Comparison of Unintended Pregnancy at 12 Months between Two Contraceptive Care Programs; a Controlled Time-Trend Design

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Abstract

Objectives: To compare unintended pregnancy rates at 12 months between women receiving structured contraceptive counseling plus usual contraceptive care, and women receiving structured contraceptive counseling, healthcare provider education, and cost support for long-acting reversible contraceptive (LARC) methods.

Study Design: Using a controlled time-trend study design, we first enrolled 502 women receiving structured contraceptive counseling in addition to usual care ("Enhanced Care") and subsequently enrolled 506 women to receiving counseling plus healthcare provider education and cost support for LARC methods ("Complete CHOICE") at three federally qualified health centers (FQHC). Cost support included funds to health centers for "on-the-shelf" LARC methods and no-cost LARC methods for uninsured women. Participants completed in-person baseline surveys and follow-up surveys by telephone at 3, 6, and 12 months. We used Kaplan-Meier survival function to estimate 12-month unintended pregnancy rates and Cox proportional hazards regression to compare unintended pregnancy rates between the two groups. We imputed pregnancy outcomes for women lost to follow-up (9%) prior to 12 months.

Results: "Complete CHOICE" participants were less likely to report an unintended pregnancy at 12 months compared to "Enhanced Care"; 5.3 vs. 9.8 pregnancies per 100 women-years (p=0.01). After adjusting for confounders (recruitment site, race, age, and federal poverty level), women in "Complete CHOICE" had a 40% lower risk of unintended pregnancy at 12 months (HR_{adj} 0.60; 95%CI 0.37-0.99).

Conclusions: Contraceptive provision that includes cost support and healthcare provider education in addition to patient counseling reduced unintended pregnancy at 12 months compared to counseling plus usual contraceptive care.

Implications: A program of contraceptive care that includes comprehensive counseling, healthcare provider education, cost support, and on-the-shelf, long-acting reversible contraception can reduce unintended pregnancy compared to contraceptive counseling in addition to usual health center care in the FQHC setting.

Keywords: Contraceptive counseling; long-acting reversible contraception; intrauterine device; contraceptive implant; unintended pregnancy

1. Introduction

Unintended pregnancy remains a persistent public health problem in the United States, with 45% of the 6.1 million annual pregnancies being unplanned (1). Due to high rates of effectiveness, long-acting reversible contraceptive (LARC) methods, including intrauterine devices (IUDs) and implants, have been proposed as a strategy to reduce unintended pregnancy (2-5). Our group previously conducted a research study, the Contraceptive CHOICE Project (CHOICE), which provided women with their preferred reversible contraceptive method at no cost and followed them over 2-3 years. The CHOICE intervention included 1) structured, evidence-based counseling, which presented reversible contraceptive methods in order of effectiveness; 2) healthcare provider education about evidence-based guidelines for contraception including IUDs and implants; 3) removal of structural barriers including patient cost; and 4) facilitation of same-day contraceptive initiation by maintaining in-clinic inventory of contraceptive methods including IUDs and implants. LARC uptake was high, with 75% of the participants choosing an IUD or implant (6). LARC users also had lower rates of unintended pregnancy compared to users of shorter-acting reversible methods (6-8).

The CHOICE model proved successful in a research setting, where the majority of participants (70%) were recruited at the university-based research clinic and contraceptive counseling was provided by a trained research assistant at all recruitment sites. However, the success of the model in real-world clinical settings is unknown. Our primary objective was to implement two contraceptive programs adapted from the CHOICE Project in community health centers and compare subsequent rates of unintended pregnancy at 12 months between women receiving these models of care. We hypothesized that a program, which included structured contraceptive counseling plus healthcare provider education and funds to purchase LARC

methods, would have a greater reduction in unintended pregnancy by 12 months compared to a program which included only structured contraceptive counseling in addition to usual contraceptive care.

2. Materials and Methods

2.1 Study Design and Interventions

We conducted a controlled time-trend design to compare two different models of contraceptive provision at three urban federally-qualified health centers (FQHCs) located in two Midwest cities. Controlled time-trend analysis is a nonrandomized study design where outcomes are compared before and after a change occurs in the healthcare setting (9). In the first study group, "Enhanced Care," women received structured contraceptive counseling adapted from the CHOICE Project (10) in addition to the usual contraceptive care provided by the health center. Counseling was provided by existing health center staff members trained by our study team. The counseling used an evidence-based script which presented reversible contraceptive methods in order of effectiveness highlighting method duration and side effects. The mean length of counseling sessions in the study was 9.0 minutes (SD 3.6). For the second study group, "Complete CHOICE," the program added healthcare provider contraceptive training and cost support for LARC methods to the same counseling. Cost support included upfront funds for health centers to purchase an in-clinic LARC inventory to provide no-cost LARC methods for uninsured patients and to ensure availability for same-day placement for all women regardless of insurance status. All three health centers already provided refillable methods of contraception such as oral contraceptive pills (OCPs) and depo-medroxyprogesterone acetate (DMPA), cost was based on a sliding fee scale. "Enhanced Care" was implemented first at all sites and a cohort of women were enrolled. The additional components of "Complete CHOICE" were then

subsequently implemented at all sites and a second cohort of women enrolled. The additional components represented the "change in the system" for the controlled time-trend design. Figure 1 shows the study design and timeline.

