IMPACT OF INTEGRATING FAMILY PLANNING SERVICES INTO HIV CARE ON REPRODUCTIVE HEALTH: A RETROSPECTIVE COHORT STUDY

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DECLARATION

This dissertation is my original work and has not been presented else where, to the best of my knowledge.

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DEDICATION

To my Grandmother Toiyoi Barmao Salil

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LIST OF ABBREVIATIONS

AIDS- Acquired Immunodeficiency Syndrome

AMRS- AMPATH Medical Records System

ARV-Anti Retrovirals

cART- Combined Anti Retroviral Therapy

FP- Family Planning

HIV-Human Immunodeficiency Virus

MCH/FP-Mother Child Health Clinic/Family Planning

MTRH-Moi Teaching and Referral Hospital

PMTCT- Prevention of Mother-To-Child Transmission of HIV/AIDS

RH-Reproductive Health

STI-Sexually Transmitted Infection

UN-United Nations

USAID-AMPATH- United States Agency for International Development - Academic Model Providing Access To Healthcare

WHO-World Health Organization

ABSTRACT

Background: HIV-infected patients like their uninfected counterparts are faced with reproductive health needs including family planning (FP). FP has been shown to play a role in primary and secondary prevention of HIV virus transmission including prevention of mother-to-child transmission of HIV/AIDS. Despite this, FP uptake is low among HIV-infected women. This is attributed, in part to the vertical nature of FP and HIV care programs. To address this challenge, the United States Agency for International Development - Academic Model Providing Access To Healthcare (USAID-AMPATH) partnership integrated FP services into one of its HIV clinics.

Objectives: Among HIV-infected women attending the USAID-AMPATH HIV Care clinic with and without integrated FP services, to: 1) determine and compare the incidence of new users of modern FP methods, 2) determine and compare the incidence of pregnancy and 3) determine the correlation between incidence of new use of modern FP methods and incidence of pregnancies with socio-demographic variables.

Methods: This was a retrospective cohort study carried out in the Eldoret clinic of the USAID-AMPATH partnership, Western Kenya. The primary outcome measures, incidence of new use of modern FP method and pregnancy were compared between HIV-infected women attending the HIV care module with integrated FP services (exposed group) and HIV-infected women attending HIV care modules which had not yet integrated FP services (unexposed group). The exposed and unexposed were matched by age on a ratio of 1:2 respectively. The secondary outcome measures were the correlations of these incidences with socio-demographic variables that were significant in the univariate analysis.

Results: Between October 2007 and February 2009, 4,138 patients met the eligibility criteria (1,498 were exposed to the integrated module and 2,640 were unexposed). There was a 10.8% ($p<0.001$; 95% CI: 7.3%, 14.3%) increase in new condom use; 7.1% ($p<0.001$; 95% CI: 3.6%, 10.6%) increase in new FP methods use other than condoms and 1.3% ($p=0.24$; 95% CI: -3.4%, 0.8%) decrease in the incidence of pregnancy among the exposed group. The incidence rate of new use of modern FP methods was 46.6 per 100 person years (95% CI: 44.0, 49.3) and 36.6 per 100 person years (95% CI: 34.7, 38.5) for the exposed and the unexposed respectively. The patients exposed to the integrated model were 27 times more likely to use modern FP methods than the unexposed (RR=1.27; 95% CI: 1.14, 1.41). The incidence rate of pregnancy was 8.69 per 100 person years (95% CI: 7.31, 10.31) and 8.37per 100 person years (95% CI: 7.34, 9.53) for the exposed and the unexposed respectively. There was no significant difference in likelihood of pregnancy between the exposed and the unexposed (RR=1.04; 95% CI: 0.83, 1.30). Disclosure to partner, sex within the last 6 months and more years of schooling was associated with an increased incidence of modern FP method use. More years of schooling, higher age at enrolment and having more children living with the patient were associated with a reduction in the incidence of pregnancy.

Conclusion: Integrating FP services into HIV care and treatment programs is associated with: a significant increase in the incidence of new condom and FP method other than condoms use of 10.8% and 7.1% respectively and a none statistical but clinical reduction in the incidence of pregnancy of 1.3%. Funding agencies and programs should consider integrating FP services into HIV care and treatment programs. There is need for further studies on strategies to increase FP uptake by HIV-infected patients.

CHAPTER 1: INTRODUCTION

1.1 Background and Literature Review

Sub-Saharan Africa carries a huge burden of the global HIV epidemic with nearly two-thirds of those living with HIV/AIDS residing in this region. Women form 60% of people living with HIV/AIDS in Africa[1]. An average of 6,800 new HIV infections and 5,700 AIDS related deaths occur globally each day[2]. The global pattern is typified in Kenya, where 60% of the estimated 1.4 million adults who are HIV-infected are women of reproductive age[3]. According to the Kenya AIDS Indicator Survey of 2007, the adult HIV prevalence in Kenya is estimated at 7.4 %[3] which is higher than in earlier surveys; 6.7% [4] and 7.3%[5] (Kenya Demographic Health Survey of 2003 and the antenatal care sentinel surveillance of 2006) respectively. Earlier research suggested that, in the absence of treatment, women who are HIV-infected were less sexually active compared to their uninfected counterparts, because of higher morbidity[6, 7]. Current evidence from resource constraint countries reveals that, combined antiretroviral therapy (cART) has dramatically improved the survival and quality of life for HIV-infected patients[8-10]. This in addition to perceptions of reduced infectivity associated with the increased use of cART, are anticipated to increase sexual activity among HIV-infected patients[11, 12]. The problem facing the majority HIV care programs in resource poor settings is how to successfully provide reproductive health (RH) services including family planning (FP) to HIV-infected women in their care programs in a feasible and sustainable manner.

According to the World Health Organization (WHO) and the United Nations (UN), FP is one of the strategies that can address the HIV/AIDS pandemic. FP is central to achieving the four prongs of the strategy of Prevention of Mother-to-child transmission of HIV/AIDS (PMTCT) proposed by the WHO and the UN[13]. In preventing HIV infection in all people, especially young women (prong 1), correct and consistent use of condoms[14, 15] will ensure that those who are not HIV-infected remain uninfected. FP will also be critical in preventing unwanted pregnancies among HIV-infected women and ultimately reducing HIV-positive births (prong 2), which is particularly significant in sub-Saharan Africa, where as many as 50% of

pregnancies among HIV-infected women are considered unintended[16, 17]. Modeling studies in Africa have demonstrated that preventing unintended pregnancies among HIV-infected women is more cost-effective as a PMTCT intervention than providing single dose nevirapine alone. For the same cost, FP services can avert nearly 30 percent more HIV-positive births than use of single dose nevirapine[18-20]. PMTCT among HIV-infected women (prong 3) and providing care and support to HIV-infected women, their infants, and families (prong 4), is achieved to a lesser extend by FP. FP achieves prongs 3 and 4 by allowing for pregnancy planning and hence pregnancies can be scheduled for a time when a woman is stable on antiretrovirals and less likely to transmit HIV. It also allows women and families to have control over the number, timing, spacing or limiting of births.

The overall FP uptake in Kenya is low. According to the Kenya Demographic health Survey of 2003, only 30.5% of married women were on a modern method of contraception (female sterilization, oral contraceptive pill, intrauterine contraceptive device, implants or injectable depo provera), and only 1.2% of them were using condoms[21]. The unmet need for FP in Kenya is estimated at 24% [22] and is thought to be even higher amongst HIV-infected women. This is attributed to the fears that HIV-infected women cannot not use majority of FP methods due to their HIV diagnosis. Contrary to this perception, its now known that with individualized care, HIV-infected patients are able to use any method of the FP methods available [23, 24].

There are data supporting the supposition that HIV-infected patients, when given access and information on FP, increase their use of contraception[25-29]. One success story is exemplified by progressive integration of primary care services including FP into HIV counseling and testing activities at a voluntary, counseling and testing (VCT) center in Port au Prince, Haiti, between 1985 and 2000. In this program, of the 6,709 adults presenting for HIV testing: 1274(19%) became new users of a contraceptive method and of the contraceptive users, 902 (70% of total FP users) chose to use condoms[30].

