Integration of family planning services into HIV care and treatment in Kenya: a cluster-randomized trial

Daniel Grossman[a,b], Maricianah Onono[c], Sara J. Newmann[b], Cinthia Blat[b], Elizabeth A. Bukusi[c], Starley B. Shade[d], Rachel L. Steinfeld[b] and Craig R. Cohen[b]

Objective: To determine whether integrating family planning services into HIV care is associated with increased use of more effective contraceptive methods (sterilization, intrauterine device, implant, injectable or oral contraceptives).

Design: Cluster-randomized trial.

Setting: Eighteen public HIV clinics in Nyanza Province, Kenya.

Participants: Women aged 18–45 years receiving care at participating HIV clinics; 5682 clinical encounters from baseline period (December 2009–February 2010) and 12 531 encounters from end-line period (July 2011–September 2011, 1 year after site training).

Intervention: Twelve sites were randomized to integrate family planning services into the HIV clinic, whereas six clinics were controls where clients desiring contraception were referred to family planning clinics at the same facility.

Main outcome measures: Increase in use of more effective contraceptive methods between baseline and end-line periods. Pregnancy rates during the follow-up year (October 2010–September 2011) were also compared.

Results: Women seen at integrated sites were significantly more likely to use more effective contraceptive methods at the end of the study [increased from 16.7 to 36.6% at integrated sites, compared to increase from 21.1 to 29.8% at controls; odds ratio (OR) 1.81, 95% confidence interval (CI) 1.24–2.63]. Condom use decreased non-significantly at intervention sites compared to controls (OR 0.64, 95% CI 0.35–1.19). No difference was observed in incident pregnancy in the first year after integration comparing intervention to control sites (incidence rate ratio 0.90; 95% CI 0.68–1.20).

Conclusions: Integration of family planning services into HIV care clinics increased use of more effective contraceptive methods with a non-significant reduction in condom use. Although no significant reduction in pregnancy incidence was observed during the study, 1 year may be too short a period of observation for this outcome.

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Introduction

An estimated 13 million HIV-infected women live in sub-Saharan Africa [1]. Among the HIV-infected women in this region, studies indicate that 62–93% of pregnancies are unintended [2–4]. The WHO has included the prevention of unintended pregnancy as one of four pillars of a comprehensive prevention of mother-to-child

[a]Ibis Reproductive Health, Oakland, California, [b]Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California, San Francisco, USA, [c]Kenya Medical Research Institute, Kisumu, Kenya, and [d]Center for AIDS Prevention, Department of Medicine, University of California, San Francisco, USA.
Correspondence to Daniel Grossman, MD, Ibis Reproductive Health, 1330 Broadway, Suite 1100, Oakland, CA 94612, USA.
Tel: +1 510 986 8941; e-mail: dgrossman@ibisreproductivehealth.org

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transmission (PMTCT) strategy [5]. Improved access to family planning among HIV-infected individuals is also expected to decrease maternal morbidity and mortality, as well as poor neonatal outcomes [6,7].

In many settings in sub-Saharan Africa, contraceptive services are provided in family planning clinics separate from clinics providing antiretroviral therapy (ART) and related care for HIV-infected individuals [8]. Recognizing the structural barriers associated with this model of care, at least six international statements have recommended integrating family planning and HIV services [9]. Advocates of integration hypothesize that it will increase contraceptive uptake, prevent pregnancy and empower women and men to determine their family size. However, there is little rigorous research evidence to support this hypothesis, and there have been no randomized trials on integrating family planning into HIV services [10]. A cohort study in Nigeria found no difference in contraceptive use between women at ART clinics providing enhanced family planning services compared to those at ART clinics providing more basic family planning counselling [11]. A recent cohort study in Kenya found that integrated services were associated with a significant increase in condom use, but there was no effect on pregnancy incidence; use of non-condom family planning methods decreased at the integrated site [12].

We aimed to determine whether integration of family planning services into HIV care and treatment improved the uptake of more effective contraceptive methods [sterilization, intrauterine device (IUD), sub-dermal implants, injectables and oral contraceptives]. A secondary aim of the study was to determine whether pregnancy incidence was affected by integration of family planning services. Because the intervention focused on changing the service-delivery model at the healthcare facility and to minimize contamination, the unit of randomization was the facility.

