Randomized Controlled Trial of Home-Based Hormonal Contraceptive Dispensing for Women At Risk of Unintended Pregnancy

CONTEXT: *Women frequently experience barriers to obtaining effective contraceptives from clinic-based providers. Allowing nurses to dispense hormonal methods during home visits may be a way to reduce barriers and improve effective contraceptive use.*

METHODS: *Between 2009 and 2013, a sample of 337 low-income, pregnant clients of a nurse home-visit program in Washington State were randomly selected to receive either usual care or enhanced care in which nurses were permitted to provide hormonal contraceptives postpartum. Participants were surveyed at baseline and every three months postpartum for up to two years. Longitudinal Poisson mixed-effects regression analysis was used to examine group differences in gaps in effective contraceptive use, and survival analysis was used to examine time until a subsequent pregnancy.*

RESULTS: *Compared with usual care participants, enhanced care participants had an average of 9.6 fewer days not covered by effective contraceptive use during the 90 days following a first birth (52.6 vs. 62.2). By six months postpartum, 50% of usual care participants and 39% of enhanced care participants were using a long-acting reversible contraceptive (LARC). In analyses excluding LARC use, enhanced care participants had an average of 14.2 fewer days not covered by effective contraceptive use 0–3 months postpartum (65.0 vs. 79.2) and 15.7 fewer uncovered days 4–6 months postpartum (39.2 vs. 54.9).*

CONCLUSION: *Home dispensing of hormonal contraceptives may improve women's postpartum contraceptive use and should be explored as an intervention in communities where contraceptives are not easily accessible.*

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Unintended pregnancies adversely affect the health of women, children and families worldwide.[1–3] Pregnancies that occur within 18 months of a previous birth to the same woman (short-interval pregnancies) are often unintended and more likely than longer interval pregnancies to involve fetal death, intrauterine growth retardation, preterm delivery and neonatal mortality.[4–7] Effective contraceptives—hormonal methods and IUDs—have failure rates of less than 10% with typical use.[4,6–10] Decreasing women's gaps in use of such methods after childbirth could reduce the incidence of unintended and short-interval pregnancies.

Several factors account for most gaps in contraceptive use; these include infrequent sexual intercourse or periodic abstinence, ambivalence about avoiding pregnancy, and difficulty accessing contraceptive supplies and care.[11] For many women at risk of unintended pregnancy, having to visit a clinic-based health care provider to obtain contraceptives poses several challenges, such as needing to arrange and pay for child care and transportation, having to take off time from work and experiencing long clinic waiting times and delays in obtaining appointments and insurance.[11–15] Policies that require women seeking contraceptives to receive a pelvic exam to initiate a hormonal method and to visit a provider before receiving refills add to this burden.[12,16]

First Stop, a clinic-based contraceptive program in California, reduced clients' use of over-the-counter methods and increased their use of more effective hormonal methods by offering hormonal contraceptives without requiring a pelvic exam or an appointment;[17] however, First Stop and similar successful programs still require women to travel to clinics to receive family planning services. In this article, we report on an intervention that addresses the structural and policy barriers to contraceptive access by supporting nurses' dispensing and administering of hormonal contraceptives during home visits with women at risk for unintended and short-interval pregnancies. Using a randomized clinical trial, we examined whether adding the contraceptive dispensing intervention to the Nurse-Family Partnership (NFP) home visit program could increase women's effective contraceptive use postpartum and their time to subsequent pregnancies.

BACKGROUND

The NFP is an evidence-based[18–21] home visit program that serves vulnerable, low-income, first-time mothers in 577 U.S. counties, as well as in six tribal communities and the U.S. Virgin Islands.[22] Pregnant women often learn about the NFP program through Women, Infants and Children's programs, or from school nurses and counselors, health

care or family planning clinic providers, or local social service agencies. Women—including adolescents—are encouraged to enroll in the program early in their pregnancy, no later than at 28 weeks' gestation. The program is voluntary, and women have an opportunity to meet with an NFP nurse to hear about the program's benefits and ask questions about its services before deciding whether to enroll. If a woman decides to participate, the nurse can enroll her in the program.

Once enrolled, participants receive intensive home visit services from registered nurses. NFP nurses and their supervisors are trained by the national NFP program on such topics as self-efficacy, human ecology, attachment theory and motivational interviewing. The national program also provides practice guidelines that nurses use to bring up topics during key transitional times throughout pregnancy and postpartum. For example, the guidelines outline family planning topics nurses can address with clients in the last trimester of the pregnancy and postpartum, including life and parenting goals, contraceptives, contraceptive side effects and changes in pregnancy intention.