Although the World Health Organization, World Bank, and the European Union support the integration of FP and HIV treatment and care, most HIV programs focus on HIV treatment and little or no emphasis is placed on FP services. Such

integration is further impeded by funding restrictions[31]. Separate funding for these two programs and the resulting vertical organization of health services undermine coordination between departments and limit providers' ability to address the contraceptive needs of HIV-infected patients[32]. Based on the evidence that FP is efficacious in both primary and secondary prevention of HIV transmission the United States Agency for International Development - Academic Model for Providing Access To Healthcare (USAID-AMPATH) Partnership referred to as AMPATH hereafter started a pilot program integrating FP services into one of its HIV clinics allowing for provision of same-day 'one stop shop care' for these two services. In this paper we describe this model's impact on the incidence of new use of modern FP methods and pregnancy.

1.2 Justification

HIV-infected patients are faced with the similar RH needs as their non-infected counterparts. HIV infection modifies but does not eliminate their reproductive desires, and intentions. Such needs include having control over the number, timing, spacing and limiting of their children. The need for safe sex among these patients is of significance because most of these patients are asymptomatic and sexually active and those who were symptomatic eventually resume sexual activity due to the positive effects of antiretroviral therapy. FP is one of the proven ways of both primary and secondary prevention including PMTCT. Until now however, the FP needs of HIV-infected people have largely been neglected. As regards to PMTCT, FP enables HIV-infected women to plan pregnancies when the probability of vertical transmission is lowest: with high CD4 counts, low viral loads, an appropriate, planned mode of delivery and availability of safe feeding practices for their infants. This study seeks to determine impact of integrating FP services into HIV care on reproductive health. Cross-sectional descriptive studies form the bulk of earlier research on this subject; this design does not show cause effect, it's only appropriate for hypothesis generation but not measure impact of integration. Retrospective cohort study design used in this study was appropriate for measuring impact, lacks observational bias, made use of available patient data and is cost-effective. The information gained will be used to construct recommendations for

other programs on how to achieve FP integration into HIV care services and will provide pilot data for future studies.

1.3 Research Question

What is the impact of integrating FP services into HIV care and treatment on the incidence of new use of modern FP methods and pregnancy among HIV-infected women of reproductive age?

1.4 Hypothesis

Integrating FP services into HIV care affects the incidence of new use of modern FP methods and the incidence of pregnancy among HIV-infected women of reproductive age.

1.5 Broad Objective

To determine and compare the impact of integrating FP services into HIV care on the incidence of new use of modern FP methods and pregnancy between HIV-infected women of reproductive age being cared for in the FP/HIV care integrated model and non-integrated model.

1.5.1 Specific Objectives

Primary Objectives

1. To determine and compare the incidence of new users of modern FP methods (female sterilization, pill, intrauterine contraceptive device, injectables, implants or condoms) between HIV-infected women being cared for in the FP/HIV care integrated model and non-integrated model.
2. To determine and compare the incidence of pregnancy between HIV-infected women being cared for in the FP/HIV care integrated model and non-integrated model.

Secondary Objectives

1. To determine the correlation between incidence of new use of modern FP methods and incidence of pregnancies with socio-demographic variables (HIV disclosure, years of school, age at enrolment, sex in the previous 6 months, children living with patient, number of live births and times pregnant).

CHAPTER 2: METHODS

2.1 Study Design

This was a retrospective cohort study of HIV-infected women enrolled in the AMPATH program. For the purpose of this study exposure was defined as care within the AMPATH model that had integrated FP services. Whereas unexposed group were patients attending care within modules without integrated FP (regular care). Since HIV care at AMPATH is protocol-led, the exposed and the unexposed groups were similar in terms of HIV care and the only difference was exposure to the FP integration described afterward. The primary outcome measures are the incidences of: new use of modern FP methods and pregnancy. On other hand secondary outcome measures are the correlations between incidences of new use of modern FP methods and pregnancy with socio-demographic variables that were significant in the univariate analysis (HIV disclosure, years of school, enrolment age, sex in the previous 6 months, children living with patient, number of children given birth to and times pregnant).

2.2 Study Site and Setting

The study was conducted at the Eldoret clinic (AMPATH Center), of the AMPATH program. AMPATH Center is located at the Moi Teaching and Referral Hospital (MTRH). It has 3 comprehensive adult HIV care clinics referred to as module I, II and III. Adult patients, when referred to the AMPATH Center, are assigned to a particular module by the records clerk; Module assignment is random. Patients, once assigned to a module, receive care within that module. Crossover from one module to another is discouraged because AMPATH believes in continuity of care (chronic care model). The AMPATH program described elsewhere[33-36] began to provide HIV care in 2001. As of end of May 2009 the program was caring for over 70,000 HIV-infected adult patients of whom 70% are women in 18 Kenya Ministry of Health facilities across western, Kenya. There were more than 17, 000 adult patients with more than 11,000 (65%) women enrolled in the AMPATH Center as of end of May 2009.

Original AMPATH HIV Care Model

In the original AMPATH care model, AMPATH enrolled patients are offered some degree of FP services in the HIV clinic in form of condom counseling which is geared toward reduction of HIV virus transmission. Condoms are strategically placed in the waiting bay, check in/out rooms and consultation rooms for those patients who need them. Patients who require FP methods other than condoms are referred to the mother child health/family planning (MCH/FP) clinic for FP services. The MCH/FP clinic and the HIV clinic are vertically integrated and independent. The HIV clinic is run under the department of internal medicine and the MCH/FP clinic is run under the departments of reproductive health and pediatrics. Patients who need FP services are referred to MCH/FP clinic after their appointment in the HIV clinic. In this model, it is the patients responsibly to ensure that they have their FP appointment after referral from the HIV clinic. Unlike HIV care which is provided free of charge, services in the MCH/FP clinic require a patient's co-pay. Based on this model, two challenges were anecdotally observed. To start with, patients who managed to get FP clinic appointments had an increased burden of hospital visits. Secondly, there was a relative underutilization of FP services by HIV-infected patients due to the fact that getting a FP appointment depended solely on the individual patient.

FP and HIV Care Integrated Model

Integration of FP services into HIV care pilot study started in October 1st 2007 and is ongoing in the AMPATH center module I HIV clinic. Modules II and III continue to offer original care model type of care described earlier. In the integrated model, FP services are housed within the HIV clinic. Nurses experienced in offering FP services were re-located to module I RH room. The RH room forms part of the patient flow in the HIV clinic. A blend of both vertical and horizontal integration is utilized. Some degree of vertical integration for both FP and HIV care is maintained to ensure that the focus and specific nature of these two service provisions is not weaken by a complete horizontal integration. The link between the two services forms the horizontal nature of the model and at module level both services are run under the same in charge. Services that are horizontally integrated are: same-day

'one-stop-shop' appointments, patient flow logistics, central check in/out, use of same patient charts, use of same patient identifier number, consultations, outreach services for loss to follow up patients, module progress meetings and passage of same messages (adherence, contraception and disclosure). During the counseling sections, structured counseling is done and the RH nurse completes a structured FP and Sexually Transmitted Infections (STI) encounter form (appendix II). Patients are allowed to make informed choices on which FP methods to use. All FP methods except surgical sterilization are offered through the module. Patients who request surgical sterilization and those in the non-integrated modules (II and III) are referred to MCH/FP clinic.

2.3 Study Population

Adult HIV-infected women attending AMPATH Center HIV clinic formed the study population. Women cared for in module I were considered the exposed group while women cared for in model II and III were considered unexposed group for this study.

2.3.1 Inclusion Criteria

1. HIV-infected female patients enrolled in AMPATH Center Age 15 to 49 years
2. Enrolled into AMPATH after October 1st 2007 (initiation date for FP integration)

2.3.2 Exclusion Criteria

1. Patients, who interchanged modules during the time period of this study
2. Patients who had only one visit after initiation of the integrated model (October 1st 2007)

2.4 Sample Size and Sampling

All 4,138 patients who met the eligibility criteria between October 1st 2007 and February 28th 2009 formed the cohort for this study and were included in the analysis; (n=1,498) and (n=2,640) for the exposed and unexposed groups respectively. The exposed and the unexposed were matched in a ratio of 1:2 by age. A match with-replacement strategy to infer the exposure effect (integration) by matching each exposed subject to two unexposed subjects was done. This figure is in excess of the calculated sample size of 250 patients per group and increased the

study power from the calculated 80% to 98%. This sample size was arrived at by using a 12% increase of FP uptake above the average baseline up take of 30% (average of FP uptake in the 3 provinces where AMPATH operates[4]). We estimated using the sample size formula in figure 1, that we would need approximately of 500 patients in total (250 per group) to achieve an 80% power to detect the stated difference of 12% in FP uptake between the exposed and unexposed groups (alpha=0.05 two-sided).

