Hormonal Contraceptive Side Effects Reported by Women Receiving Medication for Opioid Use Disorder and Living in a Rural State

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INTRODUCTION

- The low rate of hormonal contraceptive (~25%) among women receiving medication for opioid use disorder (i.e., methadone or buprenorphine, mOUD) (Black et al., 2012; Fischbein et al., 2018; Smith et al., 2019; Cornford et al., 2015) increases risk of unintended pregnancy.
- mOUD is not a stated contraindication for hormonal contraceptive use (Curtis et al., 2016) among women in this population.
- Contraceptive service providers may have concerns about potential interactions between opioids and the hormones in prescription contraception (Black et al., 2016) which may affect contraceptive counseling.
- Women in nonmetropolitan areas are less likely to receive reproductive healthcare services (ACOG, 2020; 2014). Rural health disparities may exacerbate contraceptive side effects.
- A recent systematic review of the literature did not identify any articles about the safety and tolerability of hormonal contraceptive use among women who use opioids (Ti et al., 2019).

OBJECTIVE

Secondary analysis to evaluate the safety and tolerability of hormonal contraceptive use among a group of reproductive-age women enrolled in a randomized clinical trial focused on increasing effective contraceptive use among women receiving mOUD and at risk of unintended pregnancy.

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METHODS

Parent Trial

I. Sample:
- Women 18 - 44 years old
- Enrolled in mOUD (i.e. receiving methadone or buprenorphine)
- Had heterosexual vaginal intercourse in 3 months prior to study enrollment
- No plans to become pregnant in the next 6 months
- No current use of hormonal contraception
- Medically eligible to use hormonal contraception

II. Contraceptive services provided during the trial:
- Pills, patch, ring, injection, LARCs (IUD and implant) provided at no cost
- All services provided at office co-located with mOUD treatment facility
- 14 visits scheduled during during 176-day intervention
- At each visit, participant prompted about side effects and method satisfaction since last visit

Secondary Analysis
- Data analyzed from participants enrolled in two trial conditions that offered contraceptive services
- Verbatim side effects were assigned standardized terminology using Medical Dictionary for Regulatory Activities (MedDRA) terms, version 23.0, a clinically validated, internationally recognized medical dictionary, by an RN independent of the trial

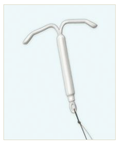
RESULTS

Participants with verified hormonal contraceptive use	50
Participants who switched contraception (n)	14% (7)
Participants who discontinued using contraception (n)	12% (6)
Total number of side effects reported during intervention	273
Serious side effects	0
Most common side effects reported overall:	
Menstrual cycle and uterine bleeding (n)	45% (124)
Complications associated with device (n)	7% (19)
Headaches (n)	7% (18)
Gastrointestinal signs and symptoms (n)	5% (15)

RESULTS Continued

Documented pill users (n=4)
1. Average (SEM) duration of use: 165 (5) days
2. % of users who experienced most common side effects:
   - Menstrual cycle and uterine bleeding: 75%
   - Headaches: 50%

Documented injection users (n=10)
1. Average (SEM) duration of use: 111 (11) days
2. % of users who experienced most common side effects:
   - Menstrual cycle and uterine bleeding: 60%
   - Physical examination and organ system status topics (i.e., weight increased): 40%



Documented IUD users (n=13)
1. Average (SEM) duration of use: 126 (17) days
2. % of users who experienced most common side effects:
   - Menstrual cycle and uterine bleeding: 60%
   - Vulvovaginal disorders: 31%
   Gastrointestinal signs and symptoms: 31%
   Physical examination and organ system status topics: 31%

Documented implant users (n=30)
1. Average (SEM) duration of use: 135 (10) days
2. % of users who experienced most common side effects:
   - Menstrual cycle and uterine bleeding: 70%
   - Complications associated with device: 33%

DISCUSSION

- Preliminary evidence that hormonal contraception is safe and tolerable for women receiving mOUD; no serious side effects or evidence of toxicity reported.
- Majority of side effects related to changes in bleeding patterns; overall, consistent with women in the general population (Hatcher et al., 2018; World Health Organization, 2018; Grunloh et al. 2013).
- Side effects prompted less than 15% of women to change or discontinue hormonal contraceptive use during the 6-month intervention period.
- Future research should examine side effects of hormonal contraceptive use in larger samples of women with OUD to increase the evidence about the safety and tolerability of hormonal contraceptive use in this population.