NFP nurses visit each client's home during her first pregnancy and throughout her child's first two years of life. The intent of the visits is to improve prenatal health behaviors and, thereby, pregnancy outcomes; improve parental caregiving and, thereby, children's health; and improve the family's economic self-sufficiency.[18–21] The nurses approach pregnancy planning by helping women think about how subsequent pregnancies will affect their ability to complete their education, participate in the work force, and protect and care for their firstborn child. Currently, more than 1,800 NFP nurses visit over 31,400 women and their children.[22] The NFP program has successfully reduced subsequent unintended pregnancies among clients, and increased the interval between their first and subsequent births; however, about a third of program participants still experience short-interval pregnancies.[18]

METHODS

Study Design

We conducted this study between 2009 and 2013 at five sites of three NFP programs managed by local health departments in urban and rural communities of Washington State. The sites were chosen because the principal investigator was a health official at one and was familiar with officials at the others, and because the NFP national service office recommended them as being ready to participate in a research study aimed at enhancing the existing program. Twenty-four nurses at the sites implemented the intervention.

All women enrolled in the NFP program at study sites were eligible to participate if they were pregnant, their pregnancy was at or before 33 weeks' gestation and they spoke either English or Spanish. Nurses visited NFP clients on a weekly or biweekly basis and used their judgment to determine when or how often to invite their clients to participate in the study, as long as they made the invitations when their clients were eligible. We did not ask nurses to record whether or how many times they invited each of their clients to participate.

Following enrollment and while still pregnant, participants completed a baseline telephone survey administered by research staff. Afterward, we randomized participants within each study site using block randomization with varying unknown sizes, which allowed us to allocate participants to one of two study arms—enhanced care (intervention) or usual care (control)—with equal probability within blocks. Randomization was performed manually by research staff who did not collect survey data or have any other contact with participants. Staff who collected survey data remained masked to each participant's random assignment.

All participants received the usual NFP home visit services beginning during the prenatal period. Nurses visited participants weekly for four weeks and then biweekly until delivery. After delivery, nurses were scheduled to visit weekly for six weeks, then biweekly until participants were 21 months postpartum, and then monthly between 21 and 24 months postpartum; however, throughout the program, families varied in their ability to follow this schedule, and nurses adjusted visit frequencies on the basis of participants' needs.[23] Home visit services included education and counseling focused on pregnancy planning, contraceptive advice, STD prevention and cervical cancer screening. In addition, nurses supplied condoms when requested, and made referrals to community primary care and family planning clinics to prescribe, dispense and administer contraceptives.

Following clinical protocols approved by each local health department's medical director, the nurses offered participants in the enhanced care group the additional opportunity to receive no-cost, home-dispensed, hormonal contraceptives—combined or progestin-only pills, the ring, the patch or the depot medroxyprogesterone acetate injectable. (For women currently breast-feeding, nurses offered only progestin-only pills and the injectable.) Nurses provided education and counseling on methods, and obtained written consent using forms similar to those used in clinic settings. During home visits at 1–2 years after delivery, nurses continued to counsel participants while dispensing additional contraceptive supplies (up to a 12-month supply) or administering injections. By phone or through subsequent visits, nurses supported continuation of the hormonal methods by addressing participant concerns, troubleshooting common side effects or adverse reactions, and providing refills or alternative hormonal methods. In addition, nurses encouraged participants to take advantage of available community family planning services through primary care and family planning providers.

We originally intended to follow participants for the entire time they were in the NFP program, until they were 24 months postpartum; however, to increase our sample size, we enrolled participants beyond the originally planned recruitment window, which required us to shorten the follow-up period for some participants. Therefore, after

random assignment, we followed participants for 12–24 months postpartum, depending on when they enrolled in the study.

Data Collection

Research staff masked to participant treatment assignment conducted phone surveys with participants at enrollment and approximately every three months postpartum for 12–24 months; participants received a $10 gift card for completing certain surveys and a $25 gift card for others. The window for surveys began two weeks prior to each three-month interval and spanned up to six weeks after, for a total of up to eight weeks. When asking questions, interviewers (who knew the precise date of the previous survey) referenced the time period since the previous survey. If a participant had missed the immediately previous survey, then the interviewer asked the participant about the previous five-month period; we chose five months because it was the maximum time between two completed surveys (three months plus the eight-week survey window). In our analysis, we standardized survey intervals to 90 days.