Methods

We performed a cluster-randomized trial comparing contraceptive prevalence and pregnancy incidence among women at HIV care and treatment clinics that offered integrated family planning services to HIV clinics that referred clients seeking family planning services to a separate maternal–child health and family planning (MCH-FP) clinic at the same facility. Data from clinical encounters were treated as serial cross-sections to assess change in study outcomes over time. More details of the study design are available in the Supplemental Digital Content (http://links.lww.com/QAD/A405).

Eligible sites were public sector HIV clinics at dispensaries, health centres, and sub-district and district hospitals in Kisumu East, Nyatike, Rongo and Suba Districts of Nyanza Province, Kenya. Prior to initiating the study, we performed site assessments at all eligible sites, and sites were excluded if they had already integrated family planning services into HIV care or if they were not offering ART on site. All sites were supported by Family AIDS Care and Education Services (FACES), a collaboration between University of California, San Francisco (UCSF) and the Kenyan Medical Research Institute (KEMRI) [13]. Women were eligible to contribute data to the study if they had a visit at one of the HIV clinic sites during the study period and were between the age of 18 and 45 years.

The study was approved by the Committee on Human Research at UCSF and the Ethical Review Committee at KEMRI. We originally planned to obtain consent from individual women at study sites; however, shortly after beginning the study, we obtained approval from both UCSF and KEMRI for an evaluation protocol that allowed analysis of de-identified data from FACES patients without individual consent.

After assessing sites for eligibility, facilities were stratified based on whether they were large (>700 patients enrolled in HIV care) or small (<700 enrolled HIV patients) and randomly allocated within these strata to receive the intervention or control in a 2 : 1 ratio. The 2 : 1 ratio was selected to respond to the Ministry of Health's interest in moving forward with integration. The allocation sequence was generated by the study's biostatistician who was not involved in fieldwork for the study. Sites were identified and recruited, and written permission to perform the study at these sites was obtained from the Provincial Medical Officer and District Medical Officers of Health prior to randomization.

Clinics, healthcare providers, patients and researchers involved in implementing the study were not blinded to the allocation. Data abstraction from medical records occurred at clinic sites, and it was not possible to blind staff who abstracted data. All outcome data for the trial were extracted from an electronic medical record system (EMRS). Although all study investigators were not blinded to allocation during the conduct of the trial, investigators did not view data by study arm until after the statistical analysis plan was finalized, data cleaning was completed and the database was locked.

In preparation for the study, starting in March 2010, peer educators at all sites were trained to conduct group educational health talks about family planning to clients waiting to be seen at the HIV clinics. These health talks focused on why some HIV-infected individuals choose to use family planning and reviewed all available contraceptive methods, including their effectiveness and common side effects.

Staff at study sites underwent training between June and August 2010 (see the Supplemental Digital Content, http://links.lww.com/QAD/A405 for more information on training). HIV clinic staff were trained to ask all clients about their current use of contraception, condom use and their interest in using family planning. Condoms were generally provided at the HIV clinic except during a period of nationwide shortage. At HIV clinics assigned to be control sites, staff continued the standard practice of referring clients interested in receiving non-condom family planning to a separate MCH-FP clinic at the same facility.

HIV clinics assigned to the intervention integrated family planning counselling and provision into the HIV clinic according to guidelines established by the Kenyan Government [14,15]. In addition to asking about interest in using family planning, HIV clinic staff at integrated sites also provided all reversible family planning methods within the HIV clinic. At control sites, all reversible family planning methods were available at the MCH-FP clinic, but family planning services were generally available at different times than the HIV clinic, often requiring women to wait or return at another time. At all sites, patients interested in female sterilization were kept on a list to receive services when a roving team came to the facility to perform the procedures, generally once every 1–3 months. Patients interested in vasectomy were referred to an outside provider.

At all sites, clinical encounters were recorded on paper forms that were then entered into an EMRS database (OpenMRS versions 1.6.1–2) [16]. More information on EMRS data entry is given in the Supplemental Digital Content (http://links.lww.com/QAD/A405).

