

Original article

Depo Now: Preventing Unintended Pregnancies among Adolescents and Young Adults

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Abstract

Purpose: We compared the immediate administration of DMPA (Depo Now) to the immediate use of short-term hormonal methods that served as a “bridge method” until later DMPA initiation. We examined whether Depo Now, as compared to initiating with a bridge method (pills, transdermal patch, or vaginal ring), resulted in greater DMPA continuation at six months.

Methods: Young women aged 14 to 26 years seeking to use DMPA were randomized (nonblinded) after meeting eligibility criteria to either the Depo Now ($n = 101$) or bridge method ($n = 232$) group. Depo Now subjects received their first injection of DMPA at the conclusion of their first visit provided each was medically suitable and had a negative urine pregnancy test regardless of menstrual cycle day. Those assigned to the bridge method group were allowed to choose their starting contraceptive method and it was provided at the first visit. All subjects were told to return to the clinic in 21 days to repeat the urine pregnancy test, and among those who were assigned to use a bridge method, to receive their first injection of DMPA. All subjects were followed to their third injection, or about 6 months later.

Results: Those randomized to a bridge method were 1.8 (1.1, 2.9) times more likely than Depo Now subjects to return for their 21-day repeat pregnancy test, but only 55% ($n = 125$) of these young women actually received their first DMPA injection. Continuation rates at the third injection were 29.7% ($n = 30$) for those in the Depo Now group and 21.1% ($n = 49$) for those assigned to the bridge method ($p = .09$). Three factors were significantly associated with adherence to the third injection: randomized to Depo Now group, knowing more women who use DMPA, and returning to clinic for the 21-day repeat pregnancy test visit. Finally, 28 pregnancies were diagnosed during the study period, and those in the bridge method group were almost 4.0 (1.2, 13.4) times more likely to be diagnosed with a pregnancy than those in the Depo Now group.

Conclusions: Immediate administration of DMPA is associated with improved adherence to DMPA continuation and fewer pregnancies. © 2007 Society for Adolescent Medicine. All rights reserved.

Keywords: DMPA; Immediate injection; Contraceptive initiation; Quick Start

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Depot medroxyprogesterone acetate (DMPA) is a birth control method that has universal appeal, especially for adolescents [1–4]. It is an injectable progestational agent that offers a highly effective, safe, convenient, reversible and almost user-independent method of contraception [4]. Effective plasma concentration for this birth control method is sustained for at least 14 weeks, and ovulation is suppressed, on average, for 18 weeks [5].

Despite the World Health Organization's (WHO) recommendation that the time of initiation of hormonal contraception need not be restricted to menstruation [6], most clinical protocols as well as product labeling require the adolescent patient return during her next menses to receive her DMPA injection, while using condoms or abstinence from sexual intercourse in the interim [6,7]. Unfortunately, sizable numbers of young women forget their appointment or lose motivation to contracept, resulting in increased risk of unintended pregnancy while waiting to begin DMPA [7,8].

Although there is no evidence that any hormonal contraceptive adversely affects a developing fetus, women are traditionally asked to wait until menses to initiate birth control to avoid such harm [9–11]. Practical problems have resulted from maintaining this conventional approach to initiation: (1) it delays the onset of contraceptive protection and (2) young women may not return to the clinic to receive their DMPA injection because of waning motivation, confusion regarding when to start their contraceptive, or both [7,8]. Thus, it should not be surprising that many adolescent and young adult women inadvertently become pregnant while waiting to receive their first injection because alternative contraceptives, i.e., condoms, foams, spermicides, or sponge are unacceptable or are used inappropriately [7,8,12,13].