The survey used closed-ended questions about contraceptive use, gaps in effective contraceptive use and repeat pregnancy, which were adapted from the National Survey of Family Growth[24] and from an earlier study.[25] Participants were asked about contraceptives used since the previous survey, the dates of effective contraceptive use and any subsequent pregnancies, including the expected date of delivery and whether they were still pregnant; we considered effective contraceptives to include the pill, ring, patch and injectable, as well as long-acting reversible contraceptive (LARC) methods, which are the IUD and implant. Survey questions addressed factors that could influence the timing of a subsequent pregnancy, such as pregnancy intention and desired timing of a next pregnancy. Specifically, participants were asked, "Looking to the future, do you intend to have another baby"; response options were "yes," "no" and "not sure/don't know." Those who answered "yes" or "not sure/don't know" were asked, "How soon, if at all, would you like to get pregnant again"; response options were "within six months," "within one year," "within 1–2 years," "within 2–5 years," "more than five years," "never" and "don't know." The NFP Clinical Information System, which stores data nurses collect from NFP clients, provided demographic and health behavior data, including information on breast-feeding and relationship status. In addition, for both usual and enhanced care participants, data were collected on the duration of home visits, but not on the time nurses spent on family planning.

Analysis

Our primary outcomes were gaps in effective contraceptive use and time to first subsequent pregnancy. We measured gaps as the number of days a participant was not using an effective contraceptive method and was not already pregnant. Each participant's total gap days were calculated using data from the postpartum surveys. We calculated time until first subsequent pregnancy by the number of days that elapsed between the birth date of a participant's first child and the approximate date of her next conception. The date of conception was estimated by subtracting 38 weeks from the women's self-reported expected due date. In the seven cases where expected due dates were not the same across surveys, we chose the midpoint of the expected due dates. For the 11 individuals for whom an expected due date was missing, we set the conception date as the middle of the month in which the pregnancy started, as provided in the NFP data set. In the 17 cases in which data on the start month were not available, we imputed the conception date by first matching these individuals with other participants. We selected matched participants if they had a reported due date and thus had a calculated date of conception, they reported being pregnant for the first time in the same survey as the individual with missing data, and all prior responses for the match were either no or a missed survey. We averaged the difference between the survey date and the calculated date of conception for all matched subjects and subtracted it from the survey date of each individual with an unknown due date to impute a conception date.

We powered our study to determine whether participants in the intervention group experienced fewer gap days in effective contraceptive use than those in the control group. In a national sample, approximately 30% of women at risk of unintended pregnancy experienced at least a one-month gap in contraceptive use over a one-year period.[11] On the basis of these national data and the fact that women who were served at the five study sites had low educational attainment and income, characteristics associated with increased risk of gaps in contraceptive use, we anticipated that 40% of women in the usual care group would experience a gap of one or more months in effective contraceptive use during the study period. We powered our study to detect a 50% reduction in gaps in effective contraceptive use in the enhanced care group. Therefore, we anticipated that 20% of the women in the enhanced care group would experience a gap of one or more months during the study. At an alpha of .05 with 80% power, we needed 91 participants in each group.

An intent-to-treat approach was used to compare gaps in effective contraceptive use and time to first pregnancy between the two study groups. We used two-sample t tests (for continuous variables) and Pearson chi-square tests (for categorical variables) to compare the study groups on baseline characteristics: age, race and ethnicity, highest educational level completed, annual household income, employment, birth control used at conception of the index child, and intendedness and timing of a subsequent pregnancy. We used a Kaplan-Meier survival curve with a log-rank test and Cox proportional hazards model to compare the enhanced and usual care groups on time to subsequent pregnancy.[26,27] Longitudinal Poisson mixed-effects regression models compared intervention conditions on gap rates over the follow-up period. To model the temporal

TABLE 1. Selected baseline characteristics of a sample of low-income clients of a nurse home-visit program, Washington State, 2009–2013