Figure 1: sample Size formula

$$n = \frac{2\left(Z_{1-\frac{\alpha}{2}} * \sqrt{2 * \bar{p} * (1-\bar{p})} + Z_{1-\beta} * \sqrt{p_I * (1-p_I) + p_C * (1-p_C)}\right)^2}{(p_I - p_C)^2}$$

Where p_I =the expected proportion in the intervention group

p_C=the expected proportion in the control group

$\bar{p}$ =the mean proportion in the intervention and control groups.

$$n = \frac{2\left(1.96 * \sqrt{2 * 0.36 * (1-0.36)} + 0.842 * \sqrt{0.42 * (1-0.42) + 0.30 * (1-0.30)}\right)^2}{(0.42-0.30)^2}$$

$$n = \frac{2\left(1.96 * \sqrt{2 * 0.23)} + 0.842 * \sqrt{0.2436 + 0.211}\right)^2}{0.0144}$$

$$n = \frac{2(1.3304 + 0.5671)^2}{0.0144}$$

$$n = \frac{7.2009}{0.0144}$$

$$n = 500$$

$$n_I = 250$$

$$n_C = 250$$

2.5 Data Collection and Management

All data used in this study were derived from existing clinical data collected during the normal patient care in module I, II and III from October 1st 2007 to February 28th 2009. All medical records of AMPATH patients are recorded on paper forms at each patient visit, and these paper forms are cross-checked by data entry clerks to ensure that they are no missing patients' records. Data is subsequently transferred by data entry to a clinical electronic database; the AMPATH Medical Records System (AMRS). Data for this analysis were extracted from the medical records by submitting a data abstraction request form defining the key variables needed for the analysis to the AMPATH research department. This study did not include new data outside the normal clinical data collected at a patient visit.

Data from the routine initial encounter form (completed on enrolment for every patient) and adult return visit form (completed on each subsequent patient visits) were used for analysis in this study (appendix II). These two forms are universal for both the exposed and unexposed groups. Data from the FP and STI forms was not used for this analysis, because this form is unique only for the exposed (module I) patients. From the initial encounter form the following variables were extracted: patient's demographics (children living with the patient, sex in the previous 6 months, years of school, patient's age at enrolment, number of children, times pregnant, HIV disclosure and days before start of the integrated model) and pregnancy status at enrollment. From the adult return visit form: pregnancy, FP method, current antiretroviral therapy regimen, and latest CD4 count were extracted.

2.6 Data Analysis and Presentation of Results

All patient identifiers were removed prior to data analysis. Data was analyzed using STATA computer package.

Descriptive Analysis: summaries and comparisons of demographic/social characteristics (children living with the patient, Sex in the previous 6 months, years of school, patient's age at enrolment, number of children, times pregnant, HIV disclosure and days of follow up since start of the integration), ARV status,

pregnancy status and CD4 counts was carried out. These were presented descriptively in form of Means, medians, standard deviations, inter quartile ranges and percentages.

Primary Outcome Analysis: Incidence of: new condom use, new FP methods use other than condoms and pregnancy was determined between the exposed and unexposed groups. Exposure effect (incidence) was based on analysis that matches (by age) 1 exposure with 2 unexposed in a ratio of 1:2. For condom use and other FP methods use other than condoms, subjects who responded "no" or had missing values during the follow-up were considered not using condoms or other FP methods other than condoms.

Secondary Outcome Analyses:

For secondary analysis univariate analysis (unadjusted odds ratios) was done followed by multi-variate analysis (adjusted odds ratios) which included only covariates that were significant ($p<0.05$) in univariate analysis. This was done to establish correlation between incidences of: new use of condoms, new use of FP methods other than condoms and pregnancy with socio-demographic variables that were significant in the univariate analysis (HIV disclosure, years of school, enrolment age, sex in the previous 6 months, children living with patient, number of live births and times pregnant).

2.7 Ethical Considerations

This study was approved by the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee and the Indiana University School of Medicine Institutional Review Board.

2.8 Limitations of the Study

1. Since the modules (clinics) are situated in the same building there was a possibly of diffusion of information across modules. This coupled with the fact that routinely in AMPATH HIV clinics some degree of FP counseling is done and condoms are issued to patient's bias the results.

2. Data was analyzed after 16 months of the pilot phase. The pilot was initially faced with problems typical to any new program. With longer follow-up and integration we anticipate the outcome variables to move more strongly toward the hypothesized outcomes. Thus in this paper we may under estimate the impact of integration.
3. Due to the retrospective nature of the study miss-classification of variables would have occurred during patient care.

CHAPTER 3: RESULTS

During the 16 month pilot period which started October 1st 2007(commencement of integrated model) and ended February 28th 2009, 4,138 patients meet the eligibility criteria and formed the analysis for this study. (n=1498) were exposed to the integrated module and (n=2640) were the unexposed group.

3.1 Descriptive Analysis

Table 1: Socio-demographic Data at Enrolment

	Exposed to integrated model (n=1498)	Unexposed (n=2640)	P value
Age (mean, sd)	32.7 (7.2)	33.4 (7.2)	0.003
Years of school (mean, sd)	9.2 (3.1)	8.8 (3.1)	<0.001
Sex previous 6 months	1045 (70%)	1684(64%)	<0.001
Number of live births (median, IQR)	2 (1-4)	3 (2-4)	<0.001
HIV disclosure to Partner	607(40%)	962(36.4%)	0.010
HIV disclosure to Healthcare provider	24 (1.6%)	22(0.8%)	0.030
HIV disclosure to Family	304 (20.3%)	616(23.3%)	0.030
HIV disclosure to Others	161 (10.7%)	216(8.2%)	0.007
Times pregnant (median, IQR)	3 (2-4)	3 (2-4)	0.06
Children living with patient (median, IQR)	2 (1-3)	2 (1-3)	0.060
HIV disclosure to Friend	73 (4.9%)	136(5.2%)	0.750
HIV disclosure to Household	15 (1.0%)	27(1.0%)	0.920
Days before commencement of pilot (mean,s	179 (308)	189 (300)	0.290

The large sample size in this cohort made many small differences in baseline characteristics statistically significant; however none of the differences between the groups were clinically significant. From table 1, between the exposed and unexposed group there were differences in: mean age 32.7 and 33.4 respectively (p=0.003), years of school 9.2 and 8.8 respectively (p<0.001), sex in the previous six months 70% and 64% respectively (p<0.001), number of live births 2 and 3 respectively (p<0.001), HIV status disclosure to partner 40% and 36.4% respectively (p=0.01), HIV disclosure to healthcare provider 1.6% and 0.8% respectively (p=0.03), HIV disclosure to family 20.3% and 23.3% respectively (p=0.03) and HIV disclosure to others 10.7% and 8.2% respectively (p=0.007). These statistically

significant variables will be presented has adjusted odds ratios in secondary analysis section. There were no statistically significant differences between the exposed and unexposed groups in: number of pregnancies, number of children living with patient, HIV disclosure to friend, HIV disclosure to household members and number of days on care before commencement of the integrated model, 179 and 189 respectively.

Table 2: At First Follow-up Visit			
	Exposed (n=1498)	**Unexposed (n=2640)**	**p-value**
Pregnant	207 (13.8%)	212(8.0%)	<0.001
On ARV's	579 (38.7%)	948(35.9%)	0.08
CD4 (median, IQR)	330 (203-526)	324 (168-532)	0.34

Table 2, shows variables at the start of follow up; first visit after October 1st 2007. For the exposed group it is the first exposure visit and for the unexposed it is the first visit since commencement of the integrated model. The percentage of those pregnant between the exposed and unexposed groups was statistically significant, 13.8 % and 8.0% respectively (p<0.001). The other two variables: number of patients on ARV's and median CD4 count were not statistically significant between the exposed and unexposed. The number of patients on ARV's was 38.7% and 35.9% respectively (p= 0.08); and the median CD4 count 330 cells/mm^3 and 324 cells/mm^3 respectively (p= 0.34).