The primary outcome for the study was reported use of more effective contraception (sterilization, IUD, implant, injectable or oral contraceptives) compared to no contraception or use of a less effective method (barrier methods, including condoms used alone, or natural family planning). We decided to focus on contraceptive prevalence, rather than just uptake of new methods, since we hypothesized that the intervention would affect both contraceptive uptake and continuation. Secondary outcomes included reported use of any family planning method, use of condoms, either alone or with another method ('dual method use' [17]) and incident pregnancy. We attempted to collect data on whether the pregnancy was intended or not, but this variable was missing from a large proportion of pregnant women's medical records. Prior to performing any analyses, we examined baseline contraceptive use among all pooled study sites (December 2009–February 2010) and observed a high prevalence of reported condom use (reported in approximately 57% of women's encounters). We therefore decided to focus on the use of more effective contraception as the primary outcome of the study.

Contraceptive method use and pregnancy status on a visit were ascertained from patient medical records. More information on study outcome ascertainment is given in the Supplemental Digital Content (http://links.lww.com/QAD/A405).

We present descriptive statistics on study variables collected during the baseline period. Categorical variables are presented using frequencies and proportions and continuous variables using median and inter-quartile range (IQR). Contraceptive prevalence estimates and odds ratios (ORs) comparing contraceptive use across intervention and control arms were derived from a series of generalized estimating equation (GEE) models fitted with robust standard errors to account for clustering of patients within sites. Each model regressed a contraceptive use outcome on integration arm, study period (end line compared to baseline), and a study period by intervention arm interaction term. The OR for the effect of the intervention was obtained from the coefficient for the interaction term, which reflects the increase in the odds of the outcome in the intervention arm compared to the control arm between baseline and follow-up. Contraceptive use prevalence estimates reflect model projections of the predicted probability of the outcome by intervention arm and study period.

Negative binomial regression was used to quantify pregnancy rates during the first year after integration (October 2009–September 2010). In addition, we present an approximate pregnancy rate over 100 person-years of follow-up for each study arm. More information on the statistical analysis of the pregnancy rate is given in the Supplemental Digital Content (http://links.lww.com/QAD/A405).

The primary outcome upon which we based our sample size calculation was prevalence of use of modern contraception. According to the 2003 Kenya Demographic and Health Survey [18], which were the most recent data available at the time the study was planned, approximately 22% of women in a union in Nyanza Province used a modern contraceptive method. We estimated that an 8% increase in contraceptive prevalence would represent a clinically significant increase. Therefore, our sample size estimate was based on the ability to detect an 8% difference in contraceptive prevalence of 30% in intervention sites compared to 22% in the control sites. Using this information, the necessary sample size was 140 women at each of the 18 sites, for a total sample of 2520 women. This estimate assumed an intra-cluster correlation coefficient (ICC) of 0.01, a two-sided alpha of 0.05 and 80% power.

SAS version 9 (Cary, North Carolina, USA) was used for data management and analysis. This study is registered at ClinicalTrials.gov, number NCT01001507.

Results

Twenty-nine health facilities in Nyanza Province, Kenya, were assessed for eligibility. Eleven sites were excluded: six sites had already integrated family planning services into the HIV clinic and five were not providing ART. Eighteen sites were randomized. Among the intervention sites, six were large and six small sites, whereas three of the control sites were large and three small (Fig. 1). Table 1 shows characteristics of the study sites in December 2009 prior to intervention launch. All sites were rural except for two located in towns with populations around 7000. The sites where only a sample of encounters were entered into OpenMRS were sites A, F, I, J, K, Q and R. In general, family planning services were free at integrated sites and control sites M, N and P; HIV clinic patients