2.2 Participants

Eligible women were 14-45 years, English or Spanish speaking, not currently pregnant, sexually active with a male partner or planning to become sexually active in the next 3 months, did not desire pregnancy in the next 12 months, at risk for unintended pregnancy (i.e. had not undergone sterilization or hysterectomy), and had an appointment at a participating health center. Women with one male sexual partner who had undergone vasectomy were ineligible. Current LARC users were only eligible to participate if they were seeking removal of their method at their healthcare appointment. Women did not have to choose a method of contraception to be eligible to participate. Site counselors primarily recruited patients scheduled for a gynecologic or family planning visit. However, any reproductive-age woman interested in contraception was eligible regardless of appointment type as long as they met the above inclusion criteria. Participants received a $20 gift card at baseline and a $10 gift card for each follow-up survey, up to $50 total for their participation. We obtained approval from the Human Research Protection Office at the Washington University in St. Louis School of Medicine prior to participant recruitment. Parental consent was not required for participants under 18 years of age, as it is not required for adolescents to access confidential reproductive health services. We registered the study with ClinicalTrials.gov (NCT02364037).

2.3 Measures

All women completed an interviewer-administered baseline questionnaire and follow-up surveys by telephone at 3, 6, and 12 months. If a woman reported a new pregnancy at any time

point during the 12 months, she was asked "At the time (you became pregnant), would you say you were trying to get pregnant?" Participants who responded "no" were coded as having an unintended pregnancy for the primary outcome. A member of the study team also administered the London Measure of Unplanned Pregnancy (11), a 6-item validated measure of pregnancy planning and intention, to all women who reported a pregnancy to assess pregnancy intention. The London Measure of Unplanned Pregnancy scores range from 0-12 and can categorize pregnancies as unplanned (0-3), ambivalent (4-9), or planned (10-12). When dichotomizing scores into planned and unplanned, unplanned and ambivalent are grouped together (11).

2.4 Sample Size

We assumed a 13% baseline annual unintended pregnancy rate for the FQHC population based on the national rate of 137 per 1,000 reproductive-age women with household incomes less than 100% of the federal poverty level (FPL) (12). We anticipated a small reduction in the unintended pregnancy rate for "Enhanced Care," from 13% to 11%, due to the structured contraceptive counseling. Based on results from CHOICE, we anticipated a reduction in unintended pregnancy from 11% in "Enhanced Care" to 5% in "Complete CHOICE."(6, 13) To account for possible clustering by health center, we performed a test of differences in proportions using a range of possible values. We increased the sample size by an additional 10% to compensate for lack of randomization and to be more conservative in our estimate. Using an alpha of 0.05, 80% power, and assuming 10% loss to follow-up, we needed 480 women in each group. We estimated a 10% loss to follow-up based on our retention rates in prior studies. We used REDCap electronic data capture tools for data collection and management (14). We performed data analysis using Stata 15 (StataCorp, College Station, TX).

2.5 Statistical Analyses

For the outcome of unintended pregnancy at 12 months, participants contributed follow-up time for the 12-month study period unless we censored them for the following: 1) discontinued method to seek pregnancy, 2) had an intended pregnancy, 3) had an unintended pregnancy, or 4) were lost to follow-up. Women with an intended pregnancy who did not report stopping contraception to conceive were censored at the estimated date of conception based on last menstrual period or estimated due date depending on reported data. Women with an unintended pregnancy were censored at the estimated date of conception.

There were 11 women who crossed over from the "Enhanced Care" to "Complete CHOICE" group, as they presented for subsequent care during "Complete CHOICE" enrollment. Following intention-to-treat principles, we analyzed outcomes for these participants in the "Enhanced Care" group only. Due to missing pregnancy outcomes for the 92 participants lost to follow-up, we performed multiple imputation to impute unintended pregnancy outcomes and follow-up time (15). The multiple imputation model included age, race, ethnicity, FPL, desired contraceptive method, health center site, and study group as predictors for unintended pregnancy. Women lost to follow-up differed from women with complete follow-up by site, insurance status, FPL, and desired method. We created 10 datasets with imputed values that were then pooled. The aggregate multiple imputation dataset contributed an additional 12 unintended pregnancies (7 in "Enhanced Care" and 5 in "Complete CHOICE").

