulmonary TB 4[] Treated pneumonia 5[] Normal 6[] Other, specify: _____ Final Action: 1[] Enrolled 2[] Excluded 3[] Declined 4[] PPD Negative 5[] Referred to TB Clinic 6[] Did not return 7[] Other, specify: _____ If referred, TB Clinic _____ 8[] Unresolved pulmonary condition 9[] Did not reach Medical booth Date of enrolment: _____ IPT no. _____ Willing to be visited at home by a trained volunteer? 1[] Yes (FILL LOCATOR CARD) 2[] No Weight _____ Kgs Version 21 24 November 2003	

ANNEX 3: IPT FOLLOW-UP PROTOCOL

REGISTER OF ATTENDANCE

NAME _____ PROGRAM NO |__|_|_|_| AICNO |__|_|_|_|_|_|_|_|_|_|_|

Weight _____Kgs

Due Date /__/_/____/ Actual Date /__/_/____/ Service provider's Code |__|_|_|_|

Follow up Category 1.Visit1 2. Visit2 3 Visit3 4.Visit 4 5.Visit5
6.Unscheduled 7.Incomplete home 8.Incomplete clinic 9.Restart.

Attended Venue 1. Clinic 2.Home

If home Why? _____

Have you had any problems with taking any of the tablets? 1:yes 2: no

If yes, what problem _____

Have you missed taking tablets? 1:yes 2:no How many days did you miss /__/_/

Why did you miss? 1: sick 2: forgot 3: side effects 4: tired of tab
5: other specify _____

Side effects (Should have started after starting on the tablets)?

Does client have signs of jaundice/hepatitis 1:yes 2: no

Have you developed a severe rash 1:yes 2: no

Do you have burning sensation, numbness of hands and feet? 1:yes 2: no

Have you developed new, persistent joint pains 1:yes 2: no

Do you have persistent feel of vomiting 1:yes 2: no

Do you have pain in the stomach 1:yes 2: no

Specify any other new symptoms have you developed _____

Signs of active TB

Do you have a cough lasting for > 2 weeks 1:yes 2: no

Do you have a fever lasting for > 2 weeks 1:yes 2: no

Have you had bloody sputum production 1:yes 2: no

Do you have night sweat(s) that Soaks the bed sheets 1:yes 2: no

No. of INH tabs remaining _____ Amount of drugs given INH _____ VitB6 _____
(Remind client not to take alcohol while on this treatment)

