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Cost-Effectiveness Analysis Of Two Contraceptive Services Interventions For Women Receiving Medication For Opioid Use Disorder And At Risk Of Unintended Pregnancy

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COST-EFFECTIVENESS ANALYSIS OF TWO CONTRACEPTIVE SERVICES INTERVENTIONS FOR WOMEN RECEIVING MEDICATION FOR OPIOID USE DISORDER AND AT RISK OF UNINTENDED PREGNANCY

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Abstract

Background: In the BCII randomized clinical trial, women receiving medication for opioid use disorder (OUD) and at risk of unintended pregnancy who received contraceptive services interventions co-located with an OUD treatment facility had significantly higher rates of prescription contraceptive use than those who received usual care. To support informed decision-making about using these interventions in community-based settings, I conducted a cost-effectiveness analysis to determine the costs and health benefits associated with these interventions.

Methods: I used the standard practice of calculating incremental cost effectiveness ratios (ICERs) between the trial conditions (i.e., usual care, contraceptive services, and contraceptive services + incentives) and derived the estimated societal cost of an unintended pregnancy for women with OUD to assess cost-effectiveness, from a societal perspective.

Results: ICERs (95% confidence intervals) were $15,223 ($8,155-$28,323) for contraceptive services vs. usual care, $13,852 ($10,298-$20,065) for contraceptive services + incentives vs. usual care, and $12,225 ($5,273-$63,725) for contraceptive services + incentives vs. contraceptive services, per unintended pregnancy averted. Based on an estimated unintended pregnancy cost of $85,122, each dollar invested in contraceptive services vs. usual care yields $5.59 in societal cost savings and $6.14 for contraceptive services + incentives vs. usual care. Every dollar spent using incentives with contraceptive services yields $6.96 in societal cost savings vs. contraceptive services with no incentives.

Discussion: The present study is the first rigorous economic evaluation of novel contraceptive services interventions for women with substance use disorders. Both interventions are highly cost-effective strategies to reduce the risk of unintended pregnancy for women in this population compared to usual care and yield substantial societal cost savings, but the most efficacious and cost-effective outcomes were achieved by combining contraceptive services with incentives.

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Introduction

Maternal opioid use and neonatal abstinence syndrome (NAS; also sometimes referred to as neonatal opioid withdrawal syndrome) have increased more than 4-fold in the United States during the last 20 years (Haight, Ko, Tong, Bohm, & Callaghan, 2018; Winkelman, Villapiano, Kozhimannil, Davis, & Patrick, 2018). NAS is a postnatal opioid withdrawal syndrome in newborns characterized by signs of central nervous system hyperirritability, gastrointestinal dysfunction, respiratory distress, and autonomic dysregulation (Finnegan, Connaughton, Kron, & Emich, 1975; McQueen & Murphy-Oikonen, 2016) that can result in morbidity and mortality if not monitored and treated. This monitoring and treatment lead to extended hospitalization after delivery, averaging nearly 16 days (Strahan, Guy, Bohm, Frey, & Ko, 2019). The increased prevalence of NAS combined with extended hospitalization has driven the average treatment costs to more than $22,000 per newborn, with 83% of these costs covered by Medicaid (Strahan et al., 2019).

Beyond immediate health consequences, newborns diagnosed with NAS are also at increased risk of adverse developmental outcomes later in childhood (Beckwith & Burke, 2015; Hall, McAllister, & Wexelblatt, 2019; Larson et al., 2019; Lee, Pritchard, Austin, Henderson, & Woodward, 2020; Yeoh et al., 2019). More specifically, these children are more likely to require early intervention and/or educational support services in school, increasing NAS-related costs even further (Fill et al., 2018; Morgan & Wang, 2019; Peacock-Chambers et al., 2019). It has been estimated that a child previously diagnosed with NAS that requires special education services has an additional education cost of over $15,000 annually (Morgan & Wang, 2019).

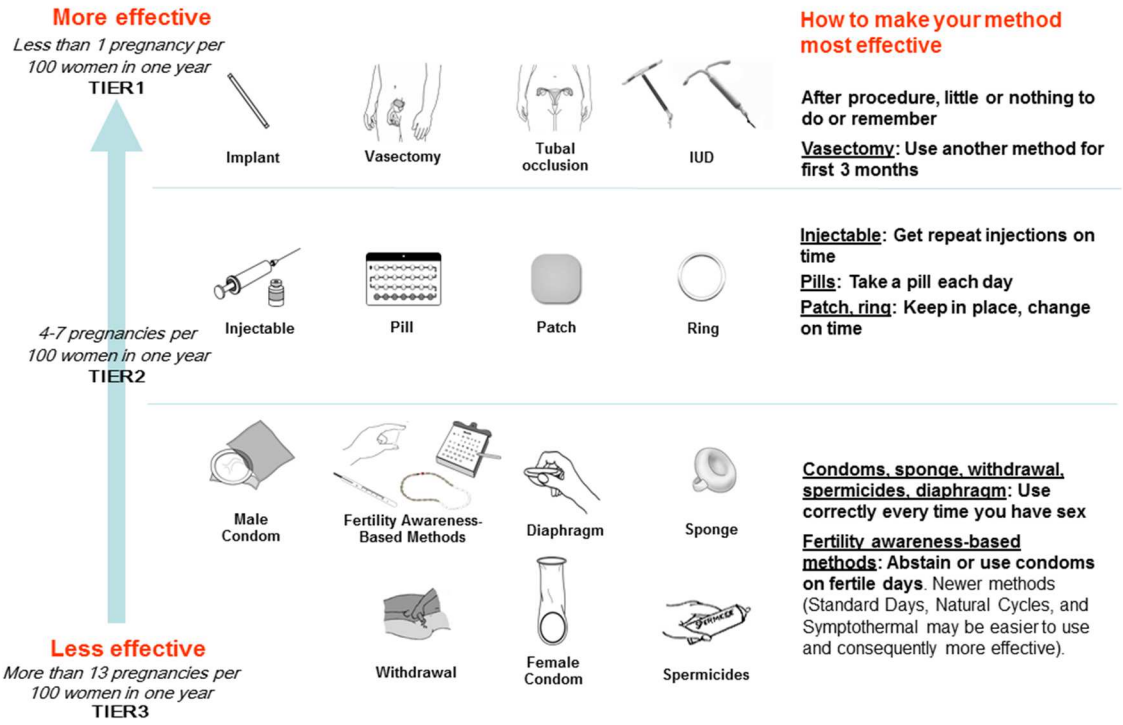
What is striking about these costs is that a significant portion could be avoided because 80% of women with opioid use disorder (OUD) report their pregnancies are unintended (Heil et al., 2011); this rate persists even among women who are receiving medication treatment for their OUD (i.e., buprenorphine or methadone, mOUD)(Black & Day, 2016; Fischbein et al., 2018; Meschke, McNeely, Brown, & Prather, 2018). In response, the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) with the support of the American College of Obstetricians and Gynecologists (ACOG) have issued statements calling for increased efforts to reduce unintended pregnancy among women with OUD as part of efforts to reduce the distressing and costly consequences of opioid use during pregnancy (Ko et al., 2017; Patrick & Schiff, 2017).

1. Contraception

Use of contraception is the most common way that women reduce their risk of unintended pregnancy, although the amount of risk reduction varies by method (Centers for Disease Control and Prevention: National Center for Chronic Disease Prevention and Health Promotion. Division of Reproductive Health, 2013). For reference, approximately 50% of women who are sexually active but not using a contraceptive method over a 12-month period will experience an unintended pregnancy (Vaughan, Trussell, Kost, Singh, & Jones, 2008). While female and male sterilization (i.e., tubal occlusion and vasectomy) reduces the risk of unintended pregnancy to <1% (Figure 1, Tier 1), these methods are permanent and rarely reversible. The most effective reversible contraceptive methods areimplants and intrauterine devices (IUDs; Figure 1, Tier 1), often collectively referred to

as long-acting reversible contraception (LARCs) because they are effective for a minimum of 3 years and fertility is rapidly restored upon removal. Their <1% failure rate is due, in

Figure 1. *Contraceptive Method Effectiveness*



Note. Reprinted from Efficacy, Safety, and Personal Considerations. In: R.A. Hatcher, A.L. Nelson, J. Trussell, et al. (eds.) Contraceptive Technology. 21st ed. Ayer Company Publishers, Inc., 2018.

part, to the fact that after placement they require virtually no effort on the woman's part. Birth control injectables, pills, patch, and ring (Figure 1, Tier 2), sometimes referred to as short-acting reversible contraception (SARCs), are also reversible but have a 4-7% failure rate. To obtain either LARCs or SARCs a woman must have a prescription.

Alternatively, male condoms (Figure 1, Tier 3) are available without a prescription and when used correctly also provide protection from sexually transmitted infections (STIs). However, they are less effective at preventing unintended pregnancy than LARCs or SARCs (i.e., 13% failure rate). Overall, the lower effectiveness of condoms is due to the

fact that they are more prone to user error and imperfect adherence as are other Tier 3 methods (Figure 1), where failure rates can be as high as 21%.

Finally, although not typically described as a method of birth control, the emergency contraception pill (EC), sometimes referred to as Plan B or colloquially as the "morning after pill," is a post-coital method women can use to avoid an unintended pregnancy. EC is available without a prescription and can prevent an unintended pregnancy if a woman uses it within 72 hours of unprotected intercourse (Haeger, Lamme, & Cleland, 2018; Trussell, Cleland, & Schwarz, 2018).

1.1. Prevalence

Although contraception is not contraindicated for women receiving mOUD (Curtis et al., 2016), this group of women use contraception at much lower rates than in the general population (~50% vs. 90%) (Black, Stephens, Haber, & Lintzeris, 2012; Cornford, Close, Bray, Beere, & Mason, 2015; Kavanaugh & Jerman, 2018; Poulton, Parlier, Scott, Fagan, & Shelley, 2015; Terplan, Hand, Hutchinson, Salisbury-Afshar, & Heil, 2015). Even among women receiving mOUD who report method use, rates of LARC use are less than 20% suggesting these women remain at greater risk of unintended pregnancy (Black et al., 2012; Cornford et al., 2015; Fischbein et al., 2018; Harding & Ritchie, 2003).

1.2. Barriers that influence use

Women receiving mOUD face a number of barriers to using contraception. One is that they demonstrate some knowledge deficits with regard to contraceptive methods and some misinformation about side effects (Fischbein et al., 2018; Matusiewicz, Melbostad, & Heil, 2017; Melbostad et al., revision under review; Smith, Morse, & Busby, 2019), both of which may contribute to less optimal decision-making about and poor adherence to

contraception. Contraceptive counseling can address misperceptions about contraception, but women must engage with contraceptive service providers to receive that counseling and women receiving mOUD often report they do not have reliable transportation to access services (Klaman, Turner, Lorvick, & Jones, 2020; MacAfee et al., 2020). Of additional concern, even when women in treatment have access to services, they often experience stigma and discrimination by healthcare providers which further decreases their likelihood of engaging with contraceptive services (Black & Day, 2016; Kramlich, Kronk, Marcellus, Colbert, & Jakub, 2018; MacAfee et al., 2020; Meschke et al., 2018; Poulton et al., 2015).

2. Integration of contraceptive services and substance use disorder treatment

There is increasing advocacy for integrating contraceptive services into substance use disorder (SUD) treatment facilities as one way to reduce many of the barriers to prescription contraceptive use (Black et al., 2012; Heil, Melbostad, & Rey, 2019; Wright, 2019). For many women with OUD who are not pregnant, mOUD treatment may be the only healthcare service they regularly and consistently engage with. Furthermore, many women receiving mOUD report they would like their SUD treatment facility to provide contraceptive services (Black et al., 2012; MacAfee et al., 2020; Meschke et al., 2018; Robinowitz, Muqueeth, Scheibler, Salisbury-Afshar, & Terplan, 2016) and more than half of SUD treatment providers are interested in providing contraception education/counseling and methods to their patients (MacAfee, Harfmann, & Terplan, 2017) although they report that concerns about reimbursement are a significant barrier to providing these services (Klaman, Lorvick, & Jones, 2019; MacAfee et al., 2017). To our knowledge, the literature regarding integration of contraceptive and other family planning services in SUD treatment

facilities is limited to two observational studies and one small experimental trial (Armstrong, Kenen, & Samost, 1991; Elko & Jansson, 2011; Heil et al., 2016).