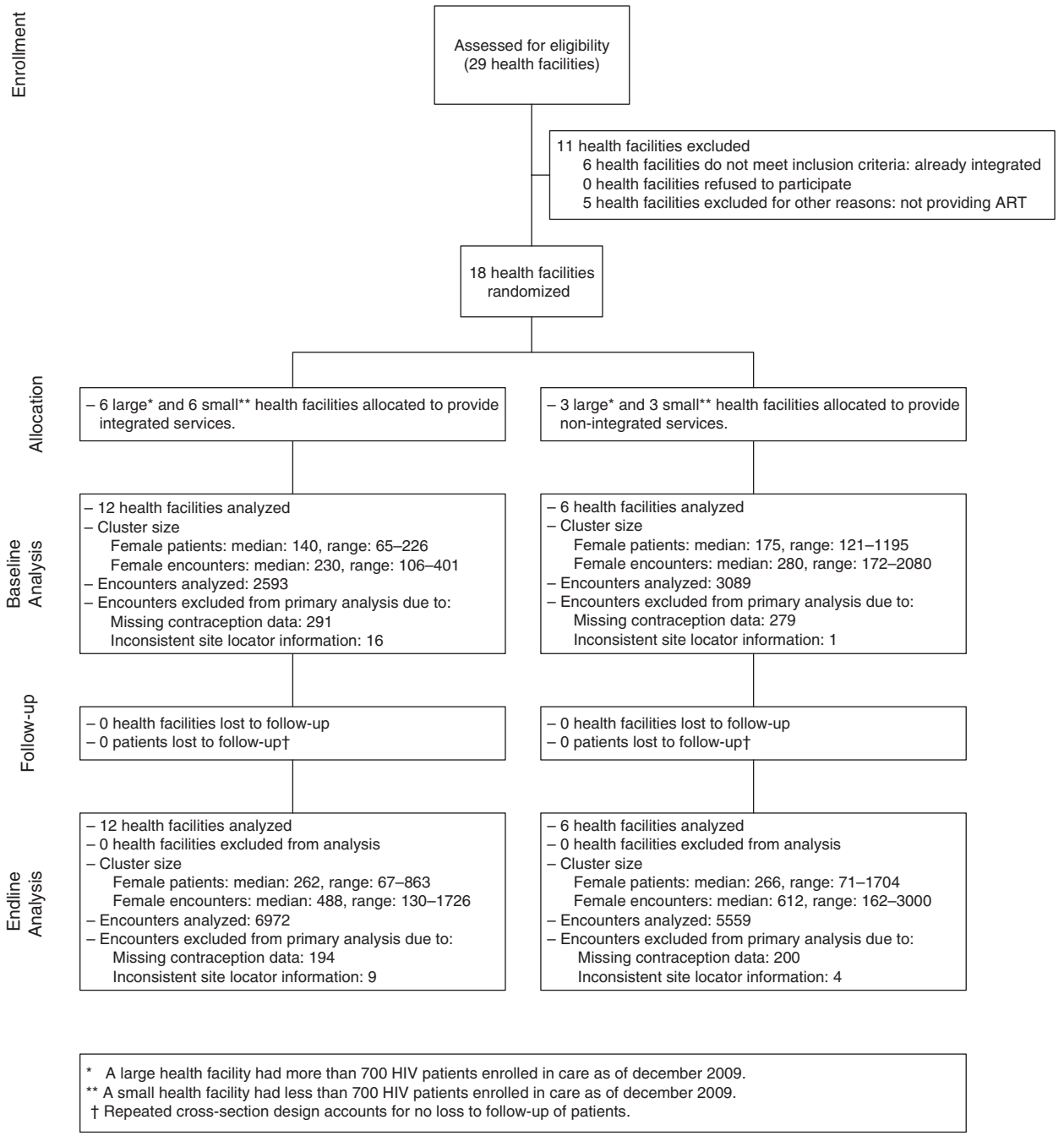

Fig. 1. Trial profile. * A large health facility had more than 700 HIV patients enrolled in care as of december 2009. ** A small health facility had less than 700 HIV patients enrolled in care as of december 2009. † Repeated cross-section design accounts for no loss to follow-up of patients.

Table 1. Characteristics of study sites at baseline, December 2009–February 2010.