An innovative contraceptive initiation protocol, called *Quick Start*, has received increased research attention [13–15]. Using this protocol, a woman initiates her hormonal contraception at the conclusion of her initial family planning visit (after a negative urine pregnancy test) regardless of where she is in her menstrual cycle. For example, a young woman who chooses birth control pills takes her first pill under direct observation of the provider and continues daily use without waiting for her next menses. She does not have to return to the clinic or remember when to begin taking her birth control pills, and effective contraception is initiated at the first visit. Multivariate analysis controlling for confounding variables found that women using birth control pills who were started with the *Quick Start* method were more likely to continue using their oral contraceptives [13].

An alternative *Quick Start* protocol also could be employed for those seeking injectable contraceptives. Building on prior experience with adult women [14], an adolescent female seeking DMPA could be safely prescribed a bridge method at her initial visit, and then schedule a second appointment three weeks later to receive her first injection. Along with using condoms or abstaining during the first week of hormone use, the adolescent is effectively protected against unintended pregnancy; her menses will occur predictably at the time of her scheduled appointment due to the regulating properties of these birth control methods. More in line with the intent of the *Quick Start* approach (i.e., receiving the desired contraceptive at the first visit), the adolescent could receive her first injection of DMPA at the conclusion of her initial family planning visit. The purpose

of this study was to determine the effectiveness of this *Quick Start* approach to DMPA initiation vs. the bridge method.

We examined whether either strategy was associated with increased continuation of DMPA, decreased number of pregnancies, and increased return to a 21-day repeat pregnancy test visit. We hypothesized that there would be (1) no difference in return rates at the 21-day repeat pregnancy test visit, (2) a decreased number of pregnancies among the Depo Now subjects as compared with those assigned to the bridge method, and (3) at the 6-month visit, greater continuation rates (receiving a third DMPA injection) seen among those randomized to Depo Now as compared with the bridge method.

Methods

Sexually active adolescent and young adult women aged 14 to 26 years who presented for care at a Family Planning Clinic operated in northern Manhattan and who were interested in using DMPA were eligible to participate in this prospective, nonblinded, randomized trial. Each young woman needed to agree to being randomized to one of two different initiation methods for DMPA (Depo Now or bridge method) and complete three additional clinic visits, each including a confidential structured interview. We excluded a potential subject if she was (1) currently menstruating; (2) currently pregnant or breastfeeding; (3) had a medical contraindication to hormonal contraception; (4) currently using DMPA (within 14 weeks of last injection); (5) consistently used birth control pills, OrthoEvra™, NuvaRing™, or another prescription method of contraceptive in the last 30 days; or (6) had a current or past history of serious mental illness. Before study enrollment, using a random number table, 350 sheets were developed that assigned each subject to either the Depo Now or the bridge method and assigned a study number to that patient. All sheets were enclosed in sealed envelopes and maintained by the research assistant.

Recruitment occurred daily beginning in April 2004 and extended to August 31, 2005; 349 young women screened after their clinic registration were deemed eligible. Based on .8 power to detect a significant difference ($p = .05$, two-sided) between the two groups where we believed the difference in continuation rates would be 17% or higher, a total of 330 patients were required with 90 in the Depo Now group and 240 in the bridge group. Time constraints led 17 eligible subjects (5%) to refuse participation. Thus, a total of 333 young women were randomly assigned to either the Depo Now ($n = 101$) or a bridge method group ($n = 232$).

Using an IRB-approved protocol, a bilingual research assistant asked interested young women if they would like to participate in a study of how women initiated and used DMPA. After obtaining informed consent, the research assistant selected from the batch the next sealed envelope,

which indicated the patient's group assignment and subject number. Each patient then completed a baseline structured interview conducted by the research assistant (in English or Spanish) designed to assess both demographic (age, race/ethnicity, education, marital status) and reproductive characteristics (number of sexual partners, parity, gravidity, relationship with partner) as well as past contraceptive practices (use and satisfaction with birth control pills, DMPA, transdermal patch, or the vaginal ring). The patient then received contraceptive counseling, a comprehensive medical interview, a urine pregnancy test, and, if indicated, a physical examination by a licensed health care professional to determine whether any contraindications to the use of DMPA existed. In addition, if a patient reported any episode of unprotected sex within the previous 72 hours, she received emergency contraception per clinic protocol. All patients assigned to a bridge method were asked which contraceptive method they wished to start and received a 21-day supply of this birth control method. Before leaving the clinic, patients received an appointment to return to the clinic in about three weeks (21–28 days) to have another urine pregnancy test, and for all assigned to the bridge method group, to receive their first injection of DMPA.