We estimated unintended pregnancy rates at 12 months using the Kaplan-Meier survival function and used the log rank test to examine differences between study groups. We performed univariate and multivariable Cox proportional hazards regressions to investigate associations between group assignment, baseline characteristics, and unintended pregnancy. We planned, *a priori*, to include age, race, Hispanic ethnicity, and FPL in the multivariable model as these

characteristics have previously been associated with unintended pregnancy (1). We also planned to include site due to baseline differences between health centers. Due to the limited number of pregnancy outcomes, we collapsed categorical variables into binary variables to reduce the number of covariates. We included age as a continuous variable. We investigated the presence of confounding by performing bivariate analyses adding baseline characteristics (i.e. age, race, ethnicity, parity) to study group indicator in the Cox regression model. Confounding was defined as a greater than 10% change in the association between study group and unintended pregnancy with or without the covariate of interest in the model. Model checking showed that Hispanic ethnicity failed the proportional hazards assumption. Therefore, we excluded ethnicity from the final multivariable model. We ran the univariate and multivariable models with and without imputed pregnancies included to assess for differences in effect size and significance. We calculated London Measure of Unplanned Pregnancy scores as previously described – scoring data were only available for participants with observed pregnancies (11).

3. Results

From June 2014 through September 2015, we enrolled 502 women into "Enhanced Care" and 506 women into "Complete CHOICE." Baseline results have previously been described (16). Approximately 90% of eligible participants in each group completed follow-up surveys at 3, 6, and 12 months. Figure 2 shows the flow of study follow-up. The overall loss to follow-up at 12 months was 9% for "Enhanced Care" and 10% for "Complete CHOICE." Women lost to follow-up were more likely to be uninsured ($p<0.01$), report a household income less than 100% FPL ($p<.0.01$), and more likely to receive OCPs, contraceptive patch, vaginal ring, or no method for their contraceptive method ($p=0.02$).

Women in "Complete CHOICE" were older, more likely to be Hispanic and uninsured, and less likely to be black, single, or report a history of unintended pregnancy (Table 1) compared to "Enhanced Care." Women in "Complete CHOICE" had a lower risk of unintended pregnancy at 12 months, 5.3 compared to 9.8 per 100 reproductive-age women-years (Table 2, p=0.01). Figure 3 shows the Kaplan-Meier curve for the probability of unintended pregnancy over the 12-month time period by group (p=0.01). Due to the higher uptake of LARC methods in "Complete CHOICE," we also assessed the risk of unintended pregnancy by contraceptive method received at enrollment visit. Women who received a LARC method were less likely to have an unintended pregnancy over 12 months (Figure 4, p<0.01).

In the univariate Cox proportional hazards model, study group, site, age, race, and FPL were all significantly associated with risk of unintended pregnancy; women in "Complete CHOICE" and women enrolled at Health Centers B or C had a decreased risk and non-white and low-income women had an increased risk of unintended pregnancy (Table 3). We did not find evidence of confounding when education, marital status, insurance status, parity, and future pregnancy plans were added to the model with study group. Therefore, we included study group, site, age, race, and FPL in our final model. In the multivariable model, women in "Complete CHOICE" had a 40% reduction in the risk of unintended pregnancy (HR_{adj} 0.60, 95%CI 0.37-0.99). Women enrolled at Health Center B also had a decreased risk of unintended pregnancy. Low-income women had an increased risk of unintended pregnancy. Non-white race no longer remained significantly associated with unintended pregnancy in our adjusted model.

We calculated London Measure of Unplanned Pregnancy scores for the 54 women who reported an unintended pregnancy and completed the survey (missing data n=5). All women had a London Measure of Unplanned Pregnancy score less than 10, which is consistent with either an

unplanned pregnancy or a pregnancy about which the woman was ambivalent; 46.3% with score 0-3 (unplanned), 53.7% with score 4-9 (ambivalent).

Due to the 11 participants who crossed over from "Enhanced Care" to "Complete CHOICE", we repeated the analysis excluding these participants from "Enhanced Care." This exclusion did not alter the effect size or statistical significance of our findings regarding unintended pregnancy rates or the Cox proportional hazards model. The unintended pregnancy rates excluding these participants were 10.1 in "Enhanced Care" vs. 5.3 per 100 reproductive-age women-years in "Complete CHOICE" (p=0.01). We also performed analyses for the outcome of unintended pregnancy with and without the imputed values. The unintended pregnancy rates excluding imputed values were 8.4 in "Enhanced Care" vs. 4.2 per 100 reproductive-age women-years in "Complete CHOICE" (p=0.01). In the multivariable Cox proportional hazards regression, the adjusted hazard ratio for unintended pregnancy without imputed values was similar to hazards ratio with imputed values at HR_{adj} 0.58 (95%CI 0.34-0.99).