3.2 Primary Analysis

Table 3: Exposure Effect (Incidence) at End of Follow Up			
	Incidence	**P-value**	**95% CI**
New Condom use	10.8% increase	p<0.001	7.3%, 14.3%
New FP use other Condoms	7.1% increase	p<0001.	3.6%, 10.6%
Incident pregnancy	1.3% decrease	p=0.24	-3.4%, 0.8%

From table 3, at the end of follow up, the exposure effect (incidence) in the exposed group was: 10.8% (p<0.001; 95% CI: 7.3%, 14.3%) increase in new condom use; 7.1% (p<0.001; 95% CI: 3.6%, 10.6%) increase in new FP methods use other than condoms and 1.3% (p=0.24; 95% CI: -3.4%, 0.8%) decrease in the incidence of pregnancy.

Table 4: Incidence Rate Per 100 Person Years		
	Exposed Incident rate(95% CI)	**Unexposed Incident rate(95% CI)**
New use of Modern FP	46.6 (44.0, 49.3)	36.6 (34.7, 38.5)
Pregnancy	8.69 (7.31,10.31)	8.37 (7.34, 9.53)

From table 4, at the end of follow up the incidence rate of new use of modern FP methods is 46.6 per 100 person years (95% CI: 44.0, 49.3) and 36.6 per 100 person years (95% CI: 34.7, 38.5) for the patients exposed to the integrated model and the unexposed respectively. On the other hand, the incidence rate of pregnancy is 8.69 per 100 person years (95% CI: 7.31, 10.31) and 8.37per 100 person years (95% CI: 7.34, 9.53) for the patients exposed to the integrated model and the unexposed respectively.

Table: 5 Relative Risk (RR)		
	RR	**95% CI**
Modern FP methods	1.27	1.14, 1.41
Pregnancy	1.04	0.83,1.30

From table 5, patients exposed to the integrated model are more likely to use modern FP methods than the unexposed (RR=1.27; 95% CI: 1.14, 1.41). There is no significant difference statistically in the likelihood of pregnancy occurrence between the patients exposed to the integrated model and the unexposed (RR=1.04; 95% CI: 0.83, 1.30).

3.3 Secondary Analysis

For secondary analysis, univariate analysis (unadjusted odds ratios) was performed followed by multi-variate analysis (adjusted odds ratios) which included only covariates that were significant with $p<0.05$ in univariate analysis. Only results of the multivariate analysis with significant adjusted Odds ratios (OR) with p-value <0.05 are presented in tables 6 and 7 for the exposed and unexposed groups respectively.

Table 6:Group- exposed; Outcome (Pregnancy/Condom Use/FP Other than Condom)

	Condom use OR (95% CI)	**FP use other than condom OR (95% CI)**	**Pregnancy OR (95% CI)**
HIV disclosure to partner	1.44 (1.14,1.82)	1.31 (1.04,1.65)	1.59 (1.05,2.39)
Years of school	Not significant	Not significant	0.91 (0.84,0.97)
Enrollment age	Not significant	Not significant	0.90 (0.87,0.94)
Sex last 6 months	1.63 (1.27,2.09)	1.80 (1.39,2.32)	Not significant

From table 6, we observe that among the exposed group: 1) HIV disclosure to partner and sex in the previous 6 months were found to be statistically significant for condom use among the exposed. Controlling for all the variables in the model: those who had disclosed to partner were more likely to use a condom (OR 1.44) and subjects who had sex in the previous 6 months were more likely to use a condom (OR 1.63), 2) HIV disclosure to partner and sex in the previous 6 months were found to be statistically significant for FP use other than condoms among the exposed. Controlling for all the variables in the model: those who had disclosed to their partner were more likely to use FP methods other than condoms (OR 1.31) and subjects who had sex in the previous 6 months were more likely to use FP methods other than condoms (OR 1.80) and 3) HIV disclosure to partner, years of school and age at enrollment were found to be statistically significant for pregnancy. Controlling for all the variables in the model: women who disclosed to their partners were more

likely to become pregnant (OR 1.59), one year increase in schooling leads to a decrease in the odds of getting pregnant (OR=0.91) and one year increase in age at enrolment leads to a decrease in the odds of getting pregnant (OR=0.90).

Table 7: Group- unexposed; Outcome(Pregnancy/Condom Use/FP Other than Condom)			
	Condom use **OR (95% CI)**	**FP use other than condom** **OR (95% CI)**	**Pregnancy** **OR (95% CI)**
HIV disclosure to partner	1.43 (1.11, 1.83)	1.42 (1.11, 1.82)	1.49 (1.10, 2.03)
Children living with the patient	Not significant	Not significant	0.86 (0.74, 0.99)
Enrollment age	Not significant	0.97 (0.96, 0.98)	0.90 (0.88, 0.93)
Sex previous months	1.51 (1.25, 1.83)	1.88 (1.55, 2.28)	Not significant
Years of school	1.03 (1.01, 1.06)	Not significant	Not significant
Enrollment age	0.97 (0.96, 0.98)	Not significant	Not significant
HIV disclosure to family	0.77 (0.60, 0.99)	Not significant	Not significant

We observe from table 7 that among the unexposed group: 1) HIV disclosure to partner, sex last 6 months, years of school, age at enrollment and HIV disclosure to other family members were found to be statistically significant for condom use among the controls. Controlling for all the variables in the model: subjects who had disclosed to partner were more likely to have used a condom (OR =1.43), subjects who had sex in the previous 6 months were more likely to have used a condom (OR =1.51), one year increase in years of schooling increases the odds of condom use (OR =1.03), one year increase in age at enrollment leads to a decrease in the odd of condom use (OR=0.97) and those who had disclosed to other family members were less likely to use condoms (OR=0.77), 2) HIV disclosure to partner, sex last 6 months and age at enrollment were found to be statistically significant with FP use other than condoms among the controls. Controlling for all the variables in the model: subjects who had disclosed to partner were likely to have used FP methods than condoms (OR =1.42), one year increase in age at enrollment leads to a decrease in the odd of using FP method other than condoms (OR=0.97), and

subjects who had sex in the last 6 months were more likely to have used FP methods other condoms (OR =1.88) and 3) HIV disclosure to partner, children living with the patient and age at enrollment were found to be significantly associated with incident pregnancy among the unexposed group. Controlling for all the variables in the model: subjects who had disclosed to partner were likely to get pregnant (OR=1.49), those who had children living with them were less likely to get pregnant (OR=0.86) and one year increase in age at enrolment leads to a decrease in the odds of getting pregnant (OR=0.90),

CHAPTER 4: DISCUSSION

This study has been able to demonstrate that integration of FP services into HIV care is associated with an increased incidence of new use of modern FP methods (10.8% and 7.1% increase in new use of condoms and FP other than condoms and the exposed are 27% likely to use FP). Like other studies[25-29] we have shown that when HIV-infected patients are given access and information on FP, uptake increases. Integration such as described in this paper makes FP services readily available and accessible to HIV-infected patients. We speculate that this increase in the uptake of FP is attributed to: the fact that health care providers in the HIV clinic become sensitive to FP planning needs of these patients, same-day 'one stop shop' service provision of both FP and HIV care lead to a reduction in the number of hospital visits improving adherence to clinic appointments, use of same patient chart/identifier number for both services, use of same check in/out and the fact that FP room is part of the patient flow in the HIV clinic just like any other rooms.

The integration was not associated with a statistical significant reduction in the incidence of pregnancy in the exposed group. However a reduction of 1.3% is clinically significant given that the confidence interval lies close to a reduction in the incidence of pregnancy among women exposed to the integrated model. Though the evidence that as many as 50% of pregnancies among HIV-infected women are considered unintended in sub-Saharan Africa can not be overlooked[910], the insignificant reduction in the incidence of pregnancy in this study, is attributed to other patient factors like the desired family size. This study was however not designed to determine these patient factors. In addition, data was analyzed after 16 months of the pilot phase which is a short period of time to objectively determine the impact of this integration on the incidence of pregnancy. With longer follow-up and integration we anticipate that there will be a reduction in the number of incident pregnancies among the exposed group. More studies are needed to evaluate pregnancy and patient factors in relation to integration such as described here.

The same socio-demographic variables were associated with incidence of new use of modern FP methods and pregnancy in the same direction for both exposed and

unexposed groups. For instance, HIV disclosure to partner and sex in the previous six months were associated with an increased use of modern FP methods. On the other hand HIV disclosure was associated with an increased likelihood of pregnancy and one year increase in age at enrolment was associated with a decreased likelihood in the odds of pregnancy. Further studies are needed to evaluate these patient factors.

