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# Home or office etonogestrel implant insertion after pregnancy: a randomized trial $^{\stackrel{\sim}{\sim}, \stackrel{\sim}{\sim}, \stackrel{\star}{\sim}, \star}$

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#### Abstract

**Objectives:** To evaluate whether home visits for contraceptive implant insertion result in an increase in postpartum uptake compared to clinic insertion and to assess the feasibility of home insertions.

**Study Design:** We randomized women within 10 weeks of a birth or dilation and curettage (D&C) for abortion or miscarriage to home or standard office insertion. The primary outcome was successful insertion of the implant. To achieve 80% power to detect a 40% difference in visit attendance, 20 women were assigned to each group. The secondary outcome was attendance of the 4-week postpartum visit.

Results: From June 2013 through February 2014, we screened 45 women and 40 were randomly assigned to home and office insertion visits. We enrolled 37 postpartum women and 3 women post-D&C. Because of the significant under enrollment of the latter, we chose to report results of only the postpartum women. The results were similar whether we included or excluded post-abortion women. A majority of women desired a home visit for their implant insertion appointment at time of enrollment. Postpartum appointment attendance rates were similar between home and office visits at 53% and 50% (p=1.00), respectively. Home visits resulted in a trend toward increased implant uptake [12/19 (63%) vs 6/18 (33%), p=.10]. Conclusion: Home insertion of the contraceptive implant may be a feasible option. Future studies that examine the feasibility and uptake in

**Implications:** Women reported preference for home insertion visits in this pilot study. We also showed that a greater proportion of women received the etonogestrel implant at a home visit compared to the current standard of care, which may warrant larger studies that would have sufficient power to evaluate smaller differences.

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both postpartum and post-D&C women are warranted.

Keywords: Contraception; Contraceptive implant; Etonogestrel implant; Home visit; Postpartum; Global fee

### 1. Introduction

Unintended pregnancy rates are high in the United States. Initiation of highly effective contraception after an abortion or birth may reduce unintended pregnancy rates. Half of all induced abortions are repeat ones, and in the postpartum population, 21% of women experience a second birth within 24 months of the first birth [1,2]. Short inter-pregnancy intervals are associated with poor maternal and perinatal outcomes [3,4].

The etonogestrel contraceptive implant has a typical use failure rate of less than 1% [5]. Immediate post-abortal or postpartum insertion of the etonogestrel implant has shown promise in the research setting, and many institutions offer implant placement after dilation and curettage (D&C) or delivery in the United States [6–8]. Policies restricting contraceptive services in conjunction with abortion services can hinder immediate post-D&C insertion, requiring an additional visit [9]. Similarly, immediate postpartum implant insertion is effectively unavailable in many US states due to policies that preclude reimbursement during admission for

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delivery or even routine outpatient postpartum care [6,10–12]. While several states have changed these policies, many postpartum women in the United States must schedule a separate insertion visit in order for health care providers to receive reimbursement for this costly medication. Post-abortion insertion remains challenging for several reasons including lack of availability of implant in the outpatient abortion setting due to high up-front cost for clinics and no insurance coverage for the abortion and therefore no coverage for the implant device and insertion [6,13]. In Ohio, postpartum patients required an additional visit for insertion separate from their postpartum office visit and post-D&C patients needed to have the insertion at the postoperative visit [6]. Home visit appointments for implant insertion are a potential solution to reduce barriers associated with childcare, transportation to the clinic, waiting times at clinics and delays in obtaining appointments, key barriers to obtaining contraception found in previous studies [14]. Home visits have been shown to improve several pregnancy outcomes, such as increasing intervals between births and reducing low birth weight [14]. To our knowledge, there have been no studies to evaluate insertion of contraceptive implants at home. Currently, home visits are not offered in our department for any indication. The goal of the study was to evaluate whether offering home visits for implant insertion would result in a 40% increase in postpartum or post-D&C implant uptake and to assess the feasibility of home insertions.

#### 2. Materials and methods

We recruited participants from a publically insured resident clinic population in an urban academic medical center in Cleveland, OH. Women were eligible if they were 18 years of age or over, were pregnant within the last to weeks, were willing to have investigators come to their homes, had running water and a bathroom, and reported having a safe and private location for the procedure. Exclusion criteria included relative contraindications listed in the manufacturer's packaging information. Women were also excluded if they lived greater than 10 miles from the hospital or were homeless.

The University Hospitals Case Medical Center Institutional Review Board approved the study prior to recruitment, and all participants gave written informed consent. We recruited women desiring the implant on postpartum day 1 or 2 during their hospital course. We recruited women at their post-D&C visit if they were ineligible for implant insertion due to unprotected intercourse since their procedure for first-trimester miscarriage or abortion. The study period for each participant was approximately 8 weeks.

We randomized 40 women in blocks of 16, 14 and 10 to home or office insertion visits. We performed randomization using randomization.com and an investigator uninvolved in recruitment created sequentially numbered opaque sealed envelopes. As participants were enrolled, we assigned them the next available study number. Participants completed

consent and baseline questionnaire prior to randomization. Recruitment began June 2013 and ended February 2014 after the desired sample size was reached. The baseline paper questionnaire inquired about contraception history, barriers to contraception and preference for home or office visits. We counseled all participants to avoid intercourse or use another short-term contraception until implant insertion. We offered condoms, progestin-only pill and depot medroxyprogesterone acetate injection as bridge methods of contraception prior to implant insertion [15].

We scheduled a 4-week postpartum appointment and a 6-week home or office visit appointment for all postpartum participants, as reimbursement issues precluded implant insertions and postpartum visits to be completed on the same day. We scheduled a 2-week insertion visit for participants recruited at the postoperative visit after miscarriage or abortion. All participants received appointment cards for all scheduled appointments. As an additional reminder, we called each participant 1 day prior to both the postpartum visit and the scheduled implant visit, regardless of study arm. We recorded attendance to the 4-week postpartum visit.

The implant insertion visit protocol was the same for both groups. We measured blood pressure and performed a urine pregnancy test for each patient. We performed insertions in participants with a negative pregnancy test and no reported unprotected intercourse since delivery or postoperative examination. For women who reported unprotected intercourse within 5 days of the insertion visit, we administered emergency contraception prior to implant insertion. We rescheduled the insertion visit appointment for women with a negative pregnancy test and unprotected intercourse more than five days before the insertion visit, and offered them bridge methods. We considered an implant inserted at the implant insertion visit to be a successful insertion. We completed a questionnaire with participants after the home or office insertion visit asking their preference for appointment type and how long they felt the appointment lasted. We called each participant 2 weeks after insertion to assess for signs of infection. We made two additional attempts to contact participants who did not answer. We asked women who did not receive an implant because they did not present for the implant insertion appointment to complete a questionnaire by telephone. After the postinsertion phone call, study participation was completed.

Home visits were a 1-hour appointment window during daylight hours and conducted by two study investigators. Researchers brought all necessary equipment, including blood pressure monitor, sterile materials for implant insertion, lidocaine for anesthesia and sharps disposal to the participant's home. If participants did not answer the door at their scheduled appointment time, we attempted to contact them via telephone and asked them to reschedule an appointment in clinic for insertion. For office insertion visits, participants received their implant with their regular healthcare provider in clinic.

The primary outcome was successful insertion of the implant. The secondary outcome was participant attendance

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