2.1. Observational studies

2.1.1. Armstrong et al., 1991. This group conducted the first observational study in the late 1980's as part of a CDC-funded demonstration project in 13 methadone maintenance and other SUD treatment sites in Philadelphia, PA. Family planning counselors were available on site at each treatment facility 1-2 days per week for 1 year to provide contraceptive counseling and STI services. A subgroup of treatment facilities (n=4) also offered some prescription contraceptive services (i.e., provision of SARCs). Qualitative results suggested integration of services promoted greater understanding about contraception and helped providers tailor family planning services to the unique needs of women in treatment. In addition, women who engaged with family planning services reported feeling less stigmatized and judged by service providers as a result of integrated services (i.e., their substance use was a given). Overall, this project provided encouraging preliminary information about the feasibility and effects of integrating family planning services into SUD treatment facilities.

2.1.2. Elko and Jansson, 2011. This group examined the effects of integrating family planning services into a multi-disciplinary substance use treatment program in Baltimore, MD (i.e., The Center for Addition and Pregnancy or CAP). Family planning services were offered 1 day per week at CAP. These services included providing education about family planning to women during the antepartum period and then offering no-cost contraception (i.e., pills, injectables, and implants) to interested postpartum women. Over the 4 years of the project, nearly 700 women were seen. On average, around 75% of all

participants requested a method antepartum, approximately 70% of them received a method postpartum, of which 45% were the most effective methods (i.e., tubal ligation, LARCs). In addition, the authors suggested that integration of family planning services with SUD treatment facilities could have economic benefits based on a very crude comparison of their annual program costs to the costs to provide inpatient medical care to opioid-exposed newborns in the immediate postnatal period. To our knowledge, this is the first study to provide any evidence of the potential economic benefits of integrating contraceptive services with SUD treatment.

2.2. Experimental trials

2.2.1. BC pilot. The first experimental trial integrating contraceptive services into an SUD treatment facility was conducted by our group (Heil et al., 2016). We devised a novel intervention informed by World Health Organization (WHO) guidelines and behavioral economic theory to promote prescription contraceptive initiation and continuation among women receiving mOUD who did not plan to become pregnant in the next 6 months. We focused on prescription contraception because these are the most effective methods at preventing unintended pregnancy.

Contraceptive services were guided by WHO's Contraception Decision-Making Tool (World Health Organization, John Hopkins Bloomberg School of Public Health, Center for Communication Programs, 2005) to promote contraception initiation by reducing some of the barriers described in section 1.2 known to interfere with effective use of prescription contraception. For example, contraceptive services were co-located with the women's OUD treatment facility and women were provided structured counseling

about contraception along with the opportunity for immediate initiation of their chosen contraceptive method, including on-site LARC insertions, at no cost.

To promote continuation of contraceptive use, this intervention included a series of 14 brief clinic visits scheduled over a 6-month period to assist women in managing potential side effects and to address any adherence issues, or the provide an opportunity for repeat contraceptive counseling if a method had not yet been initiated. These clinical visits also allowed participants to obtain EC when needed, and/or to discuss method discontinuation if they were no longer interested in using contraception. To promote attendance at these visits, and therefore increase opportunities to initiate, maintain, or switch contraception, participants received financial incentives (i.e., gift cards to local retail establishments) contingent on their attendance.

Using financial incentives is a contingency management (CM) strategy that has consistently been shown to be efficacious in promoting various kinds of health-related behavior change, including substance use and family planning behaviors, among various populations (see reviews by Davis et al., 2016 and Giles, Robalino, McColl, Sniehotta, & Adams, 2014; Heil, Gaalema, & Herrmann, 2012). Informed by behavioral economic theory and the principles of operant conditioning, CM is a psychosocial treatment approach in which individuals can receive financial incentives (e.g., vouchers such as gift cards) that are exchangeable for retail items (Higgins, Silverman, & Heil, 2007). Voucher-based CM was initially developed as a component of treatment for cocaine-dependent individuals (Higgins, Budney, Bickel, & Hughes, 1991). Subsequent research has shown that this model effectively promotes engagement in treatment of substance use and related risks, such as hepatitis C (HCV) and HIV (Kropp, Lewis, & Winhusen, 2017; Lee et al., 2020;

Stitzer et al., 2019). For example, Lee et al., (2020) recently demonstrated that use of a financial incentive program improved appointment attendance for patients receiving care at a HCV treatment program, and was particularly effective among women.

In the BC pilot trial, promoting attendance at follow-up visits for contraceptive services provided opportunities for staff to support participants in addressing any concerns about or experiences of side effects or adherence issues, provide free refills of the chosen contraceptive method, and assist participants with switching methods when indicated. Financial incentives in this intervention were solely contingent on visit attendance and were not related in any way to contraception initiation or continuation.

The value of the gift cards used in the pilot intervention started at $15 and increased by $2.50 for each consecutive visit completed, for total possible earnings of $437.50. An escalating incentive schedule with a reset contingency was used because this type of schedule is more effective than a fixed incentive schedule or an escalating incentive schedule with no reset contingency (Roll & Higgins, 2000).

In our partially randomized pilot trial (N=31) of this intervention (i.e., contraceptive services + incentives), self-reported prescription contraceptive use at the end of the 6-month intervention was compared to that in a usual care control condition in which women received condoms at no charge, a brochure about contraceptive method options, and referral information for local contraceptive service providers (Heil et al., 2016). These offerings are consistent with the American Society of Addiction Medicine's (ASAM) policy recommendation that upon substance use disorder (SUD) treatment intake, reproductive-age women are screened about pregnancy intention in the next 12 months and offered referrals to family planning services, including contraception.

At the end of the 6-month trial period, the intervention condition had significantly higher rates of self-reported prescription contraceptive use than the usual care condition (94% vs. 15%; $p<.05$). While the trial was not powered to look at unintended pregnancy rates, none of the women in the intervention condition had an unintended pregnancy compared to three women (20%) in the usual care condition ($p=.10$). These results provide the first experimental evidence supporting the efficacy of this intervention for increasing prescription contraceptive use among women in OUD treatment and at risk of unintended pregnancy. However, the small sample size, reliance on self-reported contraceptive use, and lack of a post-intervention assessment limited the strength of the conclusions that could be drawn from this study.

2.2.2. BCII. To further test the contraceptive services + incentives intervention, a larger fully randomized controlled trial (hereafter referred to as the BCII trial) was conducted. Three major modifications were made to the original trial design. First, another assessment was added 6 months post-intervention (i.e., 12 months after trial enrollment) to assess whether women continued to use contraception after the 6-month intervention (i.e., either a method started during the intervention or received from a community provider during the follow-up period). Second, prescription contraceptive use was objectively verified at the assessments conducted at the end of the intervention and the end of the follow-up period. The means of verification differed depending on the method: pills were counted; patches were observed; injectables were verified by medical records; implants were palpated; and IUDs and rings were checked during a pelvic exam. Verified prescription contraceptive use at the end of the intervention period was the primary outcome of this trial and the basis of the power calculations. Verified prescription

contraceptive use at the end of the follow-up period (i.e., 12-month assessment) and the incidence of unintended pregnancy during the 12-month trial period were secondary outcomes. Third, this trial also included a second intervention condition that received contraceptive services but did not receive financial incentives for attending the 14 clinic visits, to assess how incentives affected the use of contraceptive services (Heil et al., in preparation).

Women were recruited from an OUD treatment facility in Burlington, VT. Trial inclusion criteria were:

- Women age 18-44 years old
- Enrolled in mOUD treatment
- Pre-menopausal and no history of tubal ligation or hysterectomy
- Heterosexual vaginal sex in the past 3 months
- No plans to become pregnant in the next 6 months
- Medically eligible to use at least 3 different prescription contraceptives methods
- No reported use of pill, patch, ring, IUD, or implant in the past 7 days or of injectables in the past 3 months
- At least 8 weeks postpartum
- Not facing imminent incarceration
- No plans to leave the area in the next 12 months
- English-speaking

One hundred and thirty-eight women were enrolled and randomly assigned to one of the three conditions (i.e., usual care, contraceptive services, or contraceptive services + incentives). Demographic and other baseline characteristics are presented in Table 1.

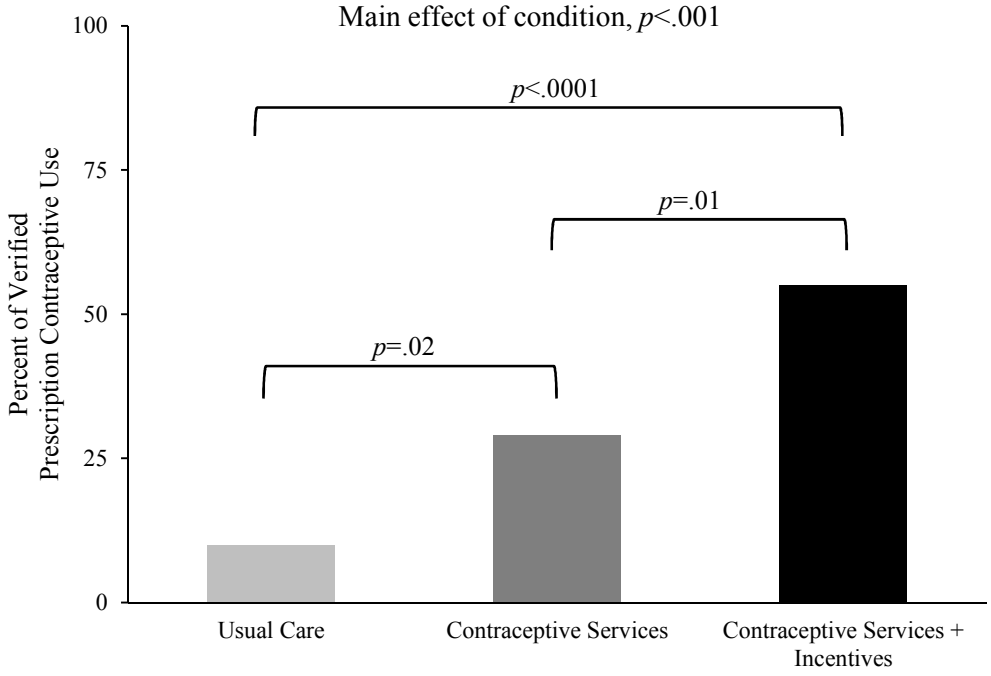
Table 1. *Characteristics of Participants by Condition*

	Usual care (n=48)	Contraceptive services (n=48)	Contraceptive services + incentives (n=42)
Age – mean ± SD, yr.	30.6 ± 6.0	32.0 ± 5.2	31.6 ± 4.9
White race – no. (%)†	43 (90)	45 (94)	40 (95)
Education – mean ± SD, yr.	12.1 ± 1.7	12.0 ± 1.7	12.0 ± 1.6
Never married – no. (%)	36 (75)	29 (62)	31 (74)
Current smoker – no. (%)	42 (88)	43 (90)	38 (90)
Has steady male sexual partner – no. (%)	40 (85)	42 (89)	37 (90)
> 1 unintended pregnancy in lifetime – no. (%)	41 (85)	42 (88)	39 (93)
Intends to start prescription birth control within next week – no. (%)	42 (88)	41 (85)	37 (88)
Prefers a long-acting contraceptive – no. (%)	24 (50)	25 (52)	22 (52)

† Race was reported by the participants.

Women assigned to the contraceptive services + incentives intervention completed almost 3 times more visits than women in the contraceptive services intervention (4.23 vs. 11.21, $p<.001$) indicating that incentives promoted clinic visit attendance and functioned as planned.