Remarks _____

Due Date for next visit /__/_/____/

OUT OF PROGRAM 1:yes 2:no

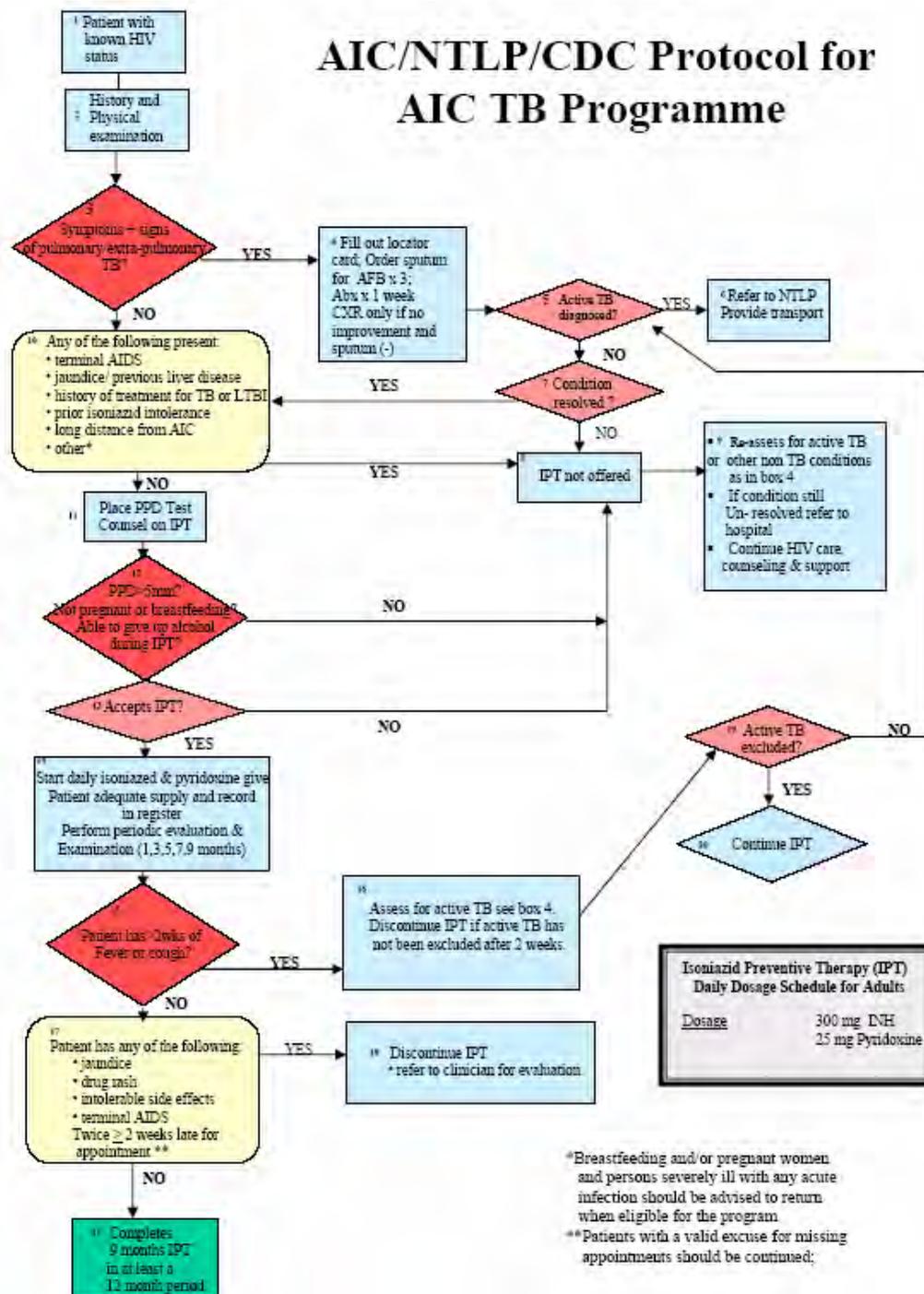
If yes, why 1: Deceased 2:Terminal aids 3: Side effects
4: Active TB 5: Transport problems 6:Shifted/moved to another place
7:Completed 8:Twice two weeks late 9:Unknown reason/lost
10:Refused drugs 11.Others _____

Form 5

06/12/2001

ANNEX 4:AIC/NTLP/CDC PROTOCOL FOR AIC TB PROGRAM

AIC/NTLP/CDC Protocol for AIC TB Programme



**CLIENTS ' TOOL
USAID OFFICE**

**Evaluating the Integration of Preventive Therapy In HIV/AIDS /TB
Prevention and Control Program in Uganda.**

July/ August 2006

Questionnaire Number: _____

Administrative Area

Name of Organization: _____

Date of Interview: _____ DD/MM/YY: ____/____/____

Name of Interviewer: _____ Starting Time: _____

INTRODUCTION

Good Morning/Afternoon, USAID-Uganda office would like to evaluate the integration of TB preventive therapy in HIV/AIDS prevention and control program in Uganda. Few centers have integrated preventive therapy into their routine activities using support from various organizations. This exercise aims at identifying levels of integrating preventive therapy into HIV/AIDS and TB program, challenges faced (in terms TB screening, adherence, toxicity, adherence and monitoring patients) and lessons learned that can serve as a learning experience for other centers that are involved in providing/ planning for HIV/AIDS and TB programs

All the information you give will be kept strictly confidential. You may refuse to answer any of the questions, and you may stop the interview any time. Do you have any questions for me now? Do you agree to participate?

1- Yes _____

2-No _____

Interviewer's signature _____

_____ Date

SECTION A: DEMOGRAPHICS

- 1. Respondent's gender(circle) 1- Male 2-Female
- 2. Date of Birth _____
- 3. Date of starting IPT _____
- 4. When were you diagnosed with HIV? _____
- 5. For how long have you been attending clinics at this organization (*in complete years*):
_____ (date of starting _____)
- 6. Ever since you started attending this clinic, have you been attending other clinics? **Yes /No**
- 7. Why? Or for what?

SECTION B: CORE QUESTIONS

- 8. As a person living with HIV/AIDS, what are the most challenging opportunistic infections you know?

- 9. Among the opportunistic infections named above, which ones do you rank as the first three which lead HIV positive individuals to progress easily to AIDS?

- 10. Have you ever heard of IPT? **Yes/ No**
- 11. Are you on IPT? **Yes/ No**
- 12. If yes to 11 above, when were you started on IPT? (date)

- 13. If yes to question 11, what drug/s are you using for IPT?