Integration of FP into HIV care model as described in this paper is in accordance to the recommendations by World Health Organization, World Bank, and the European Union. Previous studies demonstrated presence of policy commitment to such integration[37]. Little evidence has been described on the impact of integration on incidence of modern FP methods and pregnancy. This has been attributed to funding restrictions, separate funding, vertical nature of both programs and reluctance to integrate FP into HIV/AIDS funding[31, 32 38 39]. The AMPATH program has been able to demonstrate how to overcome the barriers of vertical programs by providing a same-day 'one stop shop care' service provision of both FP services and HIV care in its integrated model. This was made possible by utilizing a blend of both vertical and horizontal integration. Some degree of vertical nature of both FP and HIV care was maintained to ensure that the focus and specific nature of these two service provisions is not weaken by a complete horizontal integration. The link between the two services formed the horizontal arm of the model.

The retrospective study design used in this paper, the large sample size and power has been able to successfully determine the impact of integrating family planning services into HIV care. The main limitation on the other hand is the fact that we were not able to show a significant statistical reduction in the incidence of pregnancy in the exposed group. This is attributed to the fact that 16 months is not sufficient time to objectively determine this variable and other patients factors come into play with regard to it. From a methodological point of view, we were not able to control miss-classification because of the retrospective nature of the design. Despite this limitation, we have been able to demonstrate that integration of FP into HIV care and treatment programs is associated with a statistical increased incidence of new use of modern FP methods and a clinically statistical reduction in the incidence of pregnancy.

Conclusion and Recommendation

Integrating FP services into HIV care and treatment programs is associated with: a significant increase in the incidence of new condom and FP method other than condoms use of 10.8% and 7.1% respectively and a none statistical but clinical reduction in the incidence of pregnancy of 1.3%. Retrospective cohort design used in this study has been able to successfully answer the research question. Funding agencies and programs should consider integrating FP services into HIV care and treatment programs. There is need for further studies on strategies to increase FP uptake by HIV-infected patients.

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Appendix II: Family Planning and STI Screening Form

AMPATH: Family Planning and STI Screening Form | **Date:**

1. First Name: | **Middle Name:** | **Last Name:**

AMPATH ID: | **pMTCT ID:**

3. Location: MTRH Module: □ 1 □ 2 □ 3 □ 4 □Scheduled Visit □Unscheduled Visit

□ Amukura □ Burnt Forest □ Busia □ Chulaimbo □ Iten
□ Kabarnet □ Kapenguria □ Khunyangu □ Kitale □ Mosoriot
Elgon
□ Naitiri □ Port Victoria □ Teso □ Turbo □ Webuye
Other:

4. Please tick the appropriate section to be completed during this visit:
□ Family Planning Screening □ STI Screening

A. Family Planning:

5. **Last menstrual period** _____ **Parity** _____ **Gravida** _____ **GBD** _____

6. **Are you using any form of family planning?** □Yes □No

7. **If yes, which method are you using: (tick all that apply)**
□ Natural □ Male Condom □ Female Condom □ Injectables □ IUCD □ Oral Pills
□ BTL □ Vasectomy □ Other _____

23a. Would you say that you use condoms….?
□ Never (skip to 23e) □ Sometimes □ Most of the time □ All of the time

23b. The last time that you had sex did you use a condom? □ Yes □ No

23c. How many times do you think you had sex without a condom in the last month?
□ 0 □ 1-4 □ 5-9 □ >10

23d. Would you say that you use condoms….?
□ With none of my partners
□ With some of my partners
□ With everyone but my main partner/spouse
□ With ALL of my partners

23e. When you don't use a condom, what is the reason?
□ They are not available/I don't have any
□ My partner refuses to use them
□ I am afraid to ask my partner to use them
□ I don't know how to use them
□ I don't like having sex with them (Why_____
□ Other: _____

Number of sexual partners in last 6 months: Types of intercourse □ oral □ anal □ vaginal

8. **Do you experience any difficulties in the method you are using?** □ Yes □ No

9. **If Yes, what problems have you noticed? (tick all that apply)**
□ Nausea and Vomiting □ Weight gain □ Weight Loss □ Irregular Bleeding
Headache
□ Frequent Condom Breakage □ Painful Intercourse □ Other: _____

B. Family Planning Counseling:

10. **Counseling Performed?** □ Yes □ No □ Not Applicable (patient on family planning with no problems noted)

11. **After counseling, does the patient choose a new method?** □ Yes □ No

12. **If Yes, which method? (tick all that apply)**
□ Natural □ Male Condom □ Female Condom □ Injectables □ IUCD □ Oral Pills
□ BTL □ Vasectomy □ Other _____

13. **If refuses Family Planning, reason for refusal: (tick all that apply)**
□Religion □Culture □Trying to conceive □Want more children in Future □Fear Side E
□Other_____

C. STI Screening: Comments:

14. Are you having any abnormal discharge?	□Yes	□No	If yes: □ White □ Bloody □ Greenish-Yellow Foul smelling: □Yes □ No
15. Do you have vaginal itching?	□Yes	□No	
16. Is it painful when you urinate ?	□Yes	□No	
17. Are you urinating more frequently than usual	□Yes	□No	
18. Have you noticed a different odor of urine	□Yes	□No	
19. Do you or have you had any sore in your mouth or g area?	□Yes	□No	
20. If you practice anal sex, re you having any rectal symp (need to specify)	□Yes	□No	
21. Have you noticed a rash (perineal)	□Yes	□No	
22. Are you having any abdominal or pelvic pain	□Yes	□No	
23. Have you noticed any inguinal swelling	□Yes	□No	
24. Have you had a sexually transmitted illness before	□Yes	□No	

C. Physical Exam:

General: □Pallor □Jaundice □Oedema □Lymphadenopathy
Breast exam: □ Normal □ Abnormal
If abnormal : □ Cracked nipples □ Inverted nipples □ Other_____
Genital Exam: □ Ulcer □ Vaginal Discharge □ Warts □ Other _____
Rectal: **Ulcer warts discharge rash Other** _____
Comments:

Diagnosis: □ Normal
□ Candida Vulvovaginitis (whitish curd-like discharge, itching)
□ Trichomoniasis (greenish discharge, foul smelling)
□ PID (lower abdominal or pelvic pain, with or without discharge)
□ Gonorrhea/Chlamydia (urethral or vaginal discharge, dysuria, worse in morning, incubation 3-10 days)
□ UTI (dysuria and increased frequency without discharge)
□ Genital Ulcer Disease
□ Single
□ Primary Syphilis (painless chancre, painless lymphadenopathy, 3 week incubation)
□ Lymphogranuloma (matted lymphadenopathy, fistula may be present, 1-2 week incubation)
□ Multiple
□ Chancroid (deep extremely tender ulcers, profuse pus, 1week incubation)

	□ Herpes Genitalia (vesicles progressing to shallow, tender ulcers) □ Granuloma Inguinale (large beefy ulcers with or without lymphadenopathy)
Plan:	
Labs: □ VDRL □Urinalysis □ Other test: _____	
Treatment:	□ None
Urethral Discharge	□ Norfloxacin 800 mg stat OR □ Spectomycin 2g stat (is this in the STI kit) □ Doxycycline 100 mg bd x 7 days
Vaginitis	□ Metronidazole 2 g stat (*do not use in pregnancy*) □ Clotrimazole 1 pessary intra-vaginal x 6 days
Cervicitis	□ Norfloxacin 800 mg stat □ Doxycycline 100 mg bd x 7 days (if pregnant use:add categories and elin below)
Cervicitis in pregnan	□ Spectomycin 2g IM stat □ Erythromycin 500 mg qid x 7 days
Lower abdominal or pain in women	□ Norfloxacin 800 mg stat □ Doxycycline 100 mg bd x 7 days □ Metronidazole 400 mg bd x 10 days (*if pregnant, DO NOT TREAT NOW and refer immediately for Obstetric Review*)
Genital Ulcer Diseas	□ Erythromycin 500 mg tds x 7 days □ Benzathine Penicillin 2.4 MU stat □ Erythromycin 500 mg qid x 14 days (*Use if Penicillin allergic*) □ Ceftriaxone 250 mg IM *(alternative treatment)*
Herpes Simplex	□ acyclovir
Syphilis:	□ Benzathine Penicillin 2.4 MU IM weekly x 3 weeks
Other:	_____ _____
Referrals: □ None □ Family Planning Clinic	□ Reproductive Health Clinic □ Obstetric Review □ Other_____
Form Filled By: _____	**Provider #:** _____