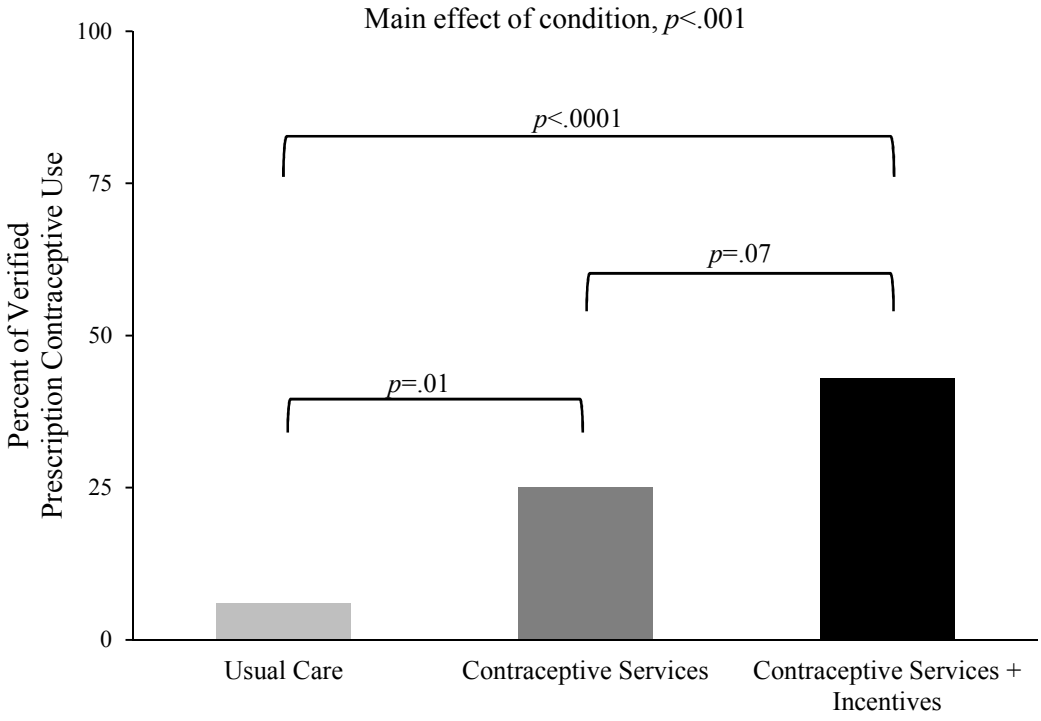
Figure 2. *Verified Prescription Contraceptive Use at the End of the Intervention*



Regarding the primary outcome, verified prescription contraceptive use was significantly higher among participants in the contraceptive services + incentives intervention (55%) as compared to the contraceptive services intervention (29%) and was significantly higher in both of these conditions as compared to the usual care control condition (10%) (Figure 2).

Regarding secondary outcomes, a similar graded result was observed at the 12-month assessment (Figure 3). The comparison of verified use between the contraceptive services + incentives intervention (43%) and the contraceptive services intervention (25%) was not significant and both remained significantly higher compared to the usual care condition (6%).

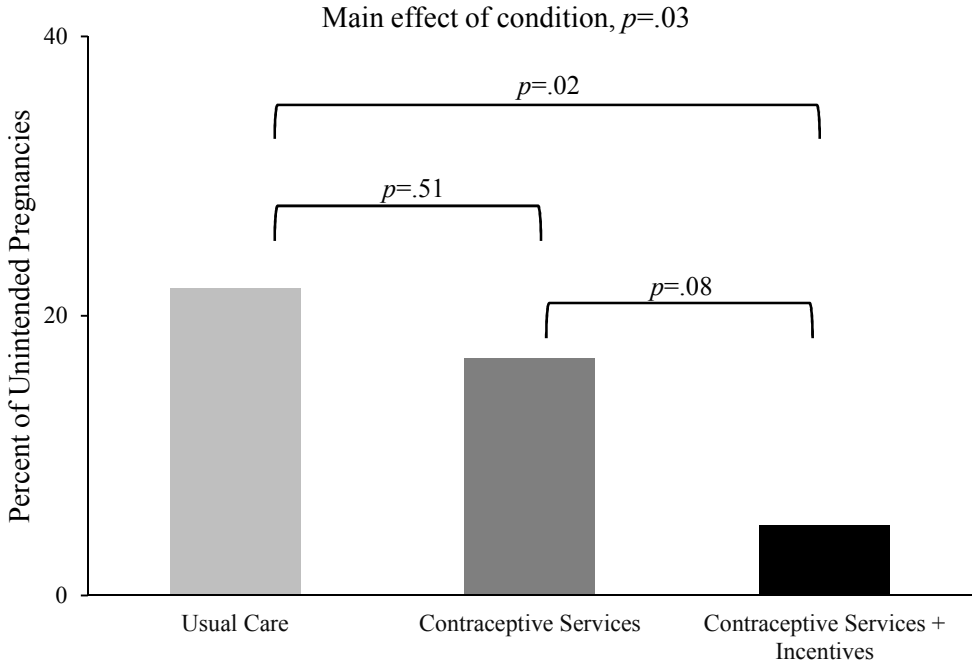
Figure 3. *Verified Prescription Contraception Use at the End of the Follow-Up Period*



There was also a graded effect on the incidence of unintended pregnancy across the 12-month trial period (Figure 4). The percent of unintended pregnancies in the

contraceptive services + incentives intervention (5%) was significantly lower than the usual care condition (22%), not significantly different from the contraceptive services intervention (17%) and the contraceptive services intervention did not differ from the usual care condition.

Figure 4. *Percent of Unintended Pregnancies That Occurred During the 12-Month Trial Period*



3. Cost-effectiveness analysis (CEA)

The BCII trial provided more compelling data on the efficacy of both contraceptive services interventions co-located with an OUD treatment facility to increase contraceptive use and reduce unintended pregnancy among women receiving mOUD. Given these results, implementation in community-based settings has tremendous potential to help reproductive-age women receiving mOUD and not planning to become pregnant achieve their family planning goals. However, there is growing expectation that researchers provide data about the economic value of their interventions in addition to efficacy data to support

informed decision-making about program utilization in community-based settings (Berwick, 2005; Lean, Mann, Hoek, Elliot, & Schofield, 2008). Cost-effectiveness analysis (CEA) is a commonly used type of economic evaluation that examines the implementation costs related to changing a particular health outcome. CEAs have been applied to a diverse set of interventions, including contraceptive and other family planning services (Cleland, Peipert, Westhoff, Spear, & Trussell, 2011; Drummond, Manca, & Sculpher, 2005; Frost, Sonfield, Zolna, & Finer, 2014; Neumann, Sanders, Russell, Siegel, & Ganiats, 2017; Sonfield & Kost, 2015).

3.1. Incremental cost-effectiveness ratios (ICERs)

The results of CEAs are routinely summarized using incremental cost-effectiveness ratios (ICERs). The Method section of this study describes in great detail how to calculate an ICER, but more generally, the purpose of an ICER is to demonstrate how much more it will cost to achieve an additional unit of health (here, a woman averting one unintended pregnancy) given the additional costs to implement an intervention to achieve that additional health unit. ICERs can be expressed as a ratio of the difference in cost between an intervention and some alternative scenario compared to the difference in effectiveness between them. The ICER is then compared to a willingness-to-pay threshold. Willingness-to-pay thresholds are the maximum amount of money that is willing to be paid to achieve a particular health outcome (again, averting the costs of an unintended pregnancy). An ICER that is higher than the cost of the willingness-to-pay threshold is deemed not cost-effective, while an ICER that is lower than this threshold is deemed cost-effective.

4. Study objective

The purpose of this study was to conduct a CEA of the two treatment interventions of the BCII trial to inform decision-making about use of these interventions in community-based settings. To obtain ICERs for both interventions, the incremental costs (e.g., staff time costs, contraceptive method costs) and incremental effects (i.e., reduction in the rate of unintended pregnancy) of each intervention were considered both in relation to the ASAM policy recommendation of offering referrals to contraceptive and other family planning services at SUD treatment intake (i.e., the usual care condition) and also in relation to each other to determine if either of these interventions were a cost-effective alternative to recommended services.

4.1. Hypotheses

1. The ICERs derived from comparing the treatment interventions (i.e., contraceptive services and contraceptive services + incentives) to recommended services (i.e., usual care control) will be less than the estimated cost of an unintended pregnancy among women with OUD, suggesting that both interventions are a cost-effective alternative to ASAM's policy recommendation of offering referrals for contraceptive and other family planning services at SUD treatment intake to reduce the high rate of unintended pregnancy among women receiving mOUD.
2. The ICER derived from comparing the two treatment interventions to each other (i.e., contraceptive services + incentives and contraceptive services) will be less than the estimated cost of an unintended pregnancy among women with OUD,

suggesting that adding financial incentives to contraceptive services is more cost-effective than contraceptive services without incentives.

Method

A CEA of BCII trial was conducted according to the five major steps of a CEA:

1. Identify the purpose and framework of the CEA:
    a) Identify the health problem being addressed;
    b) Define the intervention(s) targeting the problem;
    c) Identify the current services being implemented; and
    d) Choose a trial perspective (i.e., a viewpoint from which to consider costs and benefits of the intervention(s).
2. Determine costs:
    a) Identify service utilization based on trial data.
    b) Calculate the net costs of the intervention(s) services based on trial data.
    c) Calculate the net costs of the current services from secondary non-trial sources.
3. Identify the benefits (i.e., effectiveness or health gains) achieved by the interventions(s) and the current services.
4. Make a decision about the cost-effectiveness of the intervention(s) compared to an alternative (e.g., current services or another intervention):
    a) Estimate the societal (i.e., healthcare and non-healthcare related) costs of the health problem identified in Step 1a);
    b) Produce an ICER by calculating the ratio of the difference in the costs between the intervention and the alternative derived in Step 2 divided by the difference in effectiveness derived in Step 3; and

c) Compare the ICERs calculated in 4b) to the estimated cost of the health problem calculated in 4a). If the ICER is less than the cost of the health problem, the intervention(s) is cost-effective; if the value is more, it is not cost-effective.

5. Estimate the uncertainty of the CEA using sensitivity analyses to determine the generalizability of the results.

To test hypothesis 1, I used these steps, described in more detail in the sections below, to calculate the differences in cost and effectiveness of each of the BCII trial interventions (i.e., contraceptive services and contraceptive services + incentives) compared to the usual care control condition. After I calculated an ICER for each intervention compared to usual care, I compared the ICER to the derived cost of an unintended pregnancy among women with OUD to determine if either intervention was a cost-effective alternative to ASAM's current recommendation of offering referrals for contraceptive and other family planning services at SUD treatment intake. To test hypothesis 2, I calculated an ICER that compared the differences in cost and effectiveness between the two intervention conditions and compared the ICER to the derived cost of an unintended pregnancy among women with OUD to determine if adding financial incentives to contraceptive services was more cost-effective than contraceptive services without incentives.

To support this analysis, I consulted with Dr. Donald Shepard about economic evaluations and CEA methodology. Dr. Shepard is a preeminent health economist at the Schneider Institutes for Health Policy at the Heller School at Brandeis University and director of the Institutes' group on cost and value. He has conducted and published nearly 50 CEAs, including CEAs of intervention trials among patients with SUDs (Petersen et al.,

2011; Shepard, Daley, Neuman, Blaakman, & McKay, 2016; Shepard, Lwin, et al., 2016). I adhered to the US Public Health Service's Second Panel on Cost-Effectiveness in Health and Medicine standardized reporting guidelines to organize and present the results of this CEA (Neumann et al., 2017).

1. Purpose and framework of this CEA

1.1 Health problem being addressed

The targeted health problem of this CEA is the high rate of unintended pregnancy among women receiving mOUD. The average rate of unintended pregnancy for each trial condition was derived from participants' verified contraceptive use during the 12-month trial period combined with the published rate of unintended pregnancy risk associated with each contraceptive method type adjusted for this population.