Characteristic	Total (N=337)	Usual care (N=169)	Enhanced care (N=168)
Mean age (SD, range)	19.0 (3.0, 14.3–42.8)	19.2 (3.1, 14.6–42.8)	18.8 (2.8, 14.3–33.6)
Race/ethnicity			
Hispanic	35.6	32.0	39.3
White	30.0	29.0	31.0
Black	15.4	15.4	15.5
Asian/Pacific Islander	6.5	7.7	5.4
American Indian/Alaskan Native	3.9	5.3	2.4
Multiracial	5.0	7.1	3.0
Missing	3.6	3.6	3.6
Educational attainment			
<12th grade	65.6	63.9	67.3
GED	5.9	4.7	7.1
High school	19.6	21.9	17.3
Postsecondary	8.9	9.5	8.3
Employment status			
Employed full-time	4.5	5.3	3.6
Employed part-time	19.6	23.1	16.1
Unemployed	70.6	68.1	73.2
Missing	5.3	3.6	7.1
Annual income			
Dependent on parent/guardian	13.9	11.8	16.1
≤$6,000	24.9	29.6	20.2
$6,001–12,000	13.1	10.7	15.5
$12,001–20,000	15.1	17.2	13.1
≥$20,001	8.3	9.5	7.1
Don't know/missing	24.6	21.3	28.0
Birth control used at conception			
Hormonal	17.5	16.0	19.1
Other	28.8	29.0	28.6
None	53.7	55.0	52.4
Intend to have another baby			
Yes	72.4	72.2	72.6
No	15.1	14.2	16.1
Not sure/don't know	12.5	13.6	11.3
Desired time frame for next pregnancy			
<2 years	7.1	6.5	7.7
2–5 years	39.8	40.2	39.3
>5 years	34.7	34.3	35.1
Don't know	3.3	4.7	1.8
No more children wanted	15.1	14.2	16.1

†All participants in categories other than Hispanic were non-Hispanic. *Notes*: Figures are percentages unless otherwise noted. Significance testing was conducted, and no differences were observed at p<.10. SD=standard deviation. Full-time and part-time employment were defined as 37 or more hours per week and less than 37 hours per week, respectively.

correlation of observations within subjects, we implemented a first-order autoregressive correlation structure (decreasing correlations of each outcome with subsequent measurements of the outcome over time).

Our first calculation of gap days included data on participants' LARC use. Because LARC use was common among both the intervention and the control groups, we performed an additional exploratory analysis of the intervention effect when participants' LARC use was removed from the gap calculation. We repeated the longitudinal Poisson mixed-effects model on this new gap measure, which removed days of LARC use in the numerator and denominator for both treatment arms. In this new model, we included controls for participant characteristics.

We used Stata version 14.0 and SAS version 9.4 to perform all modeling with statistical significance set at 5%. The Oregon Health & Science University Institutional Review Board approved the study protocol.

RESULTS

Sample Characteristics

Of the 728 women eligible to participate in the study, 384 either were not invited or declined to participate. The remaining 344 women were enrolled, but seven did not complete a baseline survey and were not randomized. Thus, 337 participants were randomized—168 into the enhanced care group and 169 into the usual care group. Of these, two from each group failed to complete any survey beyond the baseline and were unavailable for subsequent analyses, which resulted in final sample sizes of 166 for the intervention group and 167 for the control group.

At the time of enrollment, the mean age of study participants was 19 years (Table 1). Thirty-six percent of the participants were Hispanic, 30% white, 15% black, 7% Asian or Pacific Islander, 4% American Indian or Alaskan Native, and 5% multiracial. Sixty-six percent had not completed high school, 71% were unemployed and only 23% reported an annual household income of above $12,000. Fifty-four percent of women reported that they had not been using any contraceptive method at the time they conceived. Seven percent of participants wanted to become pregnant again within two years, 40% within 2–5 years and 35% in more than five years; 15% reported wanting no more children. The intervention and control groups did not differ in terms of baseline characteristics.

Outcomes

Four percent of participants in both groups became pregnant within six months of enrollment (Figure 1); within 12 months of enrollment, the proportions were 11% for the enhanced care group and 9% for the usual care group, and within 18 months, the proportions were 19% and 16%, respectively. Differences were not significant. Among all participants followed for 18 months, 17% experienced a short-interval pregnancy. The hazard ratio comparing the pregnancy risk of the intervention group with that of the control group was 1.29 (95% confidence interval, 0.81–2.05).

Overall, 42% of participants in the intervention group received contraceptives during home visits; the proportion ranged from 33% to 50% across sites. During the three-month period following the first birth, the enhanced care group had, on average, 9.6 fewer gap days in effective contraceptive use than the usual care group (52.6 vs. 62.2—Table 2). No group differences in the number of gap days were found for any other period.