Site	Allocation	District	Facility type	Setting	Large or small facility[a]	Estimated number adult of women receiving HIV care	Number of eligible women analyzed
A	Intervention	Nyatike	Dispensary	Rural	Small	286	128
B	Intervention	Nyatike	Health centre	Rural	Small	397	217
C	Intervention	Nyatike	Sub-district hospital	Rural	Large	772	191
D	Intervention	Rongo	Health centre	Rural	Small	224	79
E	Intervention	Kisumu East	Sub-district hospital	Rural	Large	398	216
F	Intervention	Kisumu East	Dispensary	Rural	Small	168	120
G	Intervention	Suba	Health centre	Rural	Large	355	128
H	Intervention	Suba	Sub-district hospital	Urban	Large	1316	197
I	Intervention	Suba	Health centre	Rural	Large	557	177
J	Intervention	Suba	Health centre	Rural	Small	404	55
K	Intervention	Suba	Health centre	Rural	Small	103	77
L	Intervention	Suba	Health centre	Rural	Large	818	99
M	Control	Nyatike	Sub-district hospital	Rural	Large	383	62
N	Control	Rongo	District hospital	Urban	Large	1697	1163
O	Control	Rongo	Health centre	Rural	Small	203	125
P	Control	Kisumu East	Health centre	Rural	Small	272	169
Q	Control	Suba	Sub-district hospital	Rural	Small	268	165
R	Control	Suba	Health centre	Rural	Large	565	216

[a]Large facilities had more than 700 HIV patients enrolled in HIV care; small facilities had less than 700 enrolled HIV patients.

referred to the MCH-FP clinic at sites O, Q and R were intermittently charged USD $0.20–1.20 depending on the method.

During the baseline period (December 2009–February 2010), contraception data were available for 3584 eligible women who had at least one encounter at the study sites. Data on the size of the clusters at baseline are presented in Fig. 1 and Table 1. Table 2 shows demographic and clinical information for participants with contraception data during the baseline period. Information on education and marital status was only collected at the time of enrolment into HIV care and was available for 61.6% of women at intervention sites and 76.7% of women at control sites.

The study flow diagram (Fig. 1) gives information on the number of encounters analyzed at baseline and end line (July–September 2011), as well as the size of the clusters. The size of the clusters increased during the study period because more women entered HIV care over time.

At integrated sites, the prevalence of use of more effective family planning methods increased from 16.7 to 36.6%, whereas at control sites, it increased from 21.1 to 29.8% (Table 3). Most of the differential increase in contraceptive use at integrated sites was due to implants and injectables. The prevalence of dual method use increased from 10.1% at baseline to 20.9% at end line at integrated sites; at control sites, dual use increased from 11.5 to 19.1%. The use of less effective family planning methods (almost exclusively condoms used alone) decreased at intervention sites from 50.7% at baseline to 36.9% at end line, and at control sites increased slightly from 39.6 to 39.9%. The use of any family planning method increased at integrated sites from 67.5 to 73.4%, and at control sites from 60.8 to 69.7%.

Figure 2 presents the prevalence of contraceptive method use (use of more effective and less effective family planning and non-use of family planning) for women with encounters at integrated sites and control sites over the entire study period. The 12 months of the study following completion of training at all sites is divided into 3-month periods. By the final period of observation, the prevalence of more effective family planning use increased at both integrated and control sites, with a greater increase at integrated sites.

The odds of more effective family planning use during the final 3 months of the study relative to baseline was 1.81 [95% confidence interval (CI) 1.24–2.63] for women at intervention sites compared to control sites (Table 3). The odds of condom use for this period was 0.64 (95% CI 0.35–1.19) for women at intervention sites compared to control sites, and the odds of dual method use during this period was 1.30 (95% CI 0.77–2.17) for women at intervention sites compared to control sites. The odds of use of any family planning method during this period was 0.90 (95% CI 0.50–1.60) for women at intervention sites compared to control sites. Imputation of data for long-acting and permanent methods resulted in a change to 842 of 66 650 records (1.3%) over the course of the study. Sensitivity analyses with and without imputation resulted in similar estimates (data not shown).

During the final year of the study, the pregnancy rate was 1.5 and 1.7 new pregnancies per 100 clinic visits at integrated and control sites, respectively [incidence rate ratio (IRR) 0.90, 95% CI 0.68–1.20] (Table 3). This

Table 2. Characteristics of eligible women with encounter data at baseline, December 2009–February 2010.