Appendix III: Adult Initial Encounter Form

USAID | AMPATH PARTNERSHIP	ADULT INITIAL ENCOUNTER FORM	Date: / /

Name:	AMPATH ID:	Hospital #:	Child AMPATH ID
National ID Number:	**HCT #:**	**pMTCT ID:**	
Date of Birth:	If Birthdate Unknown, Age at last Birthday: _____	Sex: □ M □ F	
Tribe:	Location:	Sublocation:	

Clinic Location: MTRH Module: □1 □2 □3 □4 Chulaimbo □ Busia □1 □2
□ Amukura □ Burnt Forest □ Khunyangu □ Kitale □ Iten
□ Kabarnet □ Kapenguria □ Port Victoria □ Teso □ Mosoriot
□ Mt. Elgon □ Naitiri □ Turbo □ Webuye
□ UG District Hospital □ Satellite: _____ □ Other: _____

Category:
□ Pilot (PEPFAR)
□ NASCOP
□ Research
□ Other: _____

Point of HIV Testing: □ pMTCT □ VCT □ Mobile VCT □ HCT
□ TB Clinic □ Inpatient/DTC □ MCH □ Other: _____

Social History:

1. How long did it take you to travel to clinic today?
- □ Less than 30 minutes
- □ Between 30 and 60 minutes
- □ Between 1 and 2 hours
- □ More than 2 hours

2a. Have you ever attended school? □ Ye □ No

2b. If yes, how many years of school have you completed? _____ Years

3. Are you employed outside the home? □ Yes □

4. Do you have electricity inside your home?
□ Yes □ No

5. Do you have water piped (from a tap) inside your home? □ Yes □ No

6a. How many people usually live in your household are staying with you now? _____
6b. Children under 5 years of age? _____

7a. Have you disclosed your HIV status to anyone?
□ Yes □ No

7b. If yes, have you told any of the following people
- □ Partner/spouse □ Other family member
- □ Friend □ Other household memb
- □ Health care provider
- □ Other (specify): _____

10a. What is your current relationship status?
- □ Never married and not living with a partner
- □ Legally married: Number of wives _____
- □ Living with a partner
- □ Separated
- □ Divorced
- □ Widowed

10b. If widowed, suspicion of HIV as cause of death of spouse? □ Yes □ No Year of _____

10c. Discordant couple? □ Yes □ No □ Unknown

10d. Sexual Activity:
- □ Yes □ No - Spouse or partner suspected of sex partner outside of marriage/relationship
- □ Yes □ No - Patient has sex partners outside marriage or current relationship
- □ Yes □ No - Sexually active last 6 months
  Number of different partners: _____

10e. How do you think you were exposed to HIV? (Check all that apply)
- □ Patient knows spouse or partner is HIV+
- □ Suspected exposure in prior relationship
- □ Blood Transfusion _____(Year of Transfusion)
- □ History of Intravenous Drug Use
- □ Contaminated Needle Stick
- □ Unknown
- □ Other_____

Women Only:

8a. How many times have you been pregnant?____

8b. How many children have you given birth to?___

8c. Number of your children living with you now:___

8d. Number of your children living with you now <5 yrs old: _____

8e. Number of your children less < 18 months old _

Men Only:

9. How many children do you have? _____

11a. Is the patient pregnant? □ Yes
If yes: _____Weeks
If Yes: Enrolled in ANC? □ Yes □ No

11b. Is the patient Breast Feeding □ Yes □ No
(if yes, refer to nutrition for counseling and educatio

12. Is the patient or their partner currently using form of family planning? □ Yes □ No
□ Condoms *(check all that apply)*
□ Oral Contraceptive Pill
□ Intrauterine Device
□ Sterilization / Hysterectomy
□ Natural Family Planning / Rhythm
□ Diaphragm / Cervical Cap
□ Injectable Hormones (Depo-Provera or Norplant)
□ Other:

13a. Do you smoke cigarettes? □ Yes □ No
□ Stopped How long ago? ___wks ___mos ___y

13b. If Current or Past Cigarette Use:
Sticks per day: ____ # Years of Use: ____

13c. Do you sometimes drink alcohol? □ Yes □ N
□ Stopped How long ago? ___wks ___mos ___y

13d. If you drink alcohol or used to drink alcohol, kind do (did) you usually drink? *(tick all that apply)*
□ Beer □Spirits/Liquor □Wine
□ Chang'aa □ Busaa

13e. How often did you have a containing alcohol in the last yea
□ Never
□ Monthly or less
□ 2 to 4 times a month
□ 2 to 3 times a week
□ 4 to 5 times a week
□ 6 or more times a week

13f. How many drinks containing alcoh you have on a typical day when you drinking in the past year?
□ 0 drinks
□ 1 to 2 drinks
□ 3 to 4 drinks
□ 5 to 6 drinks
□ 7 to 9 drinks
□ 10 or more drinks

13g. How often did you hav or more drinks on one occ in the past year?
□ Never
□ Less than monthly
□ Monthly
□ Weekly
□ Daily or almost daily

Review of Systems:

14. CHIEF COMPLAINT: □ Feeling well □ Having symptoms

15. General : □ No complaints
□ Fever □ Chills □ Weight loss □ Night Sweats □ Rash □ Fatigue □ Weight gain
Comments:

16. HEENT : □ No complaints □ Hearing difficulties □ Vision difficulties □ Swallowing difficult
Comments:

17. Cardiopulmonary : □ No complaints
□ Cough O days O weeks O months
□ Cough productive O white O purulent O blood
□ SOB O days O weeks O months
□ At rest □ On exertion
□ Pneumonia in the past 2 years
□ Chest pain O days O weeks O months
Location: □ substernal
□ right □ left □ anterior □ posterior
Quality: □ Pleuritic □ Sharp
□ Pressure □ Burning

□ TB: □ Currently on treatment □ Defaulted _____(year)
□ Treatment completed _____ (year)
□ Known exposure to household contact with TB

Comments:

18. Gastrointestinal : □ No complaints
□ Abdominal pain □ Poor appetite □ Nausea O days O weeks O months O Continuc
□ Hx of jaundice □ Vomiting O days O weeks O months O Continuc
□ Diarrhea O days O weeks O months O Continuc
Comments:

19. Genitourinary: □ No complaints
□ LMP _____ Menstrual Cycle: □ Regular □ Irregular □ Amenorrhea □ Post-Menopau
□ Vaginal discharge O days O weeks O months □ UTI
□ Urethral discharge O days O weeks O months □ Hematuria □ Circumcized?: □ Yes □
Comments:

20. Musculoskeletal: G No complaints
□ Joint pains □ Swelling of joints □ Edema of legs □ Muscle pain □ Pain in the legs / feet
Comments:

21. Central Nervous System : □ No complaints
□ Paresthesia □ Focal Weakness □ Seizures □ Headache
□ Depression □ Confusion □ Mental Illness □ Memory problems
Comments:

Hospitalizations

22a. Has the patient been hospitalized in the previous year? □ Yes □ No

22b. If yes, how many hospitalizations did the patient have in the past year? _____
Briefly describe the reason(s) for hospitalizations:

Medication History

23. Allergies:
Penicillin Allergy □ Yes □ No Specify Reaction _____
Sulfa Allergy □ Yes □ No Specify Reaction _____
Other Allergy □ Yes □ No Name of drug/product _____ Specify Rea
_____

24a. Is the patient currently taking any of the following antiretroviral medications? □ Yes □ No
Reason for Use □ pMTCT □ PEP □ Treatment Date Started: ___/_____ Date Stc
___/_____
(Tick all that apply) m m y
m m y y y y
Combination: □ Combivir □ Triomune-30 □ Triomune-40 □ Truvada
Individual:□ Nevirapine(NVP) □ Lamivudine(3TC) □ Zidovudine(AZT)□ Stavudine-30(D4T-30 □ Stavudi
□ Efavirenz(EFV) □ Abacavir(ABC) □ Aluvia/(Kaletra) □ Didanosine-125(DDI) □ Didanosine-20
Tenofovir □ Indinavir(IDV) □ Other::

24b. Has the patient used any antiretroviral medications in the past (other than those ticked in 24a)? □Y
No
Reason for Use □ pMTCT □ PEP □ Treatment Date Started: ___/_____ Date Stc
___/_____