1.2. Intervention(s) targeting the health problem

This trial had two treatment interventions: contraceptive services and contraceptive services + incentives. As previously described, both interventions included a series of 14 clinic visits scheduled over the 6-month intervention period. At every visit a participant attended, her vital signs (i.e., blood pressure and pulse) were monitored and recorded, a urine pregnancy test was administered, weight and date of last menstrual period were recorded, and she was offered condoms and emergency contraception. The remaining content of each visit was dependent on the type of contraceptive service provided during the visit. For clarity, each clinic visit was categorized as one of five types, depending on the contraceptive service that was provided at the visit:

1. No method

2. SARC (i.e., birth control pills, patch, ring, injectable) initiation
3. LARC (i.e., implant or IUD) initiation
4. SARC maintenance (i.e., a participant is already using a SARC but completes a clinic visit, receives side effect monitoring and method adherence counseling)
5. LARC maintenance (i.e., a participant is already using a LARC but completes a clinic visit, receiving side effect monitoring and method adherence counseling)

If a participant had a LARC removed during a visit, that visit was classified by the type of method she chose to initiate going forward. The number and type of all visits each participant completed were documented.

1.3. Current services being implemented

The current services being implemented were those provided by community-based contraceptive services providers. Based on a review of the data, the types of contraceptive services a community-based practice provided were categorized as one of four types, depending on the contraceptive service that was provided at the visit:

1. SARC initiation
2. LARC initiation
3. LARC removal
4. Tubal ligation

In community-based settings, women usually meet with a family planning service provider to either initiate or discontinue a method, therefore the absence of contraceptive maintenance visits was expected.

The number and type of type of all community-based visits each participant in any of the three conditions completed were documented. It was expected that most community-

based contraceptive services would be provided to participants in the usual care condition, but it was also possible that participants in the two intervention conditions might seek services from community providers, especially once the 6-month intervention period ended. All of these costs were included to accurately assess the costs of the conditions.

1.4. Trial perspective

CEAs can be conducted from several different perspectives, namely healthcare, payer, or societal, depending on the objective of the analysis. The choice of perspective determines the types of costs and effects that are considered in the CEA (Table 2).

Table 2. *Cost Effectiveness Analysis Perspectives*

Perspective	Examples of costs	Examples of effects
Healthcare	- Medical costs paid for by third party or by patient	- Health benefits received by patients
Payer	- Medical reimbursement costs paid for by a third party (e.g., insurance company)	- Health benefits received by patients as a consequence of being insured
Societal	- Medical costs paid for by third party or by patients - Non-medical costs paid for by third party or by patients: a. Childcare and education system b. Changes in productivity c. Transportation and time	- Health benefits received by patients - Education benefits - Changes in productivity - Time loss

I used the societal perspective for this CEA because it is the most comprehensive perspective. It takes into account the broader impact of an intervention(s) across both the healthcare and non-healthcare related sectors, regardless of who incurs the costs and who benefits from the effects (Neumann et al., 2017; Sanders et al., 2016). Use of this perspective is consistent with the most recent recommendations from the Second Panel on Cost-Effectiveness in Health and Medicine (Neumann et al., 2017).

2. Costs

Costs were summarized as the average participant cost by condition. Briefly, I calculated the average medical and non-medical costs per participant as the product of the average number of each type of contraceptive service visits completed by participants times the corresponding visit type unit medical and non-medical costs. I then added these costs to the average participant costs of transportation and incentives (contraceptive services + incentives intervention) to determine the average total cost per participant. Each of these steps is described in more detail below.

2.1 Contraceptive service utilization

For each participant, the total number and type of contraceptive services she received during the 12-month trial period were identified.

2.2. Unit costs of intervention contraceptive services

I identified the unit cost of each of the five types of contraceptive service visits in both intervention conditions using a micro-costing approach. Micro-costing refers to a detailed, bottom up, tracking of all resources utilized to provide an intervention to trial participants to identify the unit costs of those resources, thereby reflecting the true cost of an intervention, in contrast to a gross or top down costing approach that uses reimbursement amounts or charges (Raftery, 2000). A micro-costing approach increases the precision of cost estimates and is frequently used with randomized controlled trials to identify the costs of new interventions (see systematic review by Xu, Nardini, & Ruger, 2014). The unit cost of each contraceptive service visit type was based on the sum of the direct and indirect medical costs and cost of participant time.

2.2.1. Direct medical costs. The direct medical costs for each contraceptive service visit type in both interventions included the costs of consumables, durable equipment, and staff time, as described in more detail below.

2.2.1.1. Consumables. Any single-use medical item (e.g., gloves, urine pregnancy test) used during a visit was designated a consumable. To calculate the total cost of consumables per visit type, I inventoried what consumable items were necessary for each type of visit, determined the quantity of each item used per visit, and obtained the 2019 US dollar (USD) cost of each item from McKesson Medical-Surgical, a leading medical supply and equipment company.

Prescription contraceptive methods were categorized as a consumable; thus, their unit cost was incorporated into the total consumables cost of either a SARC initiation visit or a LARC initiation visit, depending on the type of prescription contraceptive method initiated. The unit cost of any prescription contraceptive method reflected 12 months of contraceptive coverage; therefore, it was assumed that 13 packs would be required for pills, patch, and ring. Because the costs of birth control pills vary by type and brand, the average cost of pills was weighted to reflect the proportion of each pill type dispensed in the trial. The overall average 12-month SARC method cost was also weighted to reflect the proportion of each SARC method dispensed to participants during the trial. Although emergency contraception (EC) was made available to participants at every visit, they often declined this opportunity. Therefore, the total number of EC dispensed was documented for each intervention condition and the average cost per visit was incorporated into the no method visit cost.

Amortization was used to derive the annualized cost of IUDs and implants based on a 3% interest rate and the estimated survival rate of each method type. The FDA-approved lifespans of hormone-based IUDs are 3-5 years depending on the type, and 3 years for an implant, assuming a 100% survival rate (i.e., each woman that receives a LARC keeps the method for its entire approved lifespan and does not have it removed prematurely). Because some women chose to discontinue their LARC use prior to the approved lifespan, I used the observed survival rate of IUDs and implants (i.e., how long each participant used the method) during the 12-month trial period to estimate cost. This is an important calculation to avoid underestimating the annualized cost of each LARC method. Calculating cost based on the observed survival rate of each method ensures that methods that are discontinued prior to their approved lifespan are paid for during the time interval of their use rather than their approved lifespan. As an example (ignoring the 3% interest rate and present value calculations to simplify the example), if the total cost of an IUD is $1000, the annualized cost would be $200 based on the approved 5 year lifespan ($1000/5 years) and $1000 if it was discontinued during the first year of use ($1000/1 year). By including the observed survival rates, the precision of the cost estimate increases. Overall, the total cost of consumables for each visit type was fixed and did not differ between intervention conditions.

2.2.1.2. Durable equipment. Any multiple-use medical item (e.g., blood pressure monitor, stethoscope, cervical dilator) required during a visit was designated durable equipment. To derive the total cost of any durable equipment for each visit type, I inventoried what durable equipment was necessary for each visit type and obtain the 2019 USD cost of each item from McKesson Medical-Surgical. In addition, I calculated the

amortized cost per year of each item to derive its cost per use because durable equipment items were used more than once during this multi-year trial. The total cost of durable equipment for each visit type was fixed and did not differ between intervention conditions.

2.2.1.3. Staff time. Estimating the cost for staff to provide contraceptive services during participant visits in both interventions was similar to the two-step process that was used to calculate consumables and durable equipment costs, however the source and type of data for staff costs was different. There were two reason for this difference. First, because to my knowledge, there are no data available regarding the amount of time it takes to complete each of the five visit types, I had to derive individual visit time estimates from trial data. Second, as opposed to the fixed costs of consumable and durable equipment, the duration of each visit type differed by intervention because of the additional time necessary to provide an incentive for visit attendance in the contraceptive services + incentives intervention. Therefore, I also identified the duration of each visit type by intervention condition.

There was a total of seven staff members who worked on this clinical trial: a nurse practitioner, a registered nurse, a project manager, a post-doctoral student, a pre-doctoral student, and two research assistants. I used data collected by each staff member about their individual workdays to estimate the average number of minutes staff spent completing each of the five visit types with participants in both intervention conditions. Staff members documented each minute of their workday on at least five randomly chosen days during the four years of the trial. Staff were instructed to document their time on more than one day so that the duration of each visit type could be measured multiple times for participants in both interventions to obtain more precise time estimates. In addition to time spent in

direct contact with participants, I also incorporated any additional time staff spent completing administrative (e.g. making copies, appointment scheduling) and other participant-related activities (e.g., staff consultations) associated with each visit type (i.e., non-direct contact), weighted by intervention condition.

To determine the staff cost of each visit type in both interventions, I multiplied the average amount of time it took staff to complete each visit type by the weighted average staff pay rate in 2019 USD (i.e., salary and fringe benefits).

2.2.1.4. Total direct medical costs. This cost was calculated for each type of visit in both intervention conditions by adding together the cost of consumables (section 2.2.1.1), durable equipment (section 2.2.1.2), and staff time (section 2.2.1.3) for each visit type.

2.2.2. Indirect medical (i.e., overhead) costs. To account for the overhead costs (e.g., rent, utilities, etc.) associated with implementing the interventions at a medical office co-located with an OUD treatment facility, by convention, I multiplied the University of Vermont overhead rate associated with off campus research (28% in 2019) times the total direct medical cost of each visit type.

2.2.3. Total medical cost of each visit type. To calculate the total medical cost of each visit type, I added the total direct and indirect medical costs for each visit type.

2.2.4. Cost of participant time. To monetize the time participants spent completing any contraceptive service visits I multiplied the Vermont minimum wage rate ($10.78/hour in 2019 USD) by the estimated time to complete each visit type. The estimated time to complete each visit type was derived from the number of minutes of direct contact staff reported in their time allocation exercises described in section 2.2.1.3 for each visit type.

2.2.5. Total cost of each visit type. To derive the total cost of each visit type in each intervention as required to complete Step 2a) of a CEA, I added together the total medical cost (section 2.2.3) and cost of participant time (section 2.2.4).

2.3. Incentives costs

I identified the average amount of incentives paid to participants in the contraceptive services + incentives intervention since only this intervention received incentives. Participants could earn up to $437.50 for attending all 14 trial visits.

2.4. Unit costs of current services (i.e., community-based contraceptive services)

I derived the unit costs of contraceptive services provided by community providers any time during the 12-month trial period (i.e., visit cost and cost of 12-month duration of contraceptive coverage) from the Healthcare Cost and Utilization Project (HCUP) data and the Medicare Reimbursement Fee Schedule as described by Trussell, Hassan, Lowin, Law, & Filonenko (2015) and Trussell et al., (2009). HCUP databases centralize the data collection efforts of state data organizations, hospital associations, private data organizations, and the federal government to create a national information resource; it includes the largest collection of longitudinal hospital care data, with all-payer and encounter-level information (Healthcare Cost and Utilization Project, 2019).

Unit costs were adjusted to 2019 USD based on the Consumer Price Index for medical services. Costs were converted to Vermont equivalents based on the Centers for Medicare and Medicaid Services (CMS) estimates of Vermont's per capita healthcare expenditures (Centers for Medicare & Medicaid Services, 2019) to account for the fact that Vermont as a state tends to spend more on the healthcare of its citizens than other states. As with intervention contraceptive services costs derived from trial data and described in

section 2.2.1.1, it was assumed that 13 packs would be required for pills, patch, and ring to provide 12 months of contraceptive coverage. Similarly, amortization was used to derive the annualized cost of IUDs and implants as described in section 2.2.1.1.

The cost of participant time to attend community-based contraceptive service visits was estimated from trial costs (section 2.2.4.), minus any incentive-related costs, with the exception of tubal ligation. Since tubal ligation was not offered as part of the trial protocol and therefore costs could not be estimated from trial data, the cost of participant time to receive a tubal ligation had to be estimated from the literature (Subramaniam et al., 2018).

2.5. Participant transportation costs

Transportation costs participants attributed to attending any contraceptive service during the 12-month trial period were derived from self-report data collected with the Brief Drug Abuse Treatment Cost Analysis (DATCAP) (Knealing, Roebuck, Wong, & Silverman, 2008). The Brief DATCAP is frequently used in SUD research to identify the opportunity costs associated with intervention participation (French, Roebuck, & McLellan, 2004; McCollister et al., 2009; see also review by Roebuck, French, & McLellan, 2003). Any visit-related transportation costs were derived from costs associated with the type of transportation participants reported using to attend their visit (e.g., gas money, bus fare). The cost of transportation to obtain a tubal ligation was assumed to be zero because participants who received this procedure were already at the hospital due to childbirth (i.e., women received a tubal ligation immediately post-partum).