	Sites allocated to intervention ($n = 1684$)	Sites allocated to control ($n = 1900$)
Age in years, median (IQR)	31 (26–36)	30 (25–36)
Education[a], *n* (%)		
None	23 (1.4)	27 (1.4)
Some primary	743 (44.1)	987 (52.0)
Some secondary	112 (6.7)	220 (11.6)
Some college/university	10 (0.6)	29 (1.5)
Missing	796 (47.3)	637 (33.5)
Marital status[a], *n* (%)		
Married/living together	497 (29.5)	704 (37.1)
Single/separated/divorced	80 (4.8)	110 (5.8)
Widowed	236 (14.0)	382 (20.1)
Missing	871 (51.7)	704 (37.1)
Current ART use, *n* (%)		
On ART	893 (53.0)	960 (50.5)
Not on ART	784 (46.6)	928 (48.8)
Missing	7 (0.4)	12 (0.6)
Most recent CD4 cell count[b], median (IQR)	374 (238–541)	390 (256–555)
Missing	315 (18.7)	216 (11.4)
WHO stage, *n* (%)		
Stage 1	302 (17.9)	488 (25.7)
Stage 2	551 (32.7)	512 (27.0)
Stage 3	497 (29.5)	571 (30.1)
Stage 4	75 (4.5)	77 (4.1)
Missing	259 (15.4)	252 (13.3)
Sexual activity, *n* (%)		
Had sexual intercourse in past month	1123 (66.7)	1168 (61.5)
Did not have sexual intercourse in past month	458 (27.2)	636 (33.5)
Missing	101 (6.0)	96 (5.1)

ART, antiretroviral therapy; IQR, inter-quartile range.
[a]Information available from time of enrolment in HIV care.
[b]Within ±6 months of baseline visit date.

corresponds to a rate of 5.5 (95% CI 4.8–6.4) and 6.1 (95% CI 4.6–8.2) pregnancies per 100 person-years of follow-up at integrated and control sites, respectively. A sensitivity analysis adjusting for baseline pregnancy rates revealed a similar result (data not shown).

Discussion

The trial showed that integration of family planning services into HIV care and treatment is associated with significantly higher use of more effective contraceptive methods. We did not see a change in use of any family planning method, probably due to the high prevalence of reported condom use at baseline. Although we did not see a significant reduction in pregnancy incidence during the study, it is likely that 1 year is too short a period of observation for this outcome. In addition, the study was not powered to detect a reduction in pregnancy. Our findings build on the results of a non-randomized trial in Kenya that found that non-condom contraceptive use increased and pregnancy incidence decreased among HIV-infected women participating in a clinical trial after launching a multipronged intervention that promoted family planning use and provision in the study clinic [19]. Additional analyses from our trial will examine the cost, acceptability and feasibility of integrated services, as well as the facility characteristics at integrated sites associated with higher levels of contraceptive use.

To the best of our knowledge, this is the first randomized trial to evaluate the effectiveness of integrating family planning services into HIV care and treatment, and our results provide encouraging evidence in support of the programmatic push toward integration. Whereas cluster-randomized trials are prone to certain bias [20], we believe that this study helps to demonstrate the value of this study design to answer questions regarding models of healthcare delivery. Specifically, we found significant increases in the use of more effective family planning at control sites during follow-up, probably as a result of the system strengthening provided by the study team, including efforts to ensure that commodities were always available at all sites.

We observed a small reduction in condom use at integrated sites, although the overall change in condom use at end line between integrated and control sites was not significantly different. Dual method use was stressed in patient counselling, and we observed that reported dual method use increased as women used more effective family planning methods, although this change was not significantly different between study arms. Studies from

Table 3. Prevalence of contraceptive use by method among women's encounters at baseline and end line, adjusted odds ratios for contraceptive use categories, and pregnancy incidence[a].