4. Discussion

The results from our study show that the CHOICE program of contraceptive care can reduce unintended pregnancy when implemented in an FQHC setting. Women enrolled in "Complete CHOICE" were 40% less likely to have an unintended pregnancy at 12 months compared to women in "Enhanced Care." The proportion of women with an unintended pregnancy was 9.2% in "Enhanced Care" which was slightly lower than the 11% initially assumed for our sample size calculation. The proportion of women with an unintended pregnancy in "Complete CHOICE" was 4.9% and similar to the anticipated 5%. Using time-to-event analysis, we found a statistically significant reduction in the rate of unintended pregnancy

between the two groups. Even after adjustment for possible confounders, women in "Complete CHOICE" were less likely to have an unintended pregnancy by 12 months.

In this study, we implemented and compared our interventions among a population of predominantly low-income women seeking medical care at FQHCs. Even after adjusting for the study group, age, race, and site, low-income women (at or below the federal poverty level) had more than a two-fold increase in the risk of unintended pregnancy (HR_{adj} 2.16, 95%CI 1.03-4.52). Future research is necessary to improve our understanding of the risk of unintended pregnancy among low-income women, even when access is improved and cost removed as a barrier. One possibility is that different concepts of pregnancy planning among low-income women (17-19) may affect how women report pregnancy intention. Some studies have shown an association between black race and unintended pregnancy (20, 21). However, a recent study found no link between race and unintended pregnancy (22). In our study after adjusting for study group, enrollment site, age, and FPL, non-white race was no longer significantly associated with unintended pregnancy. In prior studies, where an association between race and unintended pregnancy was observed, race may have served as a marker for socioeconomic status or access to care.

There are several limitations to our study. The lack of a randomized controlled trial design did not allow us to control for possible unmeasured confounding between the groups. We did perform a multivariable analysis to control for these baseline differences. However, these differences may reflect a lower risk of unintended pregnancy among "Complete CHOICE" participants compared to "Enhanced Care".

We also had participants lost to follow-up over the study period. While our loss to follow-up was similar to anticipated (9%), this loss does mean that we may have missed some

pregnancies that occurred during study participation, which would have underestimated our unintended pregnancy rate. The loss to follow-up was similar between the two groups (9% vs. 10%) making it less likely that missed pregnancies would have altered the difference observed between the groups. In order to account for possible unobserved pregnancies, we performed multiple imputation to impute unintended pregnancy outcomes for participants lost to follow-up. We found similar effect sizes in our survival analysis with and without the imputed pregnancies.

Our objective was to compare two programs of contraceptive care adapted from the CHOICE Project. We found that implementation of "Complete CHOICE"—with structured contraceptive counseling, healthcare provider education, and structural changes to reduce barriers to LARC—reduced the risk of unintended pregnancy compared to "Enhanced Care." Improved access to LARC methods and the subsequent reduction in unintended pregnancies should encourage other FQHCs to consider implementing programs that reduce barriers to contraception. While contraceptive counseling is a key component of family planning care, our results demonstrate that interventions must also address other barriers, including provider practice and cost, to truly increase contraceptive access for patients.

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Conflicts of Interest

Dr. Madden serves on a data safety monitoring board for phase 4 safety studies of Bayer contraceptive products. Dr. Peipert receives research funding from Bayer Healthcare Pharmaceuticals, CooperSurgical/TEVA, and Merck & Co, Inc. and serves on an advisory board for CooperSurgical Pharmaceuticals. The other authors do not have any potential conflicts of interest to report.

Figure 1: Study design and timeline.

Figure 2: Participant flow of study follow-up through 12 months

Table 1: Baseline demographic and reproductive characteristics of participants stratified by study group.

Characteristic	Enhanced Care (n=502) N(%)	Complete CHOICE (n=506) N(%)	*P* Value *
Age			<0.01
14-19 years	88 (17.5)	92 (18.2)	
20-29 years	287 (57.2)	244 (48.2)	
30-45 years	127 (25.3)	170 (33.6)	
Race			<0.01
Black	374 (74.5)	320 (63.2)	
White	96 (19.1)	159 (31.4)	
Other	32 (6.4)	27 (5.3)	
Hispanic			0.02
Yes	39 (7.8)	66 (13.0)	
Missing	3 (0.6)	1 (0.2)	
Education			0.08
≤ High school	317 (63.2)	345 (68.2)	
Some college	153 (30.5)	123 (24.3)	
4+ years college	32 (6.4)	38 (7.5)	
Marital status			<0.01
Never married	394 (78.5)	341 (67.4)	
Married/living with partner	85 (16.9)	132 (26.1)	
Separated/divorced/widowed	23 (4.6)	33 (6.5)	
Insurance status			0.09
None	120 (23.9)	149 (29.5)	
Public	311 (62.0)	274 (54.2)	
Commercial	70 (13.9)	82 (16.2)	
Missing	1 (0.2)	1 (0.2)	
Federal poverty level			0.57
≤ 100%	382 (76.1)	384 (75.9)	
101%-200%	102 (20.3)	95 (18.8)	
≥ 201%	16 (3.2)	24 (4.7)	
Missing	2 (0.4)	3 (0.6)	
Parity			0.14
0	161 (32.1)	165 (32.6)	
1-2	245 (48.8)	221 (43.7)	
3+	96 (19.1)	120 (23.7)	
History of a prior unintended pregnancy			0.06
Yes	257 (51.2)	222 (43.9)	
Missing	1 (0.2)	2 (0.4)	
Feeling if got pregnant in the next			0.03