2.6. Average cost per participant

I added the unit costs of the average number of contraceptive service visits completed per participant during the 12-month trial period (sections 2.2.5 & 2.4), the

average cost of the incentives for participants in the contraceptive services + incentives intervention (section 2.3), and the average transportation costs incurred per participant (sections 2.5) to calculate the average total cost per participant.

3. Effectiveness (i.e., health benefits)

3.1. Documented prescription contraceptive use

The primary aim of the BCII trial was to investigate differences in contraceptive use among participants in the three trial conditions, the net benefit of both interventions being a decreased rate of unintended pregnancy. Although we know the rate of unintended pregnancy in the trial by condition and the main effect of condition was significant, this trial was not powered to compare the proportion of unintended pregnancies in each condition. In general, the variance of an estimated proportion is directly related to the overall size of the sample. Therefore, relying on the relatively small number of unintended pregnancies observed in the trial (n=19 across all three conditions) may produce imprecise estimates of the effectiveness of the interventions. To address this concern, I identified any documented prescription contraceptive use during the 12-month trial period and drew on evidence from the literature regarding contraceptive efficacy (i.e., the percentage of women experiencing an unintended pregnancy using contraception) to model the impact of the interventions on unintended pregnancy rates. Documentation for injectables, IUDs, and implants was based on verification of use via medical records, pelvic exam, and palpation, respectively for the 12-month trial period (i.e., the definition used as the trial's primary outcome). Documented use of pills, patch, and ring was based on verified 6- and 12-month 28-day period prevalence of use (i.e., again, the definition used as the trial's primary

outcome) and supplemented by participant self-report for the remaining 12-month trial period.

3.2. Unintended pregnancy rate

To estimate the risk of unintended pregnancy for each participant based on documented contraceptive use, I first derived the monthly rates of unintended pregnancy associated with each prescription contraceptive method, including no method use, from nationally representative data about the percent of women who experienced an unintended pregnancy during the first year of typical use of the method shown in Table 3 (Trussell & Aiken, 2018; Vaughan et al., 2008). I then derived each participant's overall probability of unintended pregnancy during the 12-month trial period based on her individual rates of documented contraceptive use and the share of participants not pregnant at the start of each month. As in a survival analysis, if s_1 is the proportion of participants not pregnant at the beginning of an interval, s_2 is the proportion at the end of the interval, and r is the risk during the interval, then $s_2 = s_1 (1\text{-}r)$.

Table 3. *Percent of Women Using Contraception Who Will Experience an Unintended Pregnancy During a 12-Month Period*

Method type	Unintended pregnancy rate
No method	46.00%
Pills	7.00%
Patch	7.00%
Ring	7.00%
Injectables	4.00%
IUD	0.32%
Implant	0.10%

Note. Adapted from Trussell et al., 2018; Vaughan et al., 2008.

Once the risk of unintended pregnancy for each participant was calculated, I determined the average rate of unintended pregnancy for each trial condition (by convention, reported as the number of unintended pregnancies per 1000 women) to estimate the overall effectiveness of each trial condition at averting an unintended pregnancy.

4. Cost-effectiveness of the interventions

4.1. Willingness-to-pay threshold

To estimate the societal (i.e., healthcare and non-healthcare related) cost of an unintended pregnancy among women with OUD, I used previously published nationally representative data about the estimated healthcare costs of unintended pregnancies that result in a spontaneous abortion, therapeutic abortion, ectopic pregnancy, or live birth (Trussell et al., 2013) and the additional costs associated with a live birth and raising a child 0 -18 years old. I converted all hospital charge data to cost values using the HCUP Kids' Inpatient Database-specific cost-to-charge ratios, based on hospital accounting reports from the CMS (Agency for Healthcare Research and Quality, 2020). I converted national healthcare cost estimates to Vermont equivalents based on CMS estimates of Vermont's per capita healthcare expenditures (Centers for Medicare & Medicaid Services, 2019). Pregnancy outcome costs were obtained from general population estimates as I was not aware of any evidence that suggested additional costs for pregnant women with OUD. The additional costs associated with a live birth included the estimated average healthcare costs incurred by a neonate exposed to opioids in-utero from birth to age eight (Liu et al., 2019) and the estimated average healthcare costs per child, ages 9-18 (Mirel & Carper,

2014). The average healthcare costs for children 9-18 years old were based on children not diagnosed with NAS because the differences in healthcare costs between children diagnosed with NAS vs. not appear negligible beyond age 8 (Liu, Kong, Leslie, & Corr, 2019).

The non-healthcare related costs of a live birth included the U.S. Department of Agriculture (USDA) estimates of child-rearing expenditures (i.e., costs of housing, food, transportation, out-of-pocket healthcare expenses, clothing, and miscellaneous items) from birth to age 18 based on single-parent households with incomes less than $59,200 (Lino, Kuczynski, Rodriguez, & Schap, 2017), the USDA characterization that best matched trial participants. Non-healthcare related costs of a live birth also included the average cost of childcare (6 weeks – 5 years) and educational services (5 -18 years) in Vermont (Child Care Resource, 2017; Kolbe & Kieran, 2017). Childcare costs were assumed only for those trial participants that reported employment (36%). Education costs were adjusted to account for the additional costs of special education services children with a history of NAS are more likely to incur (Fill et al., 2018).

Consistent with previous literature, the overall cost (i.e., both healthcare and non-healthcare related) of an unintended pregnancy that resulted in a live birth was reduced to take into account the proportion of unintended pregnancies in the trial that were mistimed (42% (8/19)); the full cost of these births should not be considered avoidable as it is assumed they will occur at some point in the future (Trussell et al., 2013). I then calculated a weighted average cost, based on the proportion of each unintended pregnancy outcome observed during the 12-month trial period (42% (8/19) live birth, 32% (6/19) therapeutic abortion, 21% (4/19) miscarriage, and 1% (1/19) ectopic pregnancy) to derive the estimated

average cost of an unintended pregnancy among women with OUD, from a societal perspective.

All estimated healthcare and non-healthcare related costs were adjusted for inflation using the Consumer Price Index and reported in 2019 USD. All future costs are expressed in terms of their present value, from birth, using a 3% discounting rate. Discounting is a procedure economists use to make sure that money needed to purchase something in the future is expressed in terms of its present value. The principle behind discounting is the further in the future a cost is incurred, the less it will cost today (Shepard & Thompson, 1979). For example, the cost of educating a child diagnosed with NAS as a newborn will cost less today (because she will not start school for 5 years) compared to a 5-year old child currently enrolled in school ($12,999 vs. $15,521, respectively). Behavioral economists use this same principle to explain delay discounting (i.e., the extent to which a reinforcer's value decreases as a function of its temporal distance; Bickel, Johnson, Koffarnus, MacKillop, & Murphy, 2014). Discounting differs from adjusting for inflation, which makes sure money is worth the same amount in terms of what can be purchased in the future.

4.2. Incremental cost-effectiveness ratios (ICERs)

To test my two hypotheses, I calculated three ICERs: 1) contraceptive services vs. usual care, 2) contraceptive services + incentives vs. usual care, and 3) contraceptive services + incentives vs. contraceptive services. For example, the ICER comparing contraceptive services to usual care was calculated as follows:

$$\text{ICER} = \frac{\text{(Total cost of contraceptive services from Step 2) – (Usual care cost from Step 2)}}{\text{(Contraceptive services unintended pregnancy rate from Step 3) – (Usual care rate from Step 3)}}$$

4.3. Willingness-to-pay threshold and ICERs

The estimated cost of an unintended pregnancy among women with OUD calculated in section 4.1 was compared to the value of each ICER calculated in section 4.2 to determine if the interventions were cost-effective, thereby facilitating decision-making about utilization of the interventions in community-based settings. If a given ICER was less than the willingness-to-pay threshold, the intervention was deemed cost-effective; if the value was more the intervention was deemed not cost-effective.

5. Sensitivity analysis

Whenever a CEA is conducted, there is always some uncertainty associated with the derived values. This is because we can never know the expected (i.e., mean) costs and effectiveness of an intervention with absolute certainty. Therefore, quantifying the uncertainty helps us assess the probability that a decision based on the expected costs and effectiveness of an intervention will be correct.

The method for estimating the uncertainty of a CEA is broadly referred to as sensitivity analysis. There are two important characteristics of the BCII trial CEA that dictate exactly which type of sensitivity analysis should be used: 1) the CEA is based on trial data, and 2) the uncertainty of the input parameters (i.e., cost and effectiveness values) are not considered independent of each other (e.g., the total cost of a participant's contraceptive services is related to her unintended pregnancy risk). In this scenario, probabilistic sensitivity analysis is recommended because the input parameters are derived as a whole or in part from trial data as opposed to modeling estimates based exclusively on secondary data from non-trial sources, in which case each of the model's input parameters

would have to be varied individually because they are not specific to trial data (see review by Andronis, Barton, & Bryan, 2009).

5.1. Probabilistic sensitivity analysis

I performed probabilistic sensitivity analysis to assign distributions to both input parameters (i.e., cost and effectiveness data) using nonparametric bootstrapping with 1000 simulations, randomly selecting (with replacement) participants in each condition. Repeatedly sampling parameter inputs 1000 times increased the likelihood of capturing the range of values that the input parameters were likely to be and provided a more accurate estimate of the probability of alternative outcomes (i.e., expected values) (Claxton, 2008). Using values from these simulated distributions, I estimated the statistical uncertainty of my results by calculating 95% bootstrap confidence intervals (95% CI) around the point estimates (i.e., means), taking 2.5 and 97.5 percentile values. With these calculations I estimated the lower and upper bounds around the point estimates of the costs, effectiveness, and ICERs. Results of the probabilistic sensitivity analysis were then used to create cost-effectiveness scatterplots and acceptability curves to illustrate the uncertainty.

Each point in both types of graphs represents one bootstrap simulation. Estimates in the upper left quadrant of the scatterplots represent a scenario that is more effective and more costly than the alternative, values in lower left quadrant represent a more effective and less costly scenario, values in the lower right represent a less effective and less costly scenario, and values in the upper right quadrant represent a less effective and more costly scenario compared to the alternative.

To identify the uncertainty around the ICER estimates, I constructed cost-effectiveness acceptability curves for a range of willingness-to-pay thresholds. The graphs

provide an estimate of the proportion of the sampling distribution, obtained from the bootstrap estimates, that lie below the maximum willingness-to-pay threshold to avoid an unintended pregnancy.

Analyses were conducted using StataSE version 15 (Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC). Statistical significance was determined based on α=.05.

Results

1. Costs

1.1 Contraceptive services utilization

The average number of contraceptive service visits participants completed in each condition during the 12-month trial period are presented in Table 4.

Table 4. *Average Number of Contraceptive Service Visits Completed Per Participant During the 12-Month Trial Period by Condition*

Type of service:	Usual care	Contraceptive services	Contraceptive services + incentives
Intervention-based:			
1. No method visit	-	1.15 (0.49-1.80)	1.69 (0.85-2.53)
2. SARC initiation visit	-	0.65 (0.45-0.84)	0.45 (0.29-0.62)
3. SARC maintenance visit	-	0.92 (0.37-1.47)	3.14 (1.66-4.62)
4. LARC initiation visit	-	0.42 (0.28-0.56)	0.55 (0.38-0.71)
5. LARC maintenance visit	-	1.10 (0.47-1.73)	5.38 (3.62-7.14)
Community-based:			
1. SARC initiation visit	0.19 (0.02-0.36)	0.10 (0.00-0.24)	0.00 (0.00-0.00)
2. LARC initiation visit	0.06 (0.00-0.13)	0.02 (0.00-0.06)	0.00 (0.00-0.00)
3. LARC removal visit	0.02 (0.00-0.06)	0.00 (0.00-0.00)	0.05 (0.00-0.11)
4. Tubal ligation procedure	0.02 (0.00-0.06)	0.02 (0.00-0.06)	0.00 (0.00-0.00)
Total per participant	**0.29 (0.08-0.50)**	**4.38 (3.28-5.47)**	**11.26 (9.90-12.63)**

Note. ( ) = 95%CI.