Measure	Baseline[b] (Dec 2009–Feb 2010, %)	End line[b] (Jul 2011–Sep 2011, %)	Absolute difference in percentages between baseline and end line	OR[c] (95% CI) or IRR[c,d] (95% CI)
Using more effective family planning				1.81 (1.24–2.63)
Integrated	16.7	36.6	+19.9	
Control	21.1	29.8	+8.7	
Female or male sterilization				
Integrated	1.6	4.1	+2.5	
Control	2.5	4.5	+2.0	
IUD				
Integrated	0.3	1.0	+0.7	
Control	0.0	0.5	+0.5	
Sub-dermal implant				
Integrated	0.6	8.3	+7.7	
Control	1.4	5.5	+4.1	
Injectable				
Integrated	13.1	22.5	+9.4	
Control	15.5	18.3	+2.8	
Oral contraceptives				
Integrated	1.3	1.9	+0.6	
Control	1.3	1.9	+0.6	
Dual method use (condoms + injectable, oral, implant, IUD or sterilization)				1.30 (0.77–2.17)
Integrated	10.1	20.9	+10.8	
Control	11.5	19.1	+7.6	
Using less effective family planning				
Integrated	50.7	36.9	−13.8	
Control	39.6	39.9	+0.3	
Using condoms (alone or with another method)				0.64 (0.35–1.19)
Integrated	60.5	57.7	−2.8	
Control	51.0	59.1	+8.1	
Using any family planning				0.90 (0.50–1.60)
Integrated	67.5	73.4	+5.9	
Control	60.8	69.7	+8.9	
Using no family planning				
Integrated	32.5	26.6	−5.9	
Control	39.2	30.3	−8.9	
Pregnancy				0.90 (0.68–1.20)
Integrated		1.5[d]		
Control		1.7[d]		

CI, confidence interval; IRR, incidence rate ratio; OR, odds ratio.
[a]All outcomes are reported with clinic encounter as the unit of observation.
[b]Prevalence estimates are model-based projections.
[c]Effect measures are adjusted for site-level clustering.
[d]Pregnancy rates and incidence rate ratio estimated over the final year of the study.

other settings have found a similar prevalence of dual method use [8,21], and clearly additional research is needed to identify interventions to increase condom use along with more effective family planning methods. Dual method use among HIV-infected women is critical for the prevention of heterosexual HIV transmission. Among people living with HIV in sub-Saharan Africa who are in stable relationships, up to half have an uninfected partner [22]. In addition, one study has suggested that women who use depomedroxyprogesterone acetate might have an increased risk of HIV transmission [23].

The study has several limitations. We have limited information about the study population from the EMRS and have more missing data from the time of enrolment in HIV care at integrated compared to control sites. Therefore, it is possible that unobserved differences between the two populations affected study outcomes, although the randomized design should eliminate selection bias and confounding. In addition, condom use was based on self-report, and social desirability bias may have increased reported consistent use. However, this bias is likely to be similar in both study arms. In addition, the small fee intermittently charged to patients seeking contraception at three of the control sites might have reduced use of more effective methods at these sites. There are additional limitations related to our pregnancy data, including the fact that not all incident pregnancies (especially early pregnancies) were likely detected during the follow-up period, and we did not have information on pregnancy intendedness. Finally, our findings are specific to the model of family planning–HIV integration studied here.

