

Supplemental Digital Content

Below are additional details about the study methods.

Study design

Since we are interested in assessing the effect of the intervention at the level of the clinic and not the level of the patient, it is important to capture information at the level of the clinic. Therefore, we aimed to capture information on as many patients as possible treated in each clinic within each time period, not just a pre-selected cohort of those who were in care at baseline. Data from clinical encounters were treated as serial cross-sections to assess change in study outcomes over time. This approach has been taken in recent large cluster-randomized trials.¹ Chart audits using serial cross-sections of individuals who receive care in specific clinics or from specific providers are frequently used to assess changes in clinical practice.^{2,3} Additional details of the methods are available in the study protocol (available at http://integrationforimpact.org/wp-content/uploads/2012/05/Study-Protocol_FP_HIV-Integration_03Dec10.pdf).

Training

Because of intra-facility staff rotation, training at both intervention and control sites was similar and included seven days of intensive training on the mechanism of action, efficacy, and safety of all FP methods in the context of HIV infection (training materials available at http://integrationforimpact.org/wp-content/uploads/2012/05/Supplemental-training-for-clinicians_Integration-of-FP-and-HIV-Services.pdf).⁴ They received didactic and interactive training, with models and patients, on infection prevention and counseling about and provision of all reversible contraceptive methods, including the IUD and implant. Subsequently, providers were supervised performing IUD and implant insertions prior to being certified as competent. Training at integrated sites also included modules on integration logistics and use of activity registers and reporting. Refresher trainings were provided at all sites approximately every three months, or more frequently if more than 40% of trained staff left the facility.

Electronic medical records

At 11 sites (seven integrated and four control sites), all encounters during the study period were entered into OpenMRS, the electronic medical record database. At the remaining seven sites (five integrated and two control sites), paper charts were not routinely entered. Instead clinic visits were entered into OpenMRS for the first approximately 50 female patients seen each month during the study period who met study age eligibility criteria and had several key variables documented (whether she was using contraception, if so what method(s), and whether she was pregnant). This number of charts was selected to reach the desired cluster size for each three-month analysis period (see sample size calculation below). If fewer than 50 eligible charts per month were identified, all were entered.

Study outcomes

Contraceptive method use on a visit was ascertained from patient medical records. At each visit, clinicians recorded the following: 1) current method of contraception in use by self or partner; 2) medications currently used or prescribed on day of visit; and 3) frequency of condom use in the past month (only condom use reported as “all of the time” was considered use). A method identified through any of these fields was ascribed to the patient on that visit. To improve data completeness and because we deemed removal and reimplantation of surgical methods unlikely, for IUD and implant we assumed that a patient was on the method on all visits between two intervening reports of use. Sterilization was also assumed for all visits subsequent to first report. We assessed the sensitivity of our findings to these assumptions by re-analyzing all outcomes without imputation.

For the pregnancy outcome, date of last menstrual period (LMP) and estimated date of delivery (EDD) were reviewed along with the patient’s pregnancy status in order to estimate the date of conception (DoC) to determine if conception occurred during the year after launching the intervention. Routine pregnancy testing was not done, and all pregnancies were self-reported and confirmed clinically. The DoC was estimated from the earliest clinical record of pregnancy on which either the LMP or EDD was also recorded. If the LMP was ≥ 14 days before the visit date, the DoC was computed as 14 days after the LMP. If the LMP was < 14 days before the visit date, the DoC was computed as the mid-point between the LMP and the visit date. Because we deemed the LMP more reliable than the EDD, we derived the DoC from the EDD only if the LMP was missing. In such cases, the DoC was estimated as 266 days before the EDD.

Statistical analysis

Negative binomial regression was used to quantify pregnancy rates during the first year after integration (Oct 2009 – Sep 2010). The negative binomial was chosen over a Poisson model because of evidence of overdispersion. The model regressed a count of new pregnancies during the follow-up period at a site on the integration status of the site, with the natural log of total clinic visits as the offset (which represents person-time in the computation of the rate). Visits for pregnant and recently pregnant patients (< 3 months after the EDD) were excluded from the offset because the patient was not at risk of becoming pregnant. The coefficients from the model were used to calculate the pregnancy rates at integrated and non-integrated sites per 100 clinic visits along with the associated incidence rate ratio and 95% confidence interval. In addition, we present an approximate pregnancy rate over 100 person years of follow-up for each study arm, which was estimated by repeating the regression with an offset of the natural log of total clinic visits multiplied by the mean interval between clinic visits (0.27 years) during the follow-up year among patients seen at sites where all encounters were entered into OpenMRS. The mean visit interval at these sites gives an approximate estimate of the at-risk period associated with each encounter at sites where sampling-based data collection does not allow for direct estimation of the at-risk period for each patient. Because pregnancy data were available only for three months at baseline and pregnancy incidence was expected to fluctuate seasonally,⁵ we chose to conduct

our primary analysis of pregnancy without baseline adjustment. A sensitivity analysis that included baseline adjustment was also performed.

References

¹ NIMH Project Accept. Available at <http://www.cbvct.med.ucla.edu/overview.html>. Accessed 14 February 2013.

² Shade SB, Sackett N, Khamarko K, Koester KA, Bie J, et al. Quality of Comprehensive HIV Care in Underserved Communities: Does Clinical Training Lead to Improvement. *Am J Med Qual*. 2012 Aug 14. [Epub ahead of print]

³ Petersen LA, Urech T, Simpson K, Pietz K, Hysong SJ, et al. Design, rationale, and baseline characteristics of a cluster randomized controlled trial of pay for performance for hypertension treatment: study protocol. *Implement Sci*. 2011 Oct 3;6:114.

⁴ Ministry of Medical Services and Ministry of Public Health and Sanitation. Family planning orientation package for HIV service providers. Nairobi: Government of Kenya (2009). Available at http://integrationforimpact.org/wp-content/uploads/2012/05/National_FP-HIV_Integration_Package.pdf. Accessed 26 November 2012.

⁵ Cesario SK. The "Christmas Effect" and other biometeorologic influences on childbearing and the health of women. *J Obstet Gynecol Neonatal Nurs*. 2002 Sep-Oct;31(5):526-35.