1.2. Unit costs of intervention contraceptive services

The unit costs of each of the five intervention-based contraceptive service visit types were calculated by adding the direct and indirect medical costs and cost of participant time for each visit type.

1.2.1. Direct medical costs. I calculated the total direct medical cost for each visit type by adding the consumables, durable equipment, and staff time costs for each visit.

1.2.1.1. Consumables & 1.2.1.2. Durable equipment. For ease of presentation, these two subsections have been combined. The individual consumables and durable

equipment required to provide the very basic services administered at every visit during the trial (e.g., weighing the participant, checking her blood pressure, doing a pregnancy test), regardless of type, and their related costs are shown in Table 5. The base cost for these items was $2.77 per visit.

Table 5. *Base Cost of Consumables and Durable Equipment Used at Every Visit Type*

Item	Unit cost	Quantity/visit	Cost/visit
Consumables			
Condom, Lifestyle brand	$0.14	5	$0.68
Gloves, nitrile	$0.15	2	$0.31
Hand sanitizer	$0.05	4	$0.18
Pregnancy test	$1.19	1	$1.19
Waste disposal	$0.06	1	$0.06
Durable equipment			
BP sphygmomanometer	$69.59	1	$0.09
BP cuff	$21.55	1	$0.03
Stethoscope	$39.07	1	$0.05
Scale	$71.69	2	$0.19
Total cost per visit			*$2.77*

The additional consumables and durable equipment costs added to this base cost for each visit type are described in detail below.

1.2.1.1.1. No method visits. The cost of EC dispensed during the 6-month intervention period was distributed across the total number of no method visits completed by participants in each intervention condition because EC was not dispensed at every visit (i.e., women declined use). Fifty-one EC were dispensed to contraceptive services participants and 53 were dispensed to contraceptive services + incentives participants during the intervention period. The unit cost of one EC was $25; therefore, the total cost of EC was $1,275 (51 dispensed x $25) for contraceptive services and $1,325 (53 dispensed x $25) for contraceptive services + incentives. Fifty-five no method visits were completed by participants in the contraceptive services condition and 71 in the contraceptive services + incentives condition. Therefore, the average cost of EC per visit was $23.18 ($1,275/55

total no method visits) for contraceptive services and $18.66 ($1,325/71 total no method visits) for contraceptive services + incentives. The total consumables and durable equipment costs for a no method visit are shown in Table 6; in this case the only additional cost beyond the base cost was the weighted cost of EC.

Table 6. *No Method Visit Consumables and Durable Equipment Costs by Intervention Condition*

	Contraceptive services	Contraceptive services + incentives
Base cost	$2.77	$2.77
Additional cost	$23.18	$18.66
Total cost per visit	*$25.95*	*$21.43*

1.2.1.1.2. SARC initiation visits. The majority of the additional consumable costs attributed to this visit type were the result of the cost of the method dispensed at the visit. Because there are several different types of pills, with various costs (Table 7), I calculated a weighted average cost for 12 months of use that reflected the proportion of each pill type dispensed ($316.54).

Table 7. *Contraceptive Pill Types Dispensed During the Intervention*

Pill types	% dispensed	12-month cost
Norethindrone: Nor-BE	59.94%	$147.33
Levonorgestrel/EE (Sronyx)	15.64%	$650.00
Norethindrone EE (Microgestin)	1.68%	$164.67
Levonorgestrel/EE (generic Sronyx)	15.54%	$650.00
Norethindrone/EE (generic Microgestin)	3.35%	$152.00
Desogesterol/EE (Apri)	10.89%	$351.00
Norethindrone/EE (1.5/30) (Junel)	3.35%	$975.00
Levonorgestrel/EE (0.15/.03)	5.87%	$173.33
Levonorgestrel/EE (Jolessa)	2.51%	$346.67
Weighted average cost		*$316.54*

For patch and ring, methods with only one type dispensed during the trial, the 12-month cost was $411.67 and $2,058.33, respectively. For SARC initiation visits where participants elected to initiate an injectable method, the additional consumables necessary to provide this visit type cost $86.43 (Table 8).

Table 8. *Additional Consumables Costs to Initiate an Injectable Method*

Item	Unit cost	Quantity/visit	Cost/visit
Depo-Provera: DMPA	$85.00	1	$85.00
22 g 1.5" needles	$0.06	1	$0.06
2x2 gauze pads - sterile	$0.06	3	$0.18
Alcohol swabs	$0.01	2	$0.02
Band-Aids	$0.04	1	$0.04
Cotton balls	$0.01	4	$0.04
Gloves, nitrile	$0.15	4	$0.61
Syringe/NDL	$0.26	1	$0.26
Syringe 3 cc	$0.08	1	$0.08
Table paper	$0.03	5	$0.14
Total cost per visit, injectable initiation			*$86.43*

Overall, the additional weighted average cost of consumables and durable equipment specific to a SARC initiation visit was $477.32, based on pills initiated at 84.24% of these visits, rings at 9.65%, injectables at 4.00%, and patches at 2.12%. The total cost of consumables and durable equipment for a SARC initiation visit was $480.09; the calculations are shown in Table 9.

Table 9. *Consumables and Durable Equipment Costs of a SARC Initiation Visit*

Base cost	$2.77
Additional costs	
Pills	
% of SARCS dispensed	84.24%
Cost	*x $316.54 = $266.65*
Patch	
% of SARCS dispensed	2.12%
Cost	*x $411.67 = $8.73*
Ring	
% of SARCS dispensed	9.65%
Cost	*x $2,058.33 = $198.63*
Injectable	
% of SARCS dispensed	4.00%
Cost	*x $86.43 = $3.46*
Additional costs total	$477.47
Total cost per visit	*$480.24*

1.2.1.1.3. LARC initiation visits. The additional consumables and durable equipment specific to a LARC initiation visit, and their related costs, are presented in

Tables 10 (IUD insertion) & 11 (implant insertion). The estimated survival rate of IUDs was 2.34 years and 2.19 years for implants.

Table 10. *Additional Consumables and Durable Equipment Costs for an IUD Insertion*

Item	Unit cost	Quantity/visit	Cost/visit
Consumables			
IUD		1	$403.66*
Skyla	$793.96		
Liletta	$786.97		
Mirena	$953.51		
Applicator, cotton tip	$0.05	1	$0.05
Cleanser, multi-enzymatic foam	$0.03	1	$0.03
Glove, nitrile	$0.15	6	$0.92
Glove, surgical	$2.11	1	$2.11
Indicator strip	$0.04	4	$0.16
Lubricating jelly	$0.08	1	$0.08
Pad, maxi thin	$0.16	4	$0.63
Patient drapes 40x60	$0.34	1	$0.34
Pouch, self-seal 7.5x 13	$0.15	2	$0.29
Pouch, self-seal 5.25x10	$0.14	1	$0.14
Povidone prep solution	$0.23	2	$0.47
Speculum (large)	$1.30	1	$1.30
Speculum (medium)	$1.20	1	$1.20
Speculum (small)	$2.24	1	$2.24
Swab, OB/GYN	$0.12	3	$0.35
Table paper	$0.03	5	$0.14
Tubing, autoclave 3” x 100	$0.02	3	$0.05
Under pad med absorb	$0.19	1	$0.19
STI – Lab tests	$25.78	1	$25.78
Durable equipment			
Dilator, cervical OS/canal (3/ST)	$3.27	1	$3.27
Dilator, uterine 7-8FR	$2.51	1	$2.51
Dilator, uterine 9-10FR	$2.60	1	$2.60
Forceps	$2.68	1	$2.68
Germicide tray	$0.64	1	$0.64
Illuminator, vaginal cordless	$12.95	1	$12.95
Scissor, Metzenbaum	$1.24	1	$1.24
Stand, instrument	$1.98	1	$1.98
Uterine sound, SIMS grad	$0.95	1	$0.95
Uterine sound, SIMS 13”	$0.61	1	$0.61
Total cost per visit, IUD insertion			*$469.55*

Note. *Amortized cost based on survival rate of 2.34 years and proportion of each type of IUD inserted.

Table 11. *Additional Consumables and Durable Equipment Costs for an Implant Insertion*

	Unit cost	Quantity/visit	Cost/visit
Consumables			
Implant – Nexplanon	$934.51	1	$455.66*
22 g 1.5" needles	$0.06	1	$0.06
2x2 gauze pads, non-sterile	$0.01	3	$0.04
2x2 gauze pads - sterile	$0.06	3	$0.18
Alcohol swab	$0.01	1	$0.01
Bandage, adhesive fabric patch	$0.12	1	$0.12
Bandage, cohesive color pk 3"	$3.04	0.5	$1.52
Bandage, conform stretch	$1.24	0.5	$0.62
Bandage, coban 2"rolls	$2.48	0.5	$1.24
Band-aids/fabric	$0.04	1	$0.04
Cotton balls	$0.01	4	$0.04
Gauze, rolled 2"	$0.04	2	$0.07
Gloves, surgical	$2.11	2	$4.22
Gloves, nitrile	$0.15	2	$0.31
Chlorhexidine scrub - Hibiclens cleanser	$0.03	15	$0.39
Lidocaine 1% 20mL mdv #25	$2.25	2	$4.51
Povidone prep solution	$0.23	1	$0.23
Steri stripes 1/4"	$0.92	1	$0.92
Sterile fields 18x26	$0.31	1	$0.31
Table paper	$0.03	5	$0.14
Tape, adhesive paper	$0.62	0.1	$0.03
Under pad med absorb	$0.19	1	$0.19
Durable equipment			
Bandage scissors	$0.21	1	$0.21
Hemostat, curved	$0.30	1	$0.30
Hemostat, straight	$0.24	1	$0.24
Stand, instrument	$1.98	1	$1.98
Total cost per visit, implant insertion			*$473.57*

Note. *Amortized cost based on survival rate of 2.19 years.

Overall, the additional weighted average cost of consumables and durable equipment specific to a LARC initiation visit was $472.06 based on IUDs inserted at 37.50% of these visits and implants inserted at 62.50%. The total cost of consumables and durable equipment for a LARC initiation visit was $474.83; the calculations are shown in Table 12.

Table 12. *Consumables and Durable Equipment Costs of a LARC Initiation Visit*

Base cost	$2.77
Additional costs	
IUD	
% of LARCs dispensed	37.50%
Cost	*x $469.55 = $176.08*
Implant	
% of LARCs dispensed	62.50%
Cost	*x $473.57 = $295.98*
Additional costs total	$472.06
Total cost per visit	*$474.83*

1.2.1.3. Staff time. The number of minutes of direct contact staff time varied by visit type, which staff member(s) conducted the visits, and the intervention condition (Table 13). The number of minutes of non-direct contact staff time, which included charting, staff and provider consultations, and administrative tasks was the same for each visit type and staff member, but varied by intervention condition due to the additional time spent by staff to procure and administer incentives for the contraceptive services + incentives intervention.

Table 13. *Average Number of Minutes to Complete Each Visit Type and Related Costs of Staff Time by Intervention Condition*

Visit type	Contraceptive services	Contraceptive services + incentives
1. No method		
Direct contact time	34 (22-45)	29 (26-32)
Non-direct contact time	+15 (13-16)	+18 (15-20)
Total time	49	47
Total time cost	*x $0.93 = $45.21*	*x $0.93 = $43.46*
2. SARC initiation		
Direct contact time	29 (23-35)	29 (25-33)
Non-direct contact time	+15 (13-16)	+18 (15-20)
Total time	44	47
Total time cost	*x $1.22 = $53.19*	*x $1.22 = $57.30*
3. SARC maintenance		
Direct contact time	23 (19-27)	22 (18-27)
Non-direct contact time	+15 (13-16)	+18 (15-20)
Total time	38	40
Total time cost	*x $0.93 = $35.19*	*x $0.93 = $37.17*
4. LARC initiation		
a. Nurse practitioner		
Direct contact time	59 (57-61)	53 (36-73)
Non-direct contact time	+15 (13-16)	+18 (15-20)
Total time	74	71
Time cost	*x $1.22 = $90.33*	*x $1.22 = $86.38*
b. Support staff		
Direct contact time	25 (15-35)	19 (10-27)
Time cost	*x $0.44 = $11.11*	*x $0.44 = $8.33*
Total time cost	*$90.33 + $11.11 = $101.44*	*$86.38 + $8.33 = $94.71*
5. LARC maintenance		
Direct contact time	22 (17-26)	19 (15-22)
Non-direct contact time	+15 (13-16)	+18 (15-20)
Total time	37	37
Total time cost	*x $0.93 = $33.95*	*x $0.93 = $33.66*

Note. ( ) = 95% CI.