(Tick all that apply) m m y
m m y y y y
Combination: □ Combivir □ Triomune-30 □ Triomune-40 □ Truvada
Individual:□ Nevirapine(NVP) □ Lamivudine(3TC) □ Zidovudine(AZT)□ Stavudine-30(D4T-30)
□ Stavudine-40(D4T-40) □ Efavirenz(EFV) □ Abacavir(ABC) □ Aluvia/(Kaletra) □ Didanosine-125(DD
□ Didanosine-200(DDI) □ Tenofovir(TDF) □ Indinavir(IDV) □ Other::

25. Other Current Medications:

PCP Prophylaxis: □ None □ Septrin □ Dapsone

TB Prophylaxis: □ None □ INH

TB Treatment: □ None □ Rifater (RHZ) □ Rifafour(RHZE) □ Ethizide (EH) □ Rifinah (RH)
□ Rifampicin **Start Date**_____ □ INH □ Pyrazinamide □ Ethambutol
□ Streptomycin □Other:

Cryptococcus Tx: □ None □ Diflucan

Other Drugs:

PHYSICAL EXAMINATION

26. Vitals:
BP _____/_____ Pulse_____rate/min Resp Rate_____ Temp[Co]_____ SaO2 _____%

Wt_____kg Height____ cm Karnofsky Score _____%

Karnofsky Score:
100% = Normal health
90% = Minor Symptoms
80% = Normal Activity with some effort
70% = Unable to carry on normal activity, able to car
oneself
60% = Requires help with personal needs
50% = Disabled
40% = Requires considerable assistance, m
care
30% = Severely disabled, in hospital
20% = Very sick, active support needed
10% = Moribund (near death)

27. General Exam: □ Temporal wasting Comments:

28. Skin □ Normal □ Abnormal □ Rash □ Kaposi sarcoma
Comments:

29. Lymph Nodes □ Normal □ Abnormal Comments:
□ submandibular □ cervical □ inguinal □ supraclavicular □ axillary

30. HEENT □ Normal □ Abnormal
Eyes: □ Sclera icteric □ Conjunctiva pale □ Fundal abnormality
Ears: □ Cerumen impaction □ TM injected
Neck: □ Trachea deviated □ Nuchal rigidity
Oropharynx: □ Thrush □ Kaposi sarcoma □ Significant dental caries

31. Chest □ Normal □ Abnormal
Percussion: □ Dullness
Auscultation: □ Breath sounds diminished □ Bronchial breath sounds □ Rhonchi /Wheeze
Crepitations
Comments:

32. Heart □ Normal □ Abnormal
□ Evidence for enlargement: □ LV lift □ RV lift
□ Abnormal Sounds: □ S3 Gallop □ Pericardial friction rub
□ Murmurs: □ Systolic Ejection Murmur □ Holosystolic Murmur □ Diastolic Decrescendo □ Dia
Rumble
Comments:

33. Abdomen □ Normal □ Abnormal
□ Tender to palpation Location_____ □ Ascites □ Mass

□ Hepatomegaly _____ (cm below costal margin) □ Splenomegaly _____ (cm below
margin)
Comments:

34. Urogenital □ Normal □ Abnormal □ Not done Comments:

35. Extremities □ Normal □ Abnormal □ Edema □ Leg ulcers □ Cellulitis □ K
sarcoma
Comments:

36. Musculoskeletal □ Normal □ Abnormal
Comments:

37. Neurologic □ Normal □ Abnormal
□ Cranial nerve abnormality □ Decreased sensation lower extremities □ Abnormal gait □
weakness
Comments:

38. Psychiatric □ Normal □ Abnormal □ Depressed □ Dementia / confused
Comments:

39. Does the patient currently have, or has the patient ever had, any of the following conditions?
Fill in the appropriate box next to each indicator condition P=Presumptive; C=Confirmed

WHO Stage 1			**WHO Stage 4**	**P**	**C**
Asymptomatic HIV Infection		□	HIV Wasting Syndrome	□	□
Persistent Generalized Lymphadenopathy (PG		□	Pneumocystic Pneumonia	□	□
WHO Stage 2			Recurrent severe bacterial pneumonia	□	□
Weight Loss ≤ 10% of Body Weight		□	Chronic Herpes Simplex (mucocutaneous>1 m any visceral)	□	□
Recurrent Upper Respiratory Tract Infe (bacterial)		□	Candidiasis (Oesophageal, Bronchi, Trache Lungs)	□	□
Herpes Zoster		□	Extrapulmonary Tuberculosis	□	□
Angular Cheilitis		□	Kaposi's Sarcoma (KS)	□	□
Recurrent Oral Ulceration		□	Cytomegalovirus Disease (retinitis or other orga	□	□
Papular pruritic eruptions		□	Toxoplasmosis, CNS	□	□
Seborrheic Dermatitis		□	HIV Encephalopathy	□	□
Fungal Nail Infections		□	Cryptococcosis,Extrapulmonary (includes menin	□	□
WHO Stage 3	**P**	**C**	Disseminated non-TB mycobacterial infection	□	□
Weight Loss > 10% of Body Weight	□	□	Progressive Multifocal Leukoencephalopathy PM	□	□
Unexplained Chronic Diarrhea (>1 month)	□	□	Chronic Cryptosporidiosis (> 1 month duration)	□	□
Persistent Oral Candidiasis (Thrush)	□	□	Chronic Isosporiasis	□	□
Unexplained Prolonged Fever (intermitte constant, >1 month above 37.5° C)	□	□	Disseminated mycosis (extrapulm histoplasmosis or coccidiomycosis)	□	□
Oral Hairy Leukoplakia	□	□	Recurrent septicemia (including **non**-typl Salmonella)	□	□
Pulmonary Tuberculosis	□	□	Lymphoma (cerebral or B-cell non-Hodgkin)	□	□
Severe Bacterial Infections (ie. pneum empyema, pyomyositis, bone/jt infe meningitis, bacteremia)	□	□	Invasive cervical carcinoma	□	□
Acute necrotizing stomatitis, gingivitis periodontitis	□	□	Atypical disseminated leishmaniasis	□	□
Unexplained anaemia (<8 g/dl), neutrop (<0.5 x 109/L), and/or ch thrombocytopaenia (<50 x 109/L)	□	□	Symptomatic HIV-associated nephropathy symptomatic HIV-associated cardiomyopathy	□	□

40. Tests

Test	Result	Test Date	Test	Result	Test Date
1. WBC / mm3			9. CD4		
2. Hgb g / dL			10. CD8		
3. MCV			11. CD4 %		
4. Platelets / µ L			12. VDRL		
5. ALC / mm3			13. HIV Test (Rapid)		
6. SGPT			14. HIV Test (Long ELISA)		
7. Creatinine mmol / L			15. Viral Load		
8. Other:			16. other		
17. CXR Code:			Codes : 0=normal1=Pl Effusion 2=Infiltrate 3=m 5=cavity 4=Diffuse abn/non-milliary 6 Cardiomegaly7=otherabnormality		

41. HIV-related Diagnoses/Problems

Problem	Remove	Resolved	Problem	Remove	Resolved
1.	□	□	5.	□	□
2.	□	□	6.	□	□

Non HIV-related Diagnoses/Problem* *For Other Problems, tick box only if problem needs to be added removed from summary sheet*

Problem	Add	Remove	Problem	Add	Remove
1.	□	□	4.	□	□
2.	□	□	5.	□	□

42. Plan:

ARVs: □ None □Start ARVs □Continue Regimen □Restart □Change Dose □ Substitution
□Change Regimen □ Stop All
Reason to start ARVs: □ Treatment □ Total pMTCT
Reason for stop/change: □ Failure □ Completed T-pMTCT □ Toxicity_____ □ Other____

Eligible for ARVs but not started:
□ Due to cap □ OI/TB tx □ Patient Refused □ Adherence Con
□Other_____
*If **start or change**, tick new regimen:*
Combination: □ Combivir □ Triomune-30 □ Triomune-40 □ Truvada
Individual:□ Nevirapine(NVP) □ Lamivudine(3TC) □ Zidovudine(AZT) □ Stavudine-30(D4
□ Stavudine-40(D4T-40) □ Efavirenz(EFV) □ Abacavir(ABC) □ Aluvia/(Kaletra) □ Didano
125(DDI) □ Didanosine-200(DDI) □ Tenofovir(TDF) □ Indinavir(IDV) □ Other::