We chose a 21-day follow-up interval to assure that all pregnancies would be detected via a high sensitivity urine pregnancy test. We wished to diagnosis both the pregnancies that started immediately before initiation of the bridge method as well as any that may have begun during the first week of use because the patient did not use a backup method, i.e., condoms or abstain as instructed. The research assistant conducted a structured interview to assess initiation satisfaction and adherence with their contraceptive method. Among those assigned to the bridge method group, there was a brief medical encounter during which DMPA was administered.

Additional follow-up study visits occurred at 3 and 6 months after the patient received her first DMPA injection. Relative to when each received their injections, women assigned to the bridge method group were approximately three weeks behind those randomized to the Depo Now group. At each follow-up visit, patients received their DMPA injection, if desired. The research assistant conducted a structured interview to elicit each patient's experiences and satisfaction with DMPA, information about a current partner and his feelings about DMPA use, intentions to not become pregnant, and how easy or difficult it was to return to the clinic for the injection.

Study participants were directed to contact the research assistant or medical provider if they chose to stop using DMPA. Three other conditions also qualified as discontinuation: (1) a pregnancy was detected, (2) a patient returned for her injection > 98 days from her prior injection and, among those assigned to the bridge condition, (3) a patient failed to return for the 21-day repeat pregnancy test visit where the first DMPA injection would have been given. A

pregnancy diagnosis was confirmed by clinic staff using a urine test conducted at the clinic. Each was reviewed by a single clinician (C.W.) to determine the most likely date of conception based upon medical history and a sonogram taken at the time of diagnosis.

For those categorized as "discontinued," structured interviews continued, by phone or face-to-face, using the same schedule as would have occurred should the subject have continued using DMPA. This interview concentrated on sexual behaviors, current contraceptive practices, and reasons for cessation. Each participant received \$10.00 as compensation for her effort at each study visit, and received \$25.00 at the end if she had attended all other visits.

Statistical plan and analysis

All data were manually entered into an automated database, with 20% of records evaluated for accuracy. To ensure that randomization had not resulted in bias between the two start conditions, chi-square tests were conducted on relevant demographic and reproductive health characteristics. Chi-square tests were conducted to test proposed hypotheses using an intention-to-treat analytic plan. Because contraceptive continuation is affected by many factors, a logistic regression analysis using simultaneous entry was used to identify baseline factors, including returning to clinic for the repeat pregnancy test at 21 days, associated with continuing to use DMPA at the 6-month visit. Variables significant at the $p < .10$ level were considered for entry into the logistic regression, and the colinearity among significant variables was assessed. We included potential interactions in all models, but none were significant. Multivariate odds ratios with associated 95% confidence intervals were reported. All data were analyzed using SPSS 13.0 (SPSS Inc., Chicago, IL).

Results

Of the 333 enrolled young women, 8% ($n = 27$) only completed the first visit (baseline). In contrast, at least two-thirds of the sample made three of the four required study visits (Figure 1). No differences were detected between those who only completed a baseline visit with those who completed three or more visits. Further, no adverse events were reported in either group.

The sample was largely comprised of Latina young women with about half of the structured interviews conducted in Spanish. Approximately 18% ($n = 59$) reported current tobacco use and 22% ($n = 73$) reported that they had felt sad or blue for two consecutive weeks in the last 12 months. With regard to health care utilization, 35% ($n = 116$) reported that the baseline visit was their first use of this clinic and 27% ($n = 90$) reported having a regular provider who took care of their general medical concerns. Of interest, 13% ($n = 43$) of these young women reported that they experienced "pressure" to use DMPA from their provider.