Staff pay rates (i.e., salary and fringe benefits) in 2019 USD ranged from $18.53 to $73.46 per hour. Overall, the nurse practitioner completed 61% of all contraceptive services visits for participants in both interventions, including all LARC initiation visits, the project manager completed 14%, a graduate student completed 9%, a post-doc completed 6%, a nurse completed 5%, and two research assistants completed 4%. Multiplying the proportion of all visits each staff member completed by her respective salary yielded the weighted mean staff pay rate of $55.90/hour ($0.93/minute).

The total costs of staff time for no method, SARC maintenance, and LARC maintenance visits were calculated by multiplying $0.93 by the total number of minutes to complete each visit type for each intervention since any staff member could complete these types of visits. Because the nurse practitioner completed all the SARC initiation visits, the total cost of staff time for a SARC initiation visit was calculated by multiplying $1.22 (pay rate/minute) by the total number of minutes to complete a SARC initiation visit. Because LARC initiation visits required the assistance of a second staff member acting as support staff, the total cost of staff time for LARC initiation visits was calculated by multiplying the total nurse practitioner time by $1.22 (pay rate/minute) plus the total support staff time multiplied by $0.44 (average support staff pay rate/minute). Table 13 shows the estimated number of minutes and total cost of staff time for each visit type in both interventions.

1.2.1.4. Total direct medical costs. These costs, which are a combination of the costs shown in Tables 6, 9, 12, and 13 are presented in Table 14 for both intervention conditions.

Table 14. *Total Direct Medical Costs of Each Visit Type by Intervention Condition*

Visit type	Contraceptive services	Contraceptive services + incentives
1. No method		
Consumables/durable equipment	$25.95	$21.43
Staff time	+$45.21	+$43.46
Total direct medical cost	*$71.16*	*$64.89*
2. SARC initiation		
Consumables/durable equipment	$480.09	$480.09
Staff time	+$53.19	+$57.30
Total direct medical cost	*$533.43*	*$537.54*
3. SARC maintenance		
Consumables/durable equipment	$2.77	$2.77
Staff time	+$35.19	+$37.17
Total direct medical cost	*$37.96*	*$39.94*
4. LARC initiation		
Consumables/durable equipment	$474.83	$474.83
Staff time	+$101.44	+$94.71
Total direct medical cost	*$576.27*	*$569.54*
5. LARC maintenance		
Consumables/durable equipment	$2.77	$2.77
Staff time	+$33.95	+$33.66
Total direct medical cost	*$36.72*	*$36.43*

1.2.2. Indirect (i.e., overhead) medical costs. These costs were calculated by multiplying the total direct medical costs for each visit type for each intervention condition (Table 14) by 28%, the University of Vermont overhead rate associated with off campus research. The total indirect medical cost for each visit type by intervention condition are presented in Table 15.

Table 15. *Total Indirect Medical Cost of Each Visit Type by Intervention Condition*

Visit type	Contraceptive services	Contraceptive services + incentives
1. No method		
Direct medical costs	$71.16	$64.89
Total indirect costs	*x 0.28 = $19.93*	*x 0.28 = $18.17*
2. SARC initiation		
Direct medical costs	$533.43	$537.54
Total indirect costs	*x 0.28 = $149.36*	*x 0.28 = $150.51*
3. SARC maintenance		
Direct medical costs	$37.96	$39.94
Total indirect costs	*x 0.28 = $10.63*	*x 0.28 =$11.18*
4. LARC initiation		
Direct medical costs	$576.27	$569.54
Total indirect costs	*x 0.28 = $161.36*	*x 0.28 = $159.47*
5. LARC maintenance		
Direct medical costs	$36.72	$36.43
Total indirect costs	*x 0.28 = $10.28*	*x 0.28 = $10.20*

1.2.3. Total medical cost of each visit type. These costs, which combine the costs shown in Tables 14 & 15, are presented for both intervention conditions in Table 16.

Table 16. *Total Medical Costs of Each Visit Type by Intervention Condition*

Visit type	Contraceptive services	Contraceptive services + incentives
1. No method		
Direct medical costs	$71.16	$64.89
Indirect costs	+$19.93	+$18.17
Total cost	*$91.09*	*$83.06*
2. SARC initiation		
Direct medical costs	$533.43	$537.54
Indirect costs	+$149.36	+$150.51
Total cost	*$682.79*	*$688.05*
3. SARC maintenance		
Direct medical costs	$37.96	$39.94
Indirect costs	+$10.63	+$11.18
Total cost	*$48.59*	*$51.12*
4. LARC initiation		
Direct medical costs	$576.27	$569.54
Indirect costs	+$161.36	+$159.47
Total cost	*$737.63*	*$729.01*
5. LARC maintenance		
Direct medical costs	$36.72	$36.43
Indirect costs	+$10.28	+$10.20
Total cost	*$47.00*	*$46.63*

1.2.4. Cost of participant time. The cost of participant time to complete each intervention-based visit was calculated by multiplying the average number of minutes participants spent completing each visit type (i.e., direct contact time estimates shown in Table 13) times $0.18, the Vermont minimum wage rate per minute ($10.78/hour in 2019 USD). The participant time costs of each visit type for both intervention conditions are presented in Table 17.

Table 17. *Average Number of Minutes and Cost of Participant Time to Complete Contraceptive Services Visits by Intervention Condition*

Visit type	Contraceptive services	Contraceptive services + incentives
1. No method		
Participant time	34 (22-45)	29 (26-32)
Total participant time cost	*x $0.18 = $6.06*	*x $0.18 = $5.45*
2. SARC initiation		
Participant time	29 (23-35)	29 (25-33)
Total participant time cost	*x $0.18 = $5.16*	*x $0.18 = $5.47*
3. SARC maintenance		
Participant time	23 (19-27)	22 (18-27)
Total participant time cost	*x $0.18 = $4.13*	*x $0.18 = $4.24*
4. LARC initiation		
Participant time	59 (57-61)	53 (36-73)
Total participant time cost	*x $0.18 = $10.60*	*x $0.18 = $10.07*
5. LARC maintenance		
Participant time	22 (17-26)	19 (15-22)
Total participant time cost	*x $0.18 = $3.89*	*x $0.18 = $3.57*

Note. ( ) = 95% CI.

1.2.5. Total cost of each visit type. The estimated costs of each intervention-based contraceptive services visit type are presented in Table 18. These values were calculated by combining the medical cost data presented in Table 16 and the cost of participant time presented in Table 17.

Table 18. *Total Cost of Trial Visit Types by Intervention Condition*

Visit type	Contraceptive services	Contraceptive services + incentives
1. No method		
Medical cost	$91.09	$83.06
Participant time cost	+$6.06	+$5.45
Total cost	*$97.15*	*$88.51*
2. SARC initiation		
Medical cost	$682.79	$688.05
Participant time cost	+$5.16	+$5.47
Total cost	*$687.95*	*$693.52*
3. SARC maintenance		
Medical cost	$48.60	$51.12
Participant time cost	+$4.13	+$4.24
Total cost	*$52.72*	*$55.36*
4. LARC initiation		
Medical cost	$737.63	$729.01
Participant time cost	+$10.60	+$10.07
Total cost	*$748.23*	*$739.08*
5. LARC maintenance		
Medical cost	$47.01	$46.63
Participant time cost	+$3.89	+$3.57
Total cost	*$50.90*	*$50.20*

1.3. Incentives costs

The average (95%CI) total cash value of incentives participants in the contraceptive services + incentives condition received was $312.50 ($267.19-$358.53).

1.4. Unit costs of current services (i.e., community-based contraceptive services)

The estimated medical costs of the four community-based contraceptive services visits participants completed during the 12-month trial period were calculated from the unit costs derived from the literature (Table 19). Among trial participants who received contraceptive services from community providers, pills were initiated at 14.29% of the SARC initiation visits and injectables at 85.71%; IUDs were inserted at 75.00% of the

Table 19. *Medical Cost Components of Community-Based Contraceptive Services*

	Cost
Method-related	
Pills	$563.49
Injectable	$91.30
IUD	$511.13
Implant	$465.39
Provider-related	
Pill initiation	$64.74
Injectable initiation	$113.86
IUD insertion	$266.21
Implant insertion	$364.61
Tubal ligation	$4,311.76
IUD removal	$306.09
Implant removal	$380.14

LARC initiation visits and implants at 25.00%; 66.67% of LARC removal visits were for IUDs and 33.33% were for implants. Table 20 shows the weighted average medical cost (i.e., provider and method cost) of each type of community-based contraceptive service visit. These costs did not differ by condition.

Table 20. *Weighted Average Medical Costs of Community-Based Contraception Initiation and Removal Visits*

Visit type	Total cost
1. SARC initiation	
Pills	
% of SARCS dispensed	14.29%
Cost	*x $628.23 = $89.75*
Injectables	
% of SARCS dispensed	85.71%
Cost	*x $205.16 = $175.85*
Average medical cost	*$265.60*
2. LARC initiation	
IUD	
% of LARCS inserted	75.00%
Cost	*x $777.34 = $583.00*
Implant	
% of LARCS inserted	25.00%
Cost	*x $830.00 = $207.50*
Average medical cost	*$790.50*
3. LARC Removal	
IUD	
% of LARCs removed	66.67%
Cost	*x $306.09 = $204.06*
Implant	
% of LARCs removed	33.33%
Cost	*x $380.14 = $126.71*
Average medical cost	*$330.78*

The cost of participant time to complete community-based contraceptive services visits was $5.16 for SARC initiation visits, $10.60 for LARC initiation and removal visits, and $11.68 for tubal ligation. The total costs of each community-based contraceptive services visit type, calculated from the medical and participant time costs of each visit type, are presented in Table 21.

Table 21. *Total Costs of Community-Based Contraceptive Services Visits*

Visit type	Total cost
1. SARC initiation	
Medical cost	$265.50
Participant time cost	+ $5.16
Total cost	*$270.76*
2. LARC initiation	
Medical cost	$790.50
Participant time cost	+ $10.60
Total cost	*$801.10*
3. LARC removal	
Medical cost	$330.78
Participant time cost	+ $10.60
Total cost	*$341.38*
4. Tubal ligation	
Medical cost	$4,311.76
Participant time cost	+ $11.68
Total cost	*$4,323.44*

1.5. Participant transportation costs

Among participants in the intervention conditions who completed at least one trial visit, 20% (9/44) of participants in the contraceptive services intervention and 13% (9/40) of participants in the contraceptive services + incentives intervention reported out-of-pocket transportation expenses to attend trial visits. All community-based contraceptive service visits incurred a transportation cost. The most common modes of transportation were car and bus. Overall, the average (95%CI) cost of transportation per participant was $0.52 ($0.17-$0.86) for usual care, $1.11 ($0.25-$1.96) for contraceptive services, and $0.93 ($0.00-$2.00) for contraceptive services + incentives.

1.6. Average cost per participant

The estimated cost of the average number of contraceptive services visits completed per participant during the 12-month trial period, which were calculated with data from Tables 2, 18 and 21 are presented in Table 22.