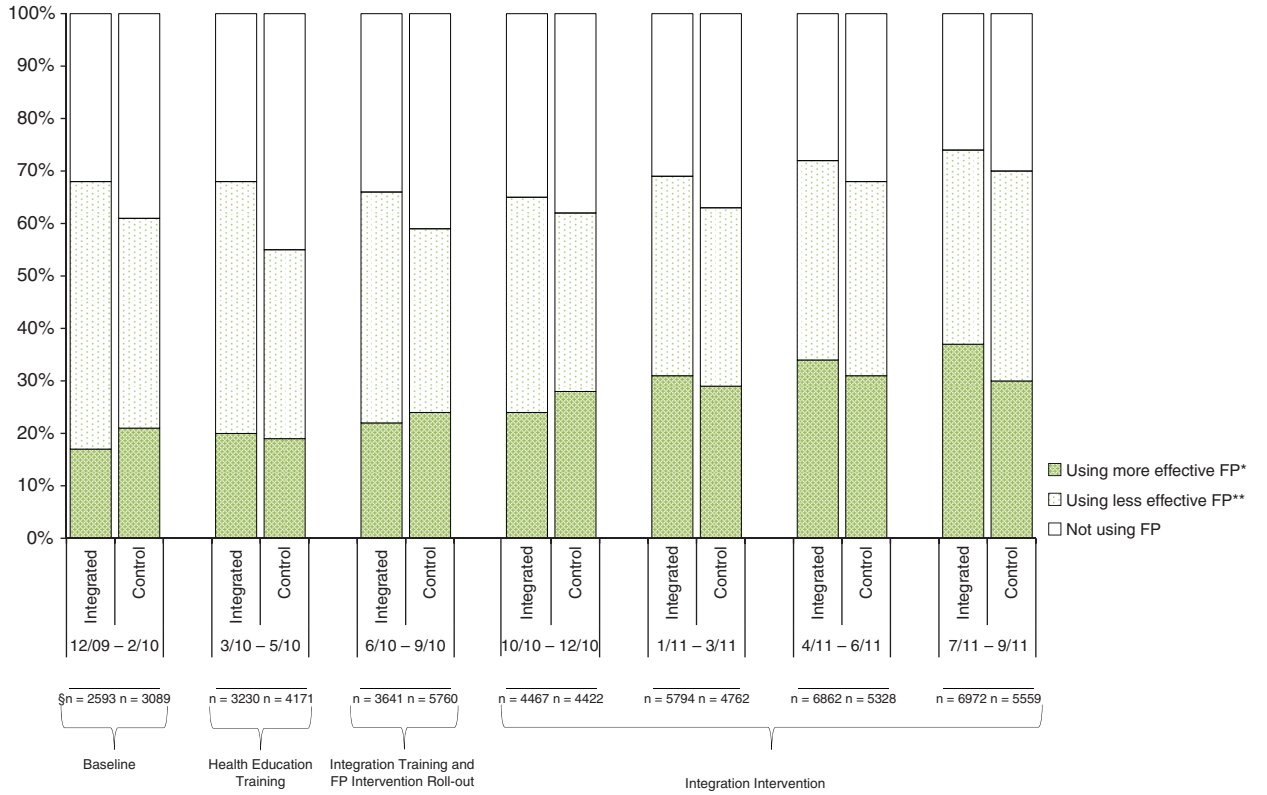

Fig. 2. Prevalence of contraceptive use among women's encounters at integrated vs. control sites, December 2009–September 2011[†]**.** [†]All outcomes are reported with clinic encounter as the unit of observation. Prevalence estimates are model-based projections. [§]Number of encounters analysed during each period by study arm. *Sterilization, intrauterine device (IUD), subdermal implants, injectable and oral contraceptives; includes dual-method use (condoms used with more effective FP methods). **Barrier or natural methods, including condoms used alone. FP, family planning.

In addition to the cluster-randomized design, strengths of this study include the system-strengthening training that was performed at both intervention and control sites to isolate the effectiveness of integration. We also included facilities of different levels of care.

The rollout of integrated family planning and HIV services will require leadership at the community, regional, national and international levels. Advocates will need to focus their efforts on including integration in national plans and budgets. Country leaders and ministries of health will need to take ownership and establish a 'minimum package' of integrated services, as has been done in Kenya [14,15]. In addition, the international donor community will need to work closely with stakeholders to support family planning–HIV integration. Whereas this study demonstrates that the 'one-stop shop' improves the use of more effective contraception among HIV-infected women, only a concerted effort by governments, donors and other key stakeholders will move family planning–HIV integration forward to help meet the unmet need for family planning services in sub-Saharan Africa.

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D.G. originated and supervised study, participated in study site training, led study design, data interpretation and writing. M.O. coordinated all aspects of study implementation and monitoring, contributed to data interpretation and writing. S.J.N. contributed to study design, training, data interpretation and writing. C.B. led data management and analysis, and contributed to writing. S.B.S. participated in study design, supervised data management and analysis, and contributed to writing. R.L.S. performed literature search, developed study and training materials, monitored study and contributed to writing. E.A.B. supervised training and data collection, contributed to data interpretation and writing. C.R.C. supervised all aspects of study, including development of the study design, analysis and writing of the manuscript.

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Conflicts of interest

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