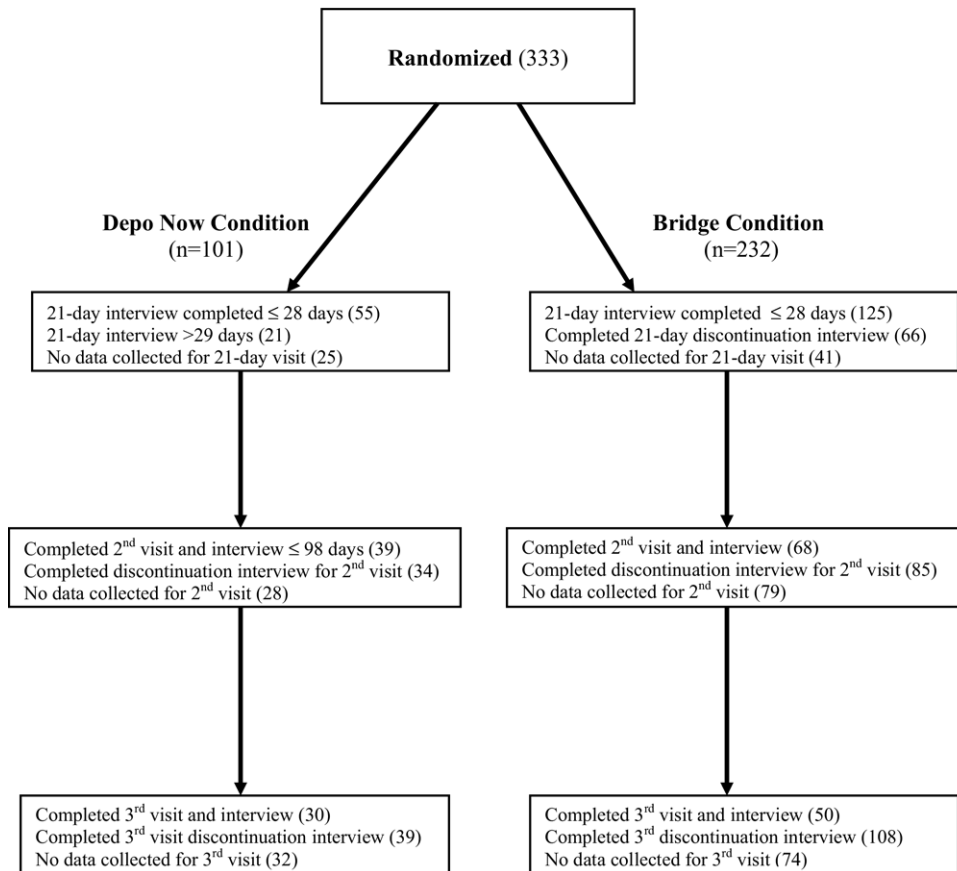


Figure 1. Study and follow-up contact.

In addition to these sample characteristics, no other differences were detected between groups on any baseline demographic or reproductive behaviors, confirming that randomization was effective in producing equal groups (Table 1).

Among those randomized to the bridge method group, 95 women chose to use oral contraceptives, 90 the transdermal patch, and 38 chose to use the vaginal ring. A comparison of these women on baseline demographic and reproductive characteristics suggested only one difference: those who chose to use the vaginal ring were significantly more likely to report having used the vaginal ring in the recent past as compared with those who chose the pill or the transdermal patch.

Many subjects missed their scheduled 21-day repeat pregnancy test visit. We found those young women who were randomized to the bridge method group were 1.5 (1.09, 2.07) times more likely to return for this visit than those who received an immediate injection of DMPA (69% vs. 55%, respectively, $p < .014$). However, only 53% ($n = 122$) of those assigned to use a bridge method chose to receive their first DMPA injection. Among those in the bridge method group who returned for their pregnancy test visit ($n = 159$), 23% ($n = 37$) did not receive their DMPA. Of these, 17 remained on their bridging method, five were

diagnosed with a pregnancy, and the remainder had discontinued using their chosen method requiring a contraceptive restart.