- 14. What challenges are you facing in taking IPT?

15. What challenges are you facing that relate to the tablets? Regarding *Color, taste, number, size, frequency, length of medication, shape etc?*

16. On the follow up visits at this clinic, on average how long do you take from time of arrival to departure? (with the medication) (*in minutes*) _____

17. Do you consider this time spent at the clinic **a) short** **b) medium** **c) long**

18. Have you ever been on IPT before being introduced to this program? **Yes / No**
Where? _____

19. Have you defaulted during treatment? **Yes / No**

20. How have the health workers at this clinic supported you to take your IPT drugs?

21. What are some of the health problems you got/get and you think are attributed to taking IPT?

22. What other preventive measures for opportunistic infections in HIV have you heard about?

23. Which of these interventions are you currently on/benefiting from?

24. Have you ever been on ART? **Yes/ NO**

25. Are you currently on ART? **Yes/ NO**

26. If No to question 25, why are you not on ART?

27. If yes to question 25, where do you get ART supplies and guidance from?

28. Why do you get supplies from there and not elsewhere?

29. Which medication combination are you on?

30. Mention any side effects you have experienced that you think or know are attributed to ART.

31. What is your main source of information related to HIV/AIDS management?

32. Regarding the use of IPT, what message do you have for the following people in relation to IPT scaling up?

a. PHAs

b. The Health workers about IPT

c. The government and donors.

d. Any other contribution?

Thank you for contributing to this study.

INTERVIEW:

1 = Complete
2 = Not completed
3 = Not done

**TOOL 2: CLINICIANS/PROVIDERS' TOOL
USAID OFFICE**

**Evaluating the Integration of Preventive Therapy In HIV/AIDS /TB
Prevention and Control Program in Uganda.**

July/August 2006

Questionnaire Number: _____

Administrative Area

Name of Organization: _____

Date of Interview: _____ DD/MM/YY: ____/____/____

Name of Interviewer: _____ Starting Time: _____

INTRODUCTION

Good Morning/Afternoon, USAID-Uganda office would like to evaluate the integration of TB preventive therapy in HIV/AIDS prevention and control programs in Uganda. Few centers have integrated preventive therapy into their routine activities using support from various organizations. This exercise aims at identifying the level of integration of preventive therapy into HIV/AIDS and TB programs, challenges faced (*in terms TB screening, adherence, toxicity, adherence and monitoring patients*) and lessons learned that can serve as a learning experience for other centers that are involved in providing/planning for HIV/AIDS and TB programs.

All the information you give will be kept strictly confidential. You may refuse to answer any of the questions, and you may stop the interview at any time. Do you have any questions for me now? Do you agree to participate?

1- Yes _____ 2-No _____

Interviewer's signature _____ Date _____

SECTION A: DEMOGRAPHICS

- 1. Respondent's gender 1- Male 2-Female
- 2. Title: _____

SECTION B: CORE QUESTIONS

- 3. What are the most challenging Opportunistic Infections (OIs) in caring for HIV positives?

- 4. Among the OIs mentioned above, which ones do you rank as the first three, which lead HIV positive individuals to progress easily to AIDS if no intervention is put in place? (*Arrange from highest to lowest risk*)
 - a. _____
 - b. _____
 - c. _____
- 5. Briefly outline the procedures followed in screening for TB among HIV positive clients in your center?

- 6. Which protocol, guideline/s and screening algorithms are you using for recruiting patients on IPT? (*please provide a copy*)

- 7. Who/which organization developed the screening algorithm that you are currently following while screening for latent TB?

8. Are you aware of MoH guidelines? **Y / N (circle)**
9. If Yes to *Question 8*, are the MoH guidelines the ones you use? **Y / N (circle)**
10. If not why?

11. How do you handle HIV positive clients with :
Active TB disease?

Latent TB:

12. Studies have recommended integration of Isoniazid Prophylactic Therapy (IPT) in HIV/AIDS prevention and control programs, to what extent are such recommendations put into practice in your organization?

Research intervention areas *(1-5 five highest)*

_____	1	2	3	4	5
_____	1	2	3	4	5
_____	1	2	3	4	5
_____	1	2	3	4	5

13. In your view to what extent has the MoH-Uganda implemented IPT? *(1-5 five highest)*

1 2 3 4 5

14. Based on your own experience, on a scale of one to five *(five is highest score)*, do you feel that it is necessary to give IPT to HIV positive clients with latent TB?

1 2 3 4 5

Why?