12 months			
Upset	322 (64.1)	293 (57.9)	
Neutral	102 (20.3)	101 (20.0)	
Pleased	49 (9.8)	60 (11.9)	
Unsure	29 (5.8)	52 (10.3)	
Contraceptive method at end of baseline visit			<0.01
Hormonal IUD	10 (2.0)	40 (7.9)	
Copper IUD	2 (0.4)	11 (2.2)	
Implant	17 (3.4)	110 (21.7)	
DMPA	220 (43.8)	145 (28.7)	
OCP/patch/ring	113 (22.5)	66 (13.0)	
Condoms	35 (7.0)	57 (11.3)	
Other	13 (2.6)	8 (1.6)	
Nothing	92 (18.3)	69 (13.6)	

* χ^2 used to estimate p values

IUD – intrauterine device; DMPA – depot medroxyprogesterone acetate; OCP – oral contraceptive pills

Table 2: Unintended pregnancy outcomes at 12 months for "Enhanced Care" and "Complete CHOICE" groups.

	Enhanced Care (N = 502)	**Complete CHOICE (N = 506)**	***P* Value**
Number of intended pregnancies, n	3	4	
Number of unintended pregnancies, n	46	25	
Person-time (years)	464.02	466.73	
Proportion with an unintended pregnancy, %	9.2	4.9	0.01†
Rate of unintended pregnancy per 100 women-years (95% CI)‡	9.8 (7.4-13.0)	5.3 (3.6-7.7)	0.01

† P value calculated using X^2 test

‡ Rates of unintended pregnancy calculated using Kaplan-Meier survival function; p value calculated using log rank test.

Figure 3: Kaplan Meier curve comparing the probability of unintended pregnancy over 12 months for “Enhanced Care” and “Complete CHOICE” groups.

Figure 4: Kaplan-Meier curve comparing the probability of unintended pregnancy over 12 months for women who received a LARC method compared to a non-LARC method at their enrollment visit

Table 3: Univariate and multivariable Cox proportional hazard regression model for baseline characteristics, group, and site and outcome of unintended pregnancy

	Univariate Analysis	**Multivariable Analysis†**
Baseline Characteristic	**HR (95% CI)**	**HR (95% CI)**
Group		
Enhanced Care	Ref.	Ref.
Complete CHOICE	0.54 (0.32-0.88)	0.60 (0.37-0.99)
Enrollment site		
Health Center A	Ref.	Ref.
Health Center B	0.21 (0.09-0.47)	0.21 (0.08-0.57)
Health Center C	0.56 (0.33-0.93)	0.62 (0.36-1.05)
Age (continuous)	0.58 (0.35-0.94)	0.94 (0.91-0.98)
Hispanic	0.85 (0.37-1.96)	---
Race		
White	Ref.	Ref.
Non-White	2.42 (1.20-4.86)	0.77 (0.32-1.83)
Federal poverty level		
≤ 100%	2.55 (1.22-5.32)	2.16 (1.03-4.52)
≥ 101%	Ref.	Ref.

† Multivariable model adjusted for site, race, age, and federal poverty level.