Continuation rates for DMPA at each follow-up visit are presented in Figure 2. Contrary to our hypothesis, no significant differences were observed between groups on continuation rates at the 6-month visit (30% vs. 21%, $p = .09$).

Owing to the many factors affecting contraceptive adherence such as parity, marital status, and past contraceptive practices, a logistic regression analysis was conducted to determine what factors at baseline, including initiation methodology contributed to DMPA continuation. We found that three factors were associated with continuation at this 6-month visit: receiving an immediate injection of DMPA at the first visit, increasing numbers of women known to be using DMPA by the patient, and returning to the clinic for the 21-day pregnancy test visit (Table 2).

With regard to contraceptive satisfaction at each visit, we only detected one significant difference between groups. Those patients who received an immediate DMPA injection were significantly more likely at the 21-day return visit to report being “very satisfied” with their contraceptive method as compared with those assigned to use a bridge method of their choice (78% vs. 39%, $p < .001$).

Table 1
Selected demographic, reproductive, and health utilization characteristics stratified by group assignment

	Depo Now (n = 101) % (n)	Bridge (n = 232) % (n)
Demographic		
Age (years)		
14–17	19 (19)	19 (44)
18–21	43 (43)	42 (97)
22+	39 (39)	39 (91)
Race/ethnicity		
Latina	95 (96)	91 (210)
African American	4 (4)	7 (17)
Other	1 (1)	2 (5)
Enrolled in school	43 (42)	47 (109)
Married/living with male partner	31 (31)	23 (54)
Not employed	60 (61)	63 (146)
Born in United States	40 (38)	46 (101)
Interview conducted in Spanish	50 (50)	60 (140)
Reproductive		
Current sexual partner	94 (95)	96 (222)
Only 1 partner in last year	61 (60)	57 (131)
Gravidity (≥ 1)	68 (67)	65 (149)
Age at menarche (mean, SD)	12.3 (1.7)	12.6 (1.8)
Age at first coitus (mean, SD)	16.2 (2.1)	15.9 (2.0)
Past use of		
ECP	33 (33)	33 (77)
OCPs	58 (58)	55 (127)
DMPA	55 (55)	57 (133)
OrthoEvra™	34 (34)	29 (67)
NuvaRing™	7 (7)	5 (12)
Condom use at last coitus	31 (30)	29 (30)
Told partner planned to use DMPA	80 (81)	78 (179)
No. of women known to use DMPA (mean, SD)	2.95 (3.83)	2.88 (3.97)
How important to NOT become pregnant		
Very	82 (83)	86 (199)
Important	6 (6)	7 (16)
Somewhat	4 (4)	4 (10)
Not important at all	8 (8)	3 (6)

ECP = emergency contraceptive pills; OCP = oral contraceptive pills; DMPA = Depot medroxyprogesterone acetate.

With regard to satisfaction at the 3-month and 6-month visits, 61% of the Depo Now subjects reported being “very satisfied” at the 3-month visit as compared with 75% of those initially assigned to a bridge method that were now using DMPA. Most especially, at the 6-month visit, 82% of those who received an immediate injection reported being very satisfied, as compared with 69% of those who were initially assigned to the bridge method.

We also inquired as to whether their experiences were better, the same, or worse than expected at the 3- and 6-month visits. At the 6-month visit, a greater number of women assigned to the immediate injection condition rated their experiences with DMPA as better than expected as compared with those who were assigned to first use a bridge method (50% vs. 18%, $p < .005$).