15. When should IPT be initiated in HIV/AIDS processes?

16. What challenges are you experiencing regarding:

a. Adherence

b. Failure Rates

c. Toxicity

d. Dropout

e. Briefly describe lessons learned so far from this exercise (consider Adherence, failure rates, toxicity, dropout, etc.).

17. Outline other challenges you have so far met while providing IPT to HIV positive clients: (*human resources, follow up, finance, etc*)

18. How do you monitor and measure the following:

a. Adherence

b. Dropout

c. Toxicity

19. What do you do to ensure that you minimize dropouts?

20. Briefly describe the benefits so far achieved ever since you introduced IPT as part of the package for HIV/AIDS care in your organization (*Comment on training, IEC materials, diagnostic tools, adherence, etc.*).

21. If IPT is to be fully integrated into the care for HIV positives, what factors should be considered in order to register and consolidate success/benefits in its implementation?

22. What are other feasible preventive therapy options available for resource constrained countries like Uganda where even HIV prevalence is still high?

23. What are your recommendations to the Ministry of Health as regards control of TB disease among HIV positive clients?

24. Are you aware of any organization/center in Uganda where IPT is part of the package provided to HIV positive clients? (List them)

25. Are you in any form of partnership with any of these organizations? Which organization and what partnership?

26. Do you think IPT should be scaled up in the districts? (1-5 five highest)

1 2 3 4 5

Why?

27. What are the envisaged challenges in scaling up IPT in the district?

28. What is the annual cost of the IPT program? _____ (Year 1/2/3/4/5)

Thank you for contributing to this study!

INTERVIEW:

- 1* = *Complete*
- 2* = *Not completed*
- 3* = *Not done*

**TOOL 3: MANAGERS AND POLICY MAKERS
USAID OFFICE**

**Evaluating the Integration of Preventive Therapy In HIV/AIDS /TB
Prevention and Control Program in Uganda.**

July/August 2006

Questionnaire Number: _____

Administrative Area

Name of Organization: _____

Date of Interview: _____ DD/MM/YY: ____/____/____

Name of Interviewer: _____ Starting Time: _____

INTRODUCTION

Good Morning/Afternoon, USAID-Uganda office would like to evaluate the integration of TB preventive therapy in HIV/AIDS prevention and control program in Uganda. Few centers have integrated preventive therapy into their routine activities using support from various organizations. This exercise aims at identify level of integrating preventive therapy into HIV/AIDS and TB program, challenges faced (in terms TB screening, adherence, toxicity, adherence and monitoring patients) and lessons learned that can serve as a learning experience for other centers that are involved in providing/ planning for HIV/AIDS and TB programs

All the information you give will be kept strictly confidential. You may refuse to answer any of the questions, and you may stop the interview any time. Do you have any questions for me now? Do you agree to participate?

1- Yes _____ 2-No _____

Interviewer's signature _____ Date _____

8. Describe the current guidelines from the Uganda Ministry of Health (MoH) on how to handle latent TB among HIV positive clients.

9. Researchers have recommended integration of Isoniazid Prophylactic Therapy (IPT) in HIV/AIDS prevention and control program. To what extent are such recommendation been put into practice by:

Your Organization

MoH Uganda

10. From your own experience, do you feel that it is it absolutely necessary to give IPT to HIV positive clients with latent TB? (**Give reasons for your answer**)

11. If IPT is to be integrated into HIV/AIDS and TB care, what is likely to be the consequences for the following: adherence, failure rates, toxicity and dropout rates?

12. Briefly describe the likely benefits if IPT is integrated as part of the package for HIV/AIDS.

13. Outline the likely challenges in providing IPT to HIV positive clients:

14. If IPT is to be fully integrated into the care for HIV positives, what factors should be considered in order to register and consolidate success/benefits in its implementation?

15. What are other feasible preventive therapy options available for resource constrained countries like Uganda where HIV prevalence is still high?

16. Are you aware of any organization/center in Uganda where IPT is part of the package provided to HIV positive clients? (List them)

17. For centers/organizations that do not provide IPT, what other preventive therapy are they giving HIV positives with latent TB?

18. For Program managers, how many officers per category are responsible for running the IPT program?

a. Doctors

b. Counselors

c. Nurses

d. Laboratory staff

e. Others

19. If the Uganda MoH is to scale up IPT, what advice would you offer them before the exercise?

20. What is your overall recommendation to the Ministry of Health in regards to prevention and control of TB disease among HIV positive clients?

21. Any other contributions?

Thank you for answering my questions!

INTERVIEW: 1 = *Complete*
 2 = *Not completed*
 3 = *Not done*