PCP Prophylaxis: □ None □ Start □ Continue Regimen □ Change Regimen □ Stop

Reason for stop/change: □ CD4>200 □ Toxicity_____ □ Other_____
New Drugs: □ Septrin ____tabs/day □ Dapsone_____ mg/day

TB Prophylaxis: □ None □ Start INH □ Continue INH □ Stop INH

Reason for stop/change: □ Completed □ Active TB □Toxicity_____ □ Other_____

TB Treatment: □ None □ Start Induction □ Change to Continuation □ Cor
Regimen
□ Restart/Retreatment Regimen □ Defaulter Regimen (using Streptomycin) □ MDR Regimen □
All
Reason for stop/change: □ Completed □ Toxicity_____ □ Other_____
_____
New Drugs:
□ Rifater (RHZ) _____tabs/day □ Rifafour (RZHE) _____tabs/day □ Ethizide (EH) _____tabs/day
□ Rifinah (RH)_____tabs/day □ Rifampicin_____mg/day □ INH_____mg/day
□ Pyrazinamide_____mg/day □ Ethambutol_____mg/day □Streptomycin_____mg/day
□ Other:

43. Additional Drugs (ordered at the time of the initial visit)

Drug	Strength	Sig	Drug	Strength	Sig
1.			4.		
2.			5.		
3.			6.		

Patient Plan Comments:

44. What tests will be ordered for the patient? □ None
□ Complete Blood Count □ ALT □ AST □ CXR □ Radiology Test (specify):
□ CD4 Count Assay □ Creatinine □ HIV ELISA □ Sputum for AFB
□ VDRL □ Electrolytes □ HIV Viral load □ Pregnancy Test
□ Other (specify):

45. What referrals will be made for the patient? □ None
□ Social Support Services □ Psychosocial counseling □ Disclosure counseling
□ Family Planning services □ Reproductive Health □ TB treatment/DOT program
□ Nutritional support □ Adherence Counseling □ Alcohol counseling/ support grou
□ Mental Health Services □ Other referral (specify):
□ Inpatient care/Hospitalization: (□ MTRH □ Local Health Centre/Hospital □ Other Facility:_____
)

46. When is the patient's next appointment? *Fill in appropriate box:*
□ 1 week □ 2 weeks □ 1 month □ 3 months □ 6 months □ Other (specify):

47. Next Scheduled Appointment Date __ __ / __ __ / __ __ __ __
d d m m y y y y

Form completed today by: Clinical Officer_____Provider #:_____

Nurse _____ Provider #:_____

Physician _____ Provider #:_____

Appendix IV: Adult Return Visit form

USAID | AMPATH PARTNERSHIP	ADULT RETURN VISIT FORM	Date: / /

2. Name:	AMPATH ID:	Previous ID:	MTCT+ ID:
National ID Number:		pMTCT ID:	
Hospital ID #	HCT#		

Clinic Location: MTRH Module: □1 □2 □3 □4 Chula Busia □1 □2 □1 □2

□ Amukura □ Burnt Fore □ Khunyangu □ Kitale □ Iten
□ Kabarnet □ Kapenguria □ Port Victoria □ Teso □ Mosoriot
□ Mt. Elgon □ Naitiri □ Webuye □ Turbo □ Other:

□ UG District Hospital □ Satellite: _____

3. Category:
□ Pilot (PEPFAR)
□ NASCOP
□ Research
□ MTCT-Plus
□ Other: _____

4.Member of Discordant Couple?
□Yes
□No
□Unknown

5. □ Scheduled Visit □ Unscheduled Visit Early □ Unscheduled Visit Late

6. Does patient have a disability? □Yes □No If Yes, specify:

7. Does the patient have any interval complaints? □Yes □No
Comments:

8. Female Patients:

8a. Is the patient pregnant? □ Yes _____Weeks □No (8d)
8b. LMP: ___/___/_____

If yes: On ARV-directed pMTCT □Yes □No □Treatment □pMTCT only □unknown pending)

8c. Has she delivered since her last visit? □Yes Date ___/___/_____ □ No (Go to 8d)
Pregnancy outcome: □ Live Birth, Child still alive □Live Birth with neonatal death 7 days
□ Live Birth with neonatal death after 7 days □ Miscarriage □ Stillbi
How was the mother treated? □Total pMTCT □On ARV Therapy for clinical indication □NVP □Untr □Unknown
Infant received NVP? □Yes □No Infant received or receiving AZT □Yes □No If yes, ___ days received
Feeding Method? *(tick all that apply)* □ Breast □Expressed Breast milk □ Formula Cow's/Animal milk
□Water □ Other liquids □ Solid Food
Baby enrolled in Peds HIV Clinic? □Yes □No AMPATH Infant ID:_____ *(If No, enroll in clinic today)*

8d. Does mother have any children less than 18 months? □Yes □No Breast feeding □Yes □No
Have all children < 18 months been enrolled in Peds HIV clinic? □Yes □No **AMPATH ID:**
AMPATH ID:

9. Male and Female Patients:

9a. Family Planning: □Yes □No If Yes, Method: _____
9b. Condom Use: □Yes, always □Yes, sometimes □No

10. Has patient been Hospitalized since last visit? □Yes □No
If yes: Location_____ Diagnosis:_____

11. Current Medications:

11a. ARVs: □Yes □No Has this patient ever changed drugs for any reason? □Yes □No
Combination: □ Combivir □ Triomune-30 □ Triomune-40 □ Truvada

Individual:□Nevirapine(NVP)□Lamivudine(3TC)□Zidovudine(AZT)□Stavudine-30(D4T-30)
□ Stavudine-40(D4t-40)□ Efavirenz (EFV)□ Abacavir(ABC□Aluvia/(Kaletra)
□Didanosine-125(DDI) □ Didanosine-200(DDI) □ Tenofovir (TDF)
Indinavir(IDV) □ Other:

11b. PCP Prophylaxis: □None □Septrin □Dapsone

11c. TB Prophylaxis: □None □INH

11d. TB Treatment: □ None □ Rifater (RHZ) □ Rifafour (RHZE) □ Ethizide (EH) Rifinah (RH)
Start Date: ___/___/____ □ Rifampicin □ INH □ Pyrazinamide □ Ethambutol □ Strepto
□Other:

11e. Cryptococcus Tx: □ None □Diflucan

11f. Other Drugs:

12. Adherence:

12a. During the last month has the patient missed any medications? □Yes □No □ Not appli
(Skip to 13)
□ ARVS □ PCP Prophylaxis □ TB Prophylaxis □ Anti-TB Medication □ Other drugs
Drugs Missed: Reason(s):

12b. During the last seven days how many of his/her pills did the patient take?
□ ARVS: □ None □ Few □ Half □ Most □ All Drug(s) missed_____
□ PCP Prophylaxis: □ None □ Few □ Half □ Most □ All Drug(s) missed_____
□ TB Prophylaxis: □ None □ Few □ Half □ Most □ All Drug(s) missed_____
□ Anti-TB Medication: □ None □ Few □ Half □ Most □ All Drug(s) missed_____
□ Cryptococcus Tx: □ None □ Few □ Half □ Most □All Drug(s) missed_____
Reason(s) for missing pills in the last 7 days:

13. Physical Exam:

BP____/____ P_____ Temp_____ Wt_____ Height _____ SaO_2___
Karnofsky Score_____

Comments:

14. WHO Stage: □ 1 □ 2 □ 3 □ 4 Criteria: _____ New Stage? □Yes □No

15. Test Results: (Please record date test was drawn, rather than date test was run)

Test	Result	Test Date	Test	Result	Test Date
WBC/mm^3			CD4		
Hgb g/dL			CD8		
MCV			CD4%		
Platelets/ mm^3			VDRL		
ALC/ mm^3			Other		
SGPT					
Creatinine mmol/L					
CXR Code			0=normal 3=Miliary 6= Cardiomegaly 1=Pl Effusion 4= Diffuse abn/non-miliary 7= abnormality 2=Infiltrate 5=Cavity		

16. Impression: New Diagnoses/Problems

** Tick "Add" to add a problem to summary sheet. Tick "Remove" to delete problem from summary shee*

Problem		Add	Remove	Problem		Add	Remove
1.		□	□	**3.**		□	□
2.		□	□	**4.**		□	□