During the study period, a total of 28 pregnancies were

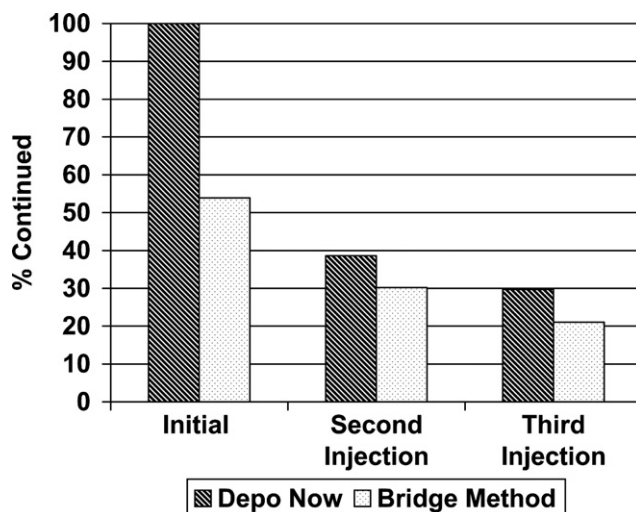


Figure 2. DMPA continuation rates by condition.

diagnosed among subjects in both groups. Three pregnancies were detected among the Depo Now group and 25 among the bridge method group (seven among those using the pill, 13 using the transdermal patch, and five using the vaginal ring). In fact, those assigned to the bridge method group were 3.95 (1.16, 13.38) times more likely to be diagnosed with a pregnancy than those who were assigned to the Depo Now group. All known pregnancies diagnosed in the Depo Now group were identified at the 21-day return visit. Each pregnancy was terminated, one spontaneously. These three subjects were categorized as “discontinued,” but continued using DMPA and received their second and third injections without interruption. Five pregnancies were diagnosed at the 21-day visit among those assigned to the bridge method group. Three of these women terminated their pregnancy, one chose to continue her pregnancy, and one subject relocated back to the Dominican Republic. Among those who terminated their pregnancy, two initiated DMPA and continued to use it uninterrupted throughout the study period, and the remaining subjects never returned to our clinic.

Table 2
Adjusted odds ratios (AOR) and 95% confidence interval of factors associated with DMPA continuation at 6 months*

Variable	AOR	95% CI
Depo Now condition	2.23	1.18–4.21
No. of women known to be using DMPA (per person ↑)	1.07	1.01–1.14
Returned for pregnancy test visit	6.41	2.77–14.8

ECP = emergency contraceptive pills; OCP = oral contraceptive pills; DMPA = Depot medroxyprogesterone acetate.

* Controlling for age; language; marital status; past use of DMPA, OCPs, OrthoEvra, NuvaRing and ECP; parity; reported provider pressure to use DMPA; importance to not become pregnant; telling partner planned use of DMPA; partner’s feelings about DMPA use; and all variables listed.

Discussion

These data suggest that using a *Quick Start* initiation strategy with DMPA among adolescent and young adult women contributes to two important contraceptive outcomes for this population. First, method continuation is enhanced. Those assigned to receive an immediate injection were significantly more likely to receive a third injection as compared with those assigned to a bridge method. Second, significantly fewer pregnancies were diagnosed during the study period among those who received DMPA at their baseline visit. Despite enrollment in this randomized trial being contingent upon participants' desire to not become pregnant, 10% ($n = 23$) of those assigned to the bridge method group became pregnant because they discontinued or did not effectively use their contraceptive method. None of those assigned to the Depo Now group became pregnant after the 21-day repeat pregnancy test visit.

The chief clinical concern with the immediate injection of DMPA outside of cycle day 1 to 5 is that a pregnancy diagnosis may be delayed. In this and previous studies [12–15], about 3% of patients were found to be pregnant after their DMPA injection. These data support the need for follow-up pregnancy testing to preclude delayed diagnosis. This 21-day follow-up visit was necessary to assure that all early pregnancies would be detected, those that started immediately before enrollment as well as any that may have begun during the first week of contraceptive use. Contrary to our hypothesis, we found that young women using a bridge method were almost twice as likely as the Depo Now group to return for this visit. In fact, only about half of those assigned to Depo Now returned (which is not surprising as they had received 3 months of contraceptive coverage).