By three months postpartum, 42% of participants in the usual care group and 36% of participants in the enhanced care group were using LARCs; by six months postpartum, the proportions were 50% and 39%, respectively. The difference in the number of days using LARCs was not

significant. In the adjusted analysis that removed LARCs from the model and controlled for sampling bias, the enhanced care group had an average of 14.2 fewer gap days in effective contraceptive use than the usual care group for the first three-month period postpartum (65.0 vs. 79.2) and 15.7 fewer for the second (39.2 vs. 54.9). After six months, the groups no longer differed in the number of gap days.

Finally, we compared the mean time nurses spent during visits with participants by group. Nurses spent significantly less time with women in the enhanced care group than with those in the usual care group (mean, 63.5 minutes vs. 65.8 minutes, p<.05).

DISCUSSION

Our intervention was successful in reaching a population of first-time mothers facing socioeconomic challenges and at risk of a short-interval second pregnancy. While 7% of participants expressed an interest in having another child within two years, historically about one-third of NFP clients nationally become pregnant within two years of their first birth.[18,21]

One of the ways to prevent unintended pregnancy is to improve the use of effective contraceptives. Although the intervention group was covered by effective contraceptive use for a greater number of days than the control group only during the first three months postpartum, these results are still promising. Many participants in our study were adolescents, who are particularly at risk of clinical, social and economic complications of pregnancies beginning within three months postpartum. According to a 2005 study among a sample of teenage first-time mothers, 58% had resumed sexual activity within three months of the birth;[9] the median time to first sexual intercourse was 11 weeks postpartum. In addition, failure to use effective contraceptives postpartum—not the resumption of sexual activity itself—was associated with pregnancy risk factors. Therefore, the researchers suggest that promoting effective contraceptive use postpartum is likely to be more effective than promoting abstinence in preventing short-interval pregnancy among this at-risk population.

Another study—of claims data for more than 117,000 high-risk, low-income women who had given birth within the past 18 months—found that only 41% had received a contraceptive method by 90 days postpartum and that the odds of avoiding a short-interval pregnancy were 1.6 times greater for those who had received a method by 90 days postpartum than for those who had not.[28] Given the high risks associated with repeat unintended pregnancies occurring within three months postpartum, effective contraceptive interventions immediately after childbirth, or at least before the typical six-week postpartum clinical visit, are critical.

Our intervention provided a choice of the pill, the ring, the patch or the injectable during home visits. While these hormonal methods are more effective than barrier methods or withdrawal, they are not as effective as LARCs;[29] however, LARC insertion requires a clinical setting and thus cannot take place during a home visit. Teenagers and other high-risk populations face barriers in obtaining LARCs, such as cost and being less likely than other clients to return for a postpartum visit and to have a health care provider recommend a LARC method.[6,30,31] Certainly, educating providers about the safety, feasibility and benefits of offering immediate postpartum LARC placement could reduce one of these barriers.

Because the prevention of short-interval pregnancies is consistent with the goals of the NFP program, and because LARCs are more effective than other methods, nurses in our study often described the benefits of LARC use to study participants, regardless of their group. The proportion of NFP clients who use an IUD by six months postpartum is 22% nationally and 39% for Washington State;[32] however, for our study sites, the proportion ranged from 35% to 53%. The high level of LARC use among usual care participants shows that our usual care group was already receiving an intervention—specifically, the NFP program—that has consistently reduced the rates of short-interval pregnancies.[18–21] Thus, the usual care condition set a high bar for detecting the added value of the enhanced care

FIGURE 1. Survival curve showing the proportion of study participants who remained nonpregnant after the index birth, by number of days since the birth, according to study group

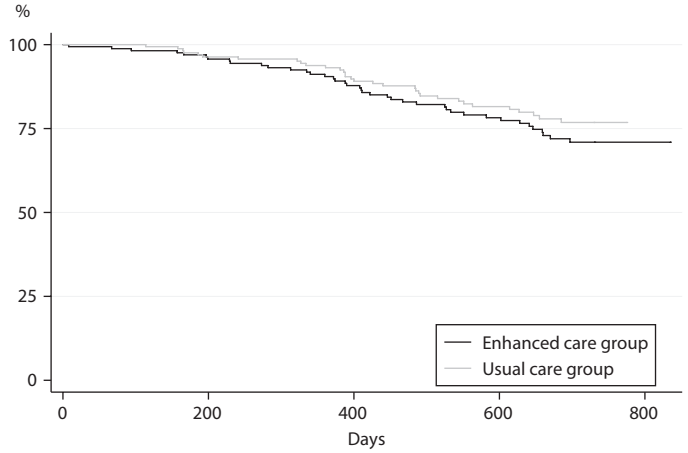

TABLE 2. Mean number of days during which nonpregnant study participants did not use an effective contraceptive method, by number of months since first birth, according to study group