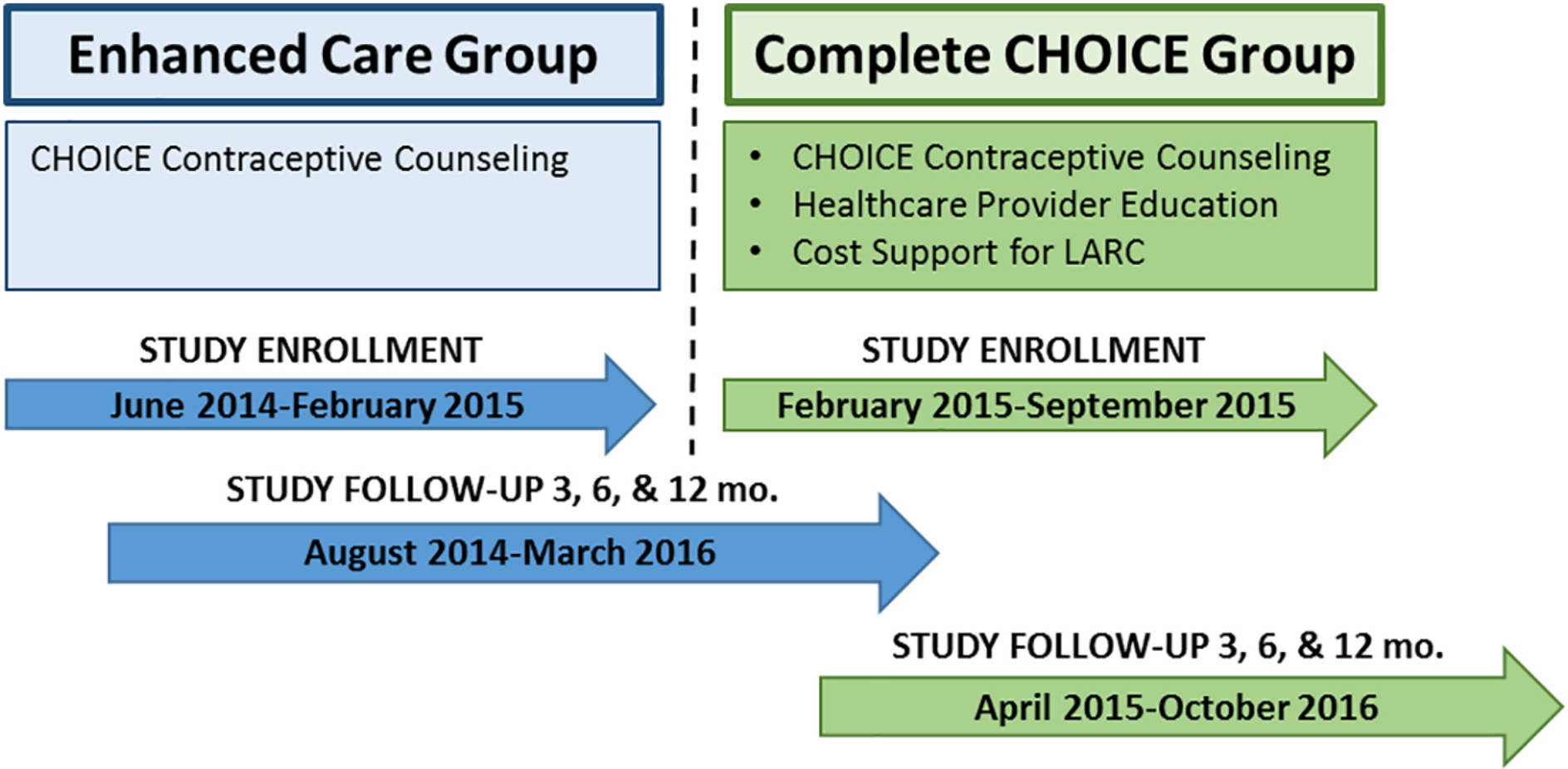
Enhanced Care Group
CHOICE Contraceptive Counseling
Complete CHOICE Group
• CHOICE Contraceptive Counseling
• Healthcare Provider Education
• Cost Support for LARC
STUDY ENROLLMENT
June 2014-February 2015
STUDY ENROLLMENT
February 2015-September 2015
STUDY FOLLOW-UP 3, 6, & 12 mo.
August 2014-March 2016
STUDY FOLLOW-UP 3, 6, & 12 mo.
April 2015-October 2016

Figure 1

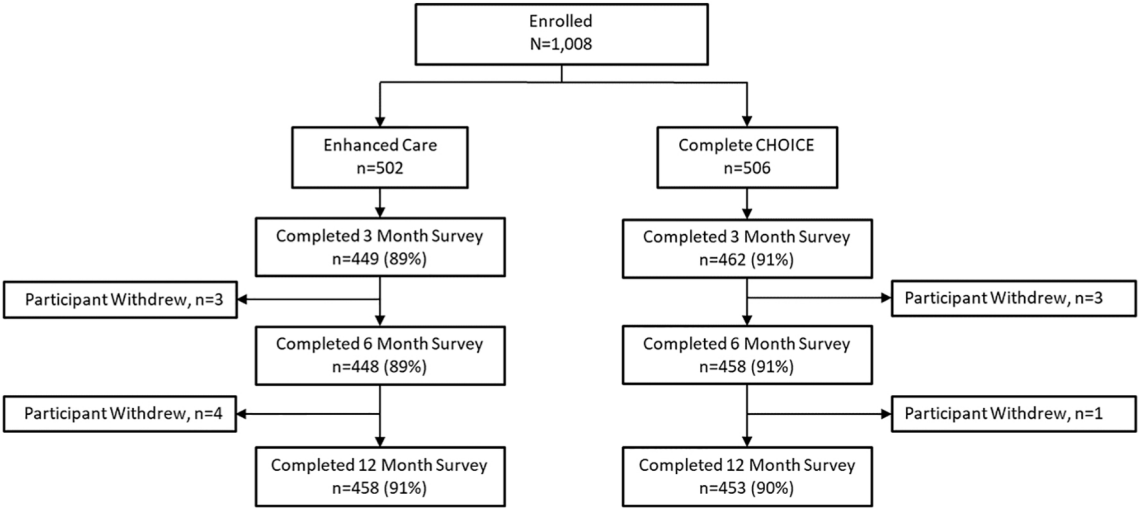
Enrolled
N=1,008
Enhanced Care
n=502
Complete CHOICE
n=506
Completed 3 Month Survey
n=449 (89%)
Completed 3 Month Survey
n=462 (91%)
Participant Withdrew, n=3
Participant Withdrew, n=3
Completed 6 Month Survey
n=448 (89%)
Completed 6 Month Survey
n=458 (91%)
Participant Withdrew, n=4
Participant Withdrew, n=1
Completed 12 Month Survey
n=458 (91%)
Completed 12 Month Survey
n=453 (90%)