Clinical concerns about the failure of a urine pregnancy test to detect a window pregnancy and the need to return for a follow-up visit must be discussed with each patient and include information about the possible, but unproven [11], effects of DMPA on the developing fetus. The difficulties we experienced having women return for this 21-day visit are not unique. Prior research among adult patients found that the use of routine phone calls for clinic-based pregnancy tests requires many reminders and is impractical for most settings [14,15].

Clearly, adolescents who report recent unprotected intercourse at the time of their clinic visit are of greatest concern. Emergency contraception (EC) must be available and administered, but as our data indicate, EC alone is not sufficient. Patient education is critical. To further ensure follow-up testing, patients could be asked to return to the clinic or given a home pregnancy test with instructions. This approach for the high-risk patient requires some additional, yet manageable, safeguards, including further provider contact by phone.

Although young women assigned to the bridge method expressed a desire to start DMPA at their initial visit, only

slightly more than half of them went on to receive their first injection. Ohlemeyer [7] conducted a retrospective chart review of patients who arrived at the clinic with the desire to begin DMPA but were asked to return during menses. She found that the average length of return was approximately three months when a conventional DMPA start was used. The number of young women in this group who returned and actually starting using DMPA was not expected given our prior work where 55% of adult women initiated DMPA using a bridge method [14,15]. These data highlight that motivation to use contraception, including DMPA, does diminish after the family planning visit.

Method satisfaction is one component of contraceptive adherence [15]. At the 21-day visit, we found that those who received an immediate injection of DMPA were significantly more likely to endorse the highest ratings of satisfaction when compared with those in the bridge group. This finding was anticipated and most likely due to fact that the Depo Now group received their method of choice at the first visit and did not have to “wait” to obtain DMPA for an additional three weeks. What was unexpected was that the highest satisfaction ratings at the second injection visit were more likely to be reported by the bridge method group, but then reversed at the third injection visit—once again favoring the Depo Now group. Because the temporal elements of each group were the same, it is difficult to speculate what the mechanism is for these differences. Regardless, only 24% of our entire sample received a third DMPA injection. This rate is lower than prior reports. Given the effectiveness of this method relative to user requirements and the high rates of user satisfaction at the 3- and 6-month follow-up, this is particularly disappointing. One-year continuation rates have been reported to be between 32% and 45% among nonparenting adolescent samples [16,17], whereas 6-month reported rates in nonpostpartum adolescent samples range between 63% and 70% [17,18]. As expected, among those who discontinued, the most frequently reported side effects leading to their discontinuation were irregular menstrual bleeding, weight gain, and breaking up with their partners. Each of these is consistent with prior reports [4,16–18].

Certain limitations require comments. First, our sample was primarily urban Latina and more than half of these women were born outside of the United States. The return and continuation rates using DMPA may be different among younger women, those of varying racial/ethnic backgrounds, and those born within the United States. Secondly, we did not randomize women to a conventional DMPA initiation group. Our current protocol at our facility allows all women seeking DMPA to use a bridge when initiating, and does not require anyone to wait for contraception (i.e., return to clinic during menses). Although it would have been methodologically more rigorous to include a conventional initiation group, we believe that the differences in continuation and

number of pregnancies would be equally discrepant, favoring the use of immediate DMPA injection.

Rates of unintentional pregnancy are high among those adolescents who choose to use hormonal methods of contraception, despite method efficacy [19–23]. Although some of these unintentional pregnancies may occur because of incorrect use or discontinuation, a large number of adolescent and young adult women fail to initiate their chosen method after receiving a prescription from a health care provider [7,24,25]. Initiating DMPA at the first visit is an adolescent-friendly procedure that overcomes many of these obstacles.

Acknowledgments

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