Months since first birth	All methods		LARC use removed	
	Enhanced care	Usual care	Enhanced care	Usual care
0–3	52.6 (48.3–57.3)**	62.2 (58.2–66.6)	65.0 (56.1–75.3)**	79.2 (70.1–89.3)
4–6	20.5 (15.8–26.6)	28.0 (22.6–34.6)	39.2 (30.9–49.7)*	54.9 (45.2–66.5)
7–9	22.6 (17.5–29.2)	27.1 (21.5–34.1)	43.3 (34.2–54.8)	54.4 (45.2–65.5)
10–12	24.4 (19.0–31.3)	29.1 (23.3–36.2)	47.4 (38.0–59.1)	57.9 (48.5–69.2)
13–15	27.3 (21.3–35.0)	33.8 (27.4–41.5)	53.4 (42.9–66.3)	66.2 (56.0–78.3)
16–18	34.8 (28.1–43.1)	31.4 (25.3–39.1)	64.1 (52.5–78.2)	67.4 (56.5–80.4)
19–21	35.5 (28.6–43.9)	35.5 (28.5–44.1)	62.5 (50.7–77.0)	66.2 (55.7–78.8)
22–24	35.5 (28.7–44.0)	36.9 (29.5–46.2)	62.2 (50.5–76.7)	73.2 (61.7–86.8)

*Significantly different from mean number of days for the usual care group at p<.05.**Significantly different from mean number of days for the usual care group at p<.01. *Notes:* Survey intervals were standardized to 90 days. Figures in parentheses are 95% confidence intervals. LARC=long-acting reversible contraceptive.

intervention. Nevertheless, we found that our enhanced care group had more days of effective contraceptive coverage during the first three months postpartum than controls. Additionally, in our study population, only 17% of all participants experienced a short-interval pregnancy within 18 months postpartum. Given the barriers at-risk women face in obtaining LARCs and the frequency with which teenagers resume sexual activity soon after childbirth, our intervention could be effective in preventing pregnancy within three months and perhaps even six months postpartum. Also, nurses were able to implement the intervention without adding visits or time to each visit. In fact, the average length of a visit with an enhanced care participant was two minutes less than that with a usual care participant. Therefore, the only added cost of the intervention was that of the contraceptives themselves.

Limitations

Length of survey intervals and question sensitivity were study limitations that could have led to recall bias. Three additional limitations could have reduced our study's power to detect outcome differences between groups. Because the nurses followed NFP guidelines regarding when they might raise topics such as family planning, they used their judgment in determining when and whether to offer contraceptives. Also, the enhanced care group participants could choose whether to receive a contraceptive method; consequently, only 42% of enhanced care participants actually received a method during home visits, and the proportion ranged from 33% to 50% across sites. In addition, because we did not ask nurses to record whether or how many times they invited each of their clients to participate, we cannot describe the characteristics of the 384 women who did not participate; although randomization occurred after enrollment, participants' characteristics might have differed from those of nonparticipants.

Although the relatively high level of LARC use was welcome, it reduced the power of our study to estimate the intervention's impact on gaps in effective contraceptive coverage, as well as our ability to determine whether the intervention was effective in reducing subsequent short-interval pregnancies. It is possible that our outcomes would have been significant beyond three months postpartum in communities where providers were less likely to provide LARCs or women were less likely to request them.

Conclusions

Supporting NFP nurses to dispense hormonal contraceptives during home visits appears to be an effective way to improve use of such methods among first-time mothers at risk of short-interval pregnancies within three months postpartum. While provider education may help increase the use of more effective methods immediately after childbirth, postpartum access barriers remain especially acute in communities where providers are unlikely to offer LARCs or where women are unlikely to request them. In these circumstances, home dispensing by nurses could serve as a bridge to improve hormonal contraceptive use until women are able to obtain effective methods from community providers. Although the NFP program is available in hundreds of communities and has been found to have a positive return on investment,[33] it is expensive compared with less-intensive home visiting programs and is not available for all at-risk, first-time mothers. Future studies should address whether supporting NFP nurses—as well as nurses working in less resource-intensive programs—to dispense contraceptives during home visits could be an effective, ongoing family planning intervention in communities where contraceptive care and supplies are not easily accessible.

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