Figure 2

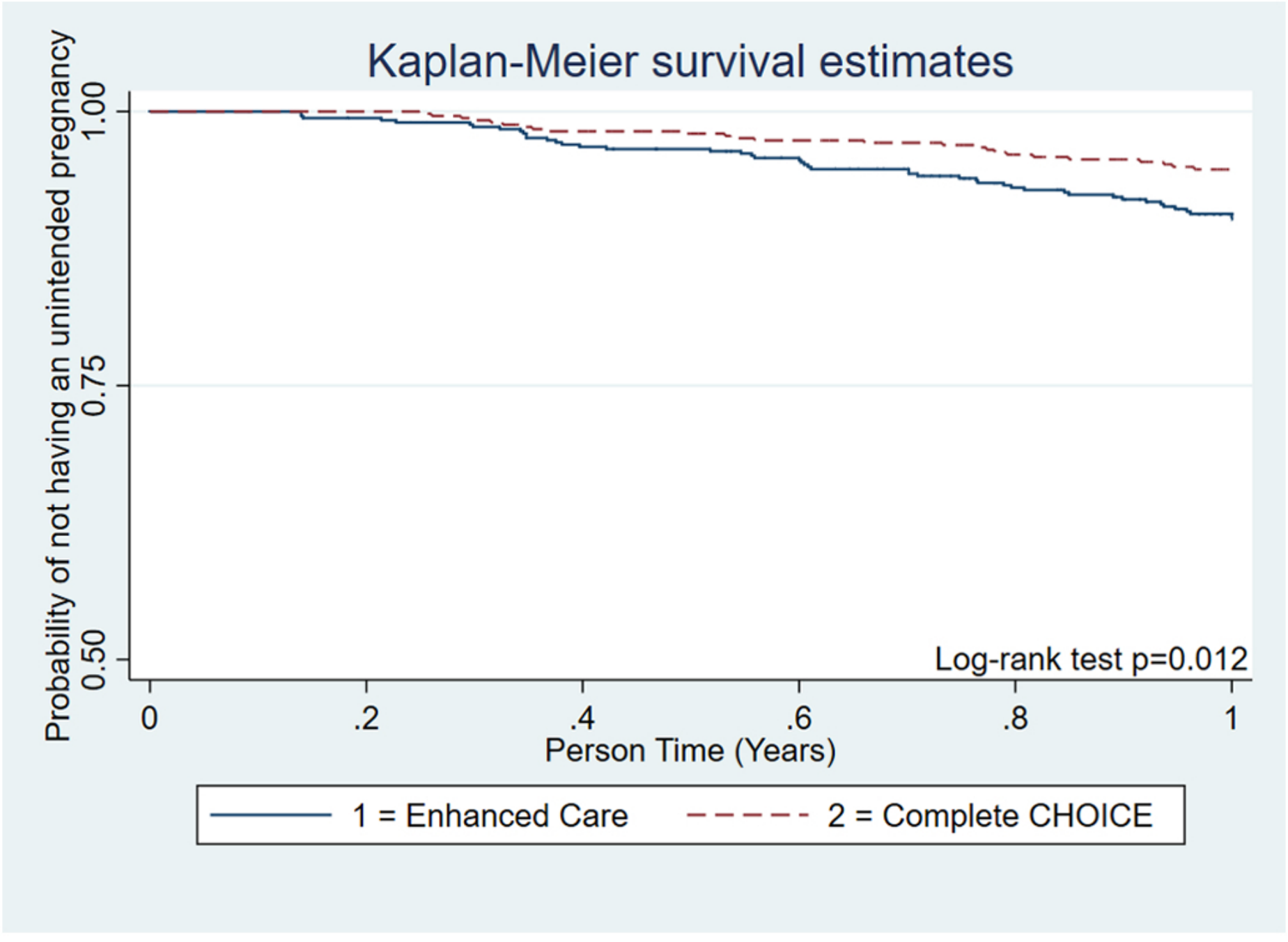
Kaplan-Meier survival estimates
Probability of not having an unintended pregnancy
1.00
0.75
0.50
Log-rank test p=0.012
0
.2
.4
.6
.8
1
Person Time (Years)
1 = Enhanced Care
2 = Complete CHOICE

Figure 3

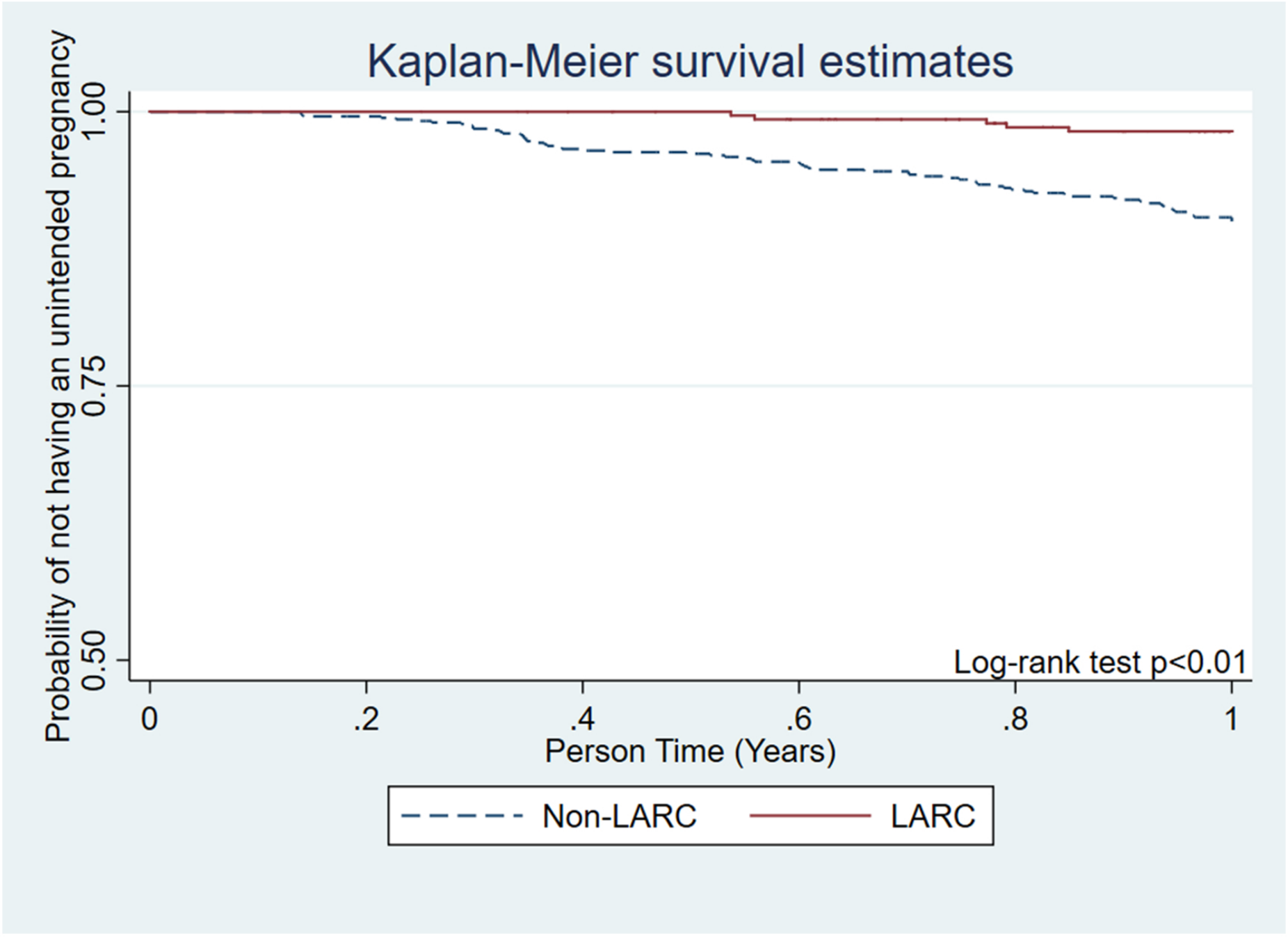
Kaplan-Meier survival estimates
Probability of not having an unintended pregnancy
1.00
0.75
0.50
Log-rank test p<0.01
0
.2
.4
.6
.8
1
Person Time (Years)
Non-LARC
LARC

Figure 4