Table 22. *Estimated Cost of the Average Number of Contraceptive Service Visits Completed Per Participant During the 12-Month Trial Period by Visit Type and Condition*

Type of service:	Usual care	Contraceptive services	Contraceptive services + incentives
Intervention-based:			
1. No method visit	-		
Average number of visits		1.15	1.69
Unit cost		x $97	x $89
Total cost		*$111*	*$150*
2. SARC initiation visit	-		
Average number of visits		0.65	0.45
Unit cost		x $688	x $694
Total cost		*$444*	*$314*
3. SARC maintenance visit	-		
Average number of visits		0.92	3.14
Unit cost		x $53	x $55
Total cost		*$48*	*$174*
4. LARC initiation visit	-		
Average number of visits		0.42	0.55
Unit cost		x $748	x $739
Total cost		*$312*	*$405*
5. LARC maintenance visit	-		
Average number of visits		1.10	5.38
Unit cost		x $51	x $50
Total cost		*$56*	*$270*
Community-based:			
1. SARC initiation visit			
Average number of visits	0.19	0.10	0.00
Unit cost	x $271	x $271	
Total cost	*$51*	*$28*	*$0*
2. LARC initiation visit			
Average number of visits	0.06	0.02	0.00
Unit cost	x $801	x $801	
Total cost	*$51*	*$17*	*$0*
3. LARC removal visit			
Average number of visits	0.02	0.00	0.05
Unit cost	x $341		x $341
Total cost	*$7*	*$0*	*$16*
4. Tubal ligation procedure			
Average number of visits	0.02	0.02	0.00
Unit cost	x $4,323	x $4,323	
Total cost	*$90*	*$90*	*$0*
Total	*$198*	*$1,106*	*$1,329*

To determine the average participant cost, I added the cost of the average number of contraceptive services visits completed per participant, including both intervention- and

community-based services (Table 22), the average cost of incentives for participants in the contraceptive services + incentives condition (section 1.3), and the average cost of any transportation costs participants incurred (section 1.5). These calculations are shown in Table 23.

Table 23. *Average Cost of Participants by Condition*

Input	Usual care	Contraceptive services	Contraceptive services + incentives
Average total visit cost	$198	$1,106	$1,329
Incentives cost	$0	$0	$313
Transportation cost	+ $1	+ $1	+ $1
Total cost	*$199*	*$1,107*	*$1,643*

Overall, the contraceptive services + incentives condition had the highest average cost per participant and the usual care condition had the lowest average cost per participant. The contraceptive services + incentives condition cost approximately 8 times more, per participant, than usual care and approximately 1.5 times more than contraceptive services with no incentives. Contraceptive services cost approximately 6 times more than usual care.

3. Effectiveness (i.e., health benefits)

3.1. Documented prescription contraceptive use

A total of eight (16%) participants in usual care, 26 (54%) participants in contraceptive services, and 26 (62%) participants in contraceptive services + incentives had documented use of at least one prescription contraceptive method at some time during the 12-month trial period. One participant in usual care, four in contraceptive services, and four in contraceptive services + incentives had documented use of more than one prescription contraceptive method. The number of participants with documented

contraceptive use any time during the 12-month trial period and the type of contraceptive method documented are presented in Table 24.

Table 24. *Documented Prescription Contraceptive Use by Participants During the 12-Month Trial Period by Condition*

	Usual care	Contraceptive services	Contraceptive services + incentives
Pills	2	1	3
Ring	0	1	0
Injectable	4	8	3
IUD	2	5	9
Implant	1	15	15
Total	9	30	30

The average (95%CI) number of days of documented prescription contraceptive use, by method type, and no method use during the 12-month trial period are shown in Table 25. If contraceptive use data was unavailable for a participant, it was assumed she was not using a method.

Table 25. *Average Number of Days of Documented Prescription Contraceptive Use During the 12-Month Trial Period by Condition*

	Usual care	Contraceptive services	Contraceptive services + incentives
No Method	327 (305-349)	217 (174-260)	148 (98-197)
Pills	251 (113-388)	307	265 (149-381)
Ring	0	188	0
Injectable	210 (151-269)	162 (95-229)	120 (61-179)
IUD	84	81 (27-135)	285 (213-358)
Implant	0	245 (177-311)	287 (238-335)

Note. ( ) = 95% CI.

3.2. Unintended pregnancy rate

The cumulative risk of unintended pregnancy for each participant varied because participants elected to use different methods for different periods of time and at different times during the trial. Identifying the total duration of documented contraceptive use (and no method use) by all participants during the 12-month trial period and applying the percentages of unintended pregnancy risk associated with use of each method reported in the literature, I would have expected an unintended pregnancy rate of 327 per 1000 women.

In the trial, 19 of the 128 participants we had complete data for had an unintended pregnancy during the 12-month trial period, which translates to an unintended pregnancy rate of 148 per 1000 women, approximately half the expected rate. To ensure the expected rates of unintended pregnancy associated with each method were reflective of the observed unintended pregnancy rates in our population, I adjusted the published rates (Trussell, Aiken, Micks, & Guthrie, 2018; Vaughan, Trussell, Kost, Singh, & Jones, 2008) of unintended pregnancy risk by a factor of 0.459 (Table 26). Using this factor made the expected rate (0.327) consistent with the overall observed rate (0.148) of unintended pregnancies per participant over the 12-month trial period.

Table 26. *Annual Rate of Unintended Pregnancy Risk*

Method type	Published rate	mOUD adjusted rate
No method	46.00%	21.09%
Pills	7.00%	3.21%
Patch	7.00%	3.21%
Ring	7.00%	3.21%
Injectables	4.00%	1.83%
IUD	0.32%	0.15%
Implant	0.10%	0.05%

I calculated the average (95%CI) rate of unintended pregnancy for each condition based on the duration of any documented contraceptive use (Table 25) and the corresponding adjusted rates of unintended pregnancy risk (Table 26). The average (95%CI) rate of unintended pregnancy per participant for each trial condition was 0.1948 (0.1808-0.2043) for usual care, 0.1438 (0.1193-0.1657) for contraceptive services, and 0.1008 (0.0715-0.1289) for contraceptive services + incentives. Based on these results, the estimated rate of unintended pregnancy per 1000 women is 195 for usual care, 144 for contraceptive services, and 101 for contraceptive services + incentives. Relative to usual care, contraceptive services reduced the unintended pregnancy rate by 26% (1 – 144/195) and contraceptive services + incentives reduced the rate by 48% (1-101/195). Adding

incentives to contraceptive services decreased the unintended pregnancy rate by 30% (1 - 101/144) compared to contraceptive services with no incentives.

4. Cost-effectiveness of the interventions

4.1. Willingness-to-pay threshold

The inputs and associated costs used to derive the cost of an unintended pregnancy among women with OUD in Vermont from a societal (i.e., healthcare and non-healthcare related sectors) perspective are presented in Table 27. These costs were weighted to reflect pregnancy outcomes observed during the trial: 42% (8/19) live births, 32% (6/19)

Table 27. *Estimated Costs Associated with an Unintended Pregnancy Among Women with OUD in Vermont*

	Published cost	Source	Vermont adjusted cost
Pregnancy outcome costs			
Healthcare costs:			
Spontaneous abortion	$895	Trussell et al., 2013	$297
Induced abortion	$725	Trussell et al., 2013	$361
Ectopic pregnancy	$4,511	Trussell et al., 2013	$375
Live birth	$4,729	Trussell et al., 2013	$1,714
Additional average costs, per child, incurred by all live births			
Healthcare costs:			
0-12 mo.	$11,913/yr.	Liu et al., 2019	$8,015
1-8 yrs.	$2,735/yr.	Liu et al., 2019	$4,059
9-17 yrs.	$1,836/yr.	Mirel & Carper, 2014	$1,803
Non-healthcare related costs:			
1. Childcare (6 weeks - 5 yrs.)	$10,284/yr.	Child Care Resource, 2017	$4,127
2. Education (5 - 17 yrs.)	$15,521/yr.	Kolbe & Kieran, 2017	$32,717
3. Family expenditures (0-17 yrs.)	$10,018/yr.	Lino, et al., 2017	$26,999
Additional average costs incurred by children diagnosed with NAS as an infant			
Healthcare costs:			
0-12 mo.	$58,110/yr.	Liu et al., 2019	$1,643
1-8 yrs.	$4,192/yr.	Liu et al., 2019	$2,648
Non-healthcare related costs:			
Special education services	$21,840/yr.	Kolbe & Kieran, 2017	$365
Total societal (healthcare and non-healthcare related) cost			$85,122

Note. All costs are in 2019 USD and shown as present value, calculated from birth.

therapeutic abortions, 21% (4/19) miscarriages, and 1% (1/19) ectopic pregnancies. For live births, the cost per birth was further reduced to account for mistimed pregnancies (42%), thereby incorporating only those costs that were avoidable.

4.2. Incremental cost-effectiveness ratio (ICERs)

Table 28 shows the incremental costs, incremental effectiveness, and ICERs for both intervention conditions compared to usual care and to each other.

Table 28. *Incremental Costs, Incremental Effectiveness, and Cost-Effectiveness Ratios (ICERs) for the 12-Month Trial Period*

	Contraceptive services	Contraceptive services + incentives
Incremental cost		
- Compared to usual care	$777 ($440-$1,076)	$1,302 ($1,025-$1,549)
- Compared to contraceptive services		$525 ($187-$833)
Decrease in unintended pregnancies per 1000 women		
- Compared to usual care	51 (27-77)	94 (62-124)
- Compared to contraceptive services		43 (5-78)
Cost per unintended pregnancy avoided (i.e., ICERs)		
- Compared to usual care	$15,223 ($8,155-$28,323)	$13,852 ($10,298-$20,065)
- Compared to contraceptive services		$12,225 ($5,73-$63,725)

Note. () = 95% confidence intervals. Incremental costs calculated from average cost of each condition.

4.3. Willingness-to-pay threshold and ICERs

From a societal perspective ($85,122 threshold), both contraceptive services interventions were cost saving in reducing the rate of unintended pregnancy among women receiving mOUD compared to usual care (ICERs: $15,223 and $13,852 respectively). The addition of incentives to promote visit attendance to contraceptive services resulted in an ICER of $12,225, suggesting additional cost savings of the contraceptive services interventions + incentives compared to contraceptive services, from a societal perspective.

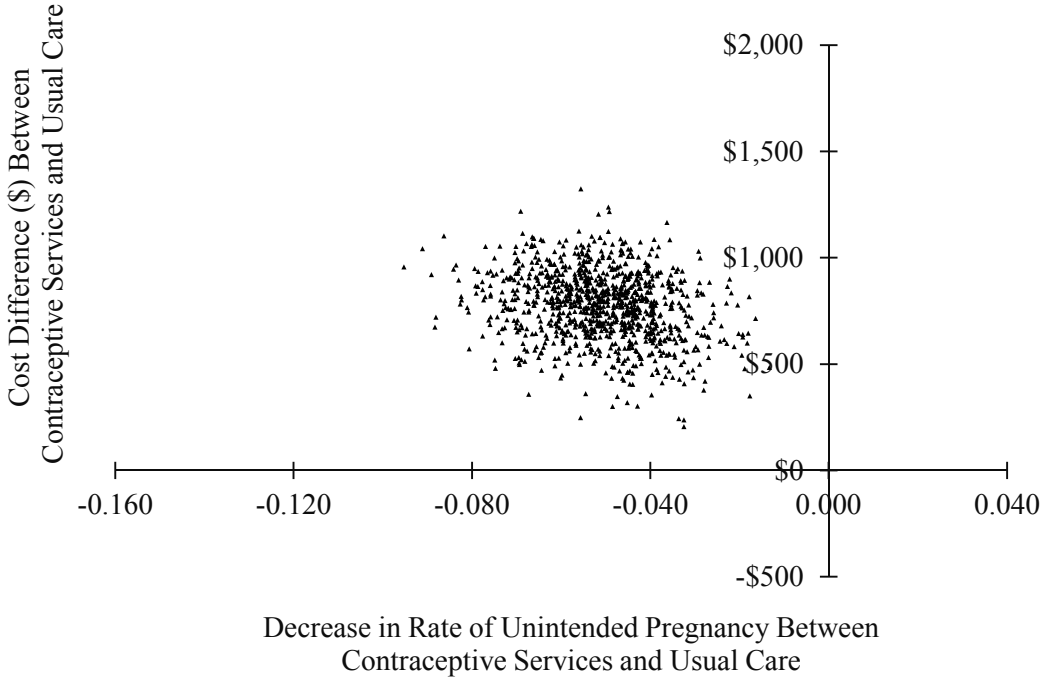
5. Sensitivity analysis

5.1. Probabilistic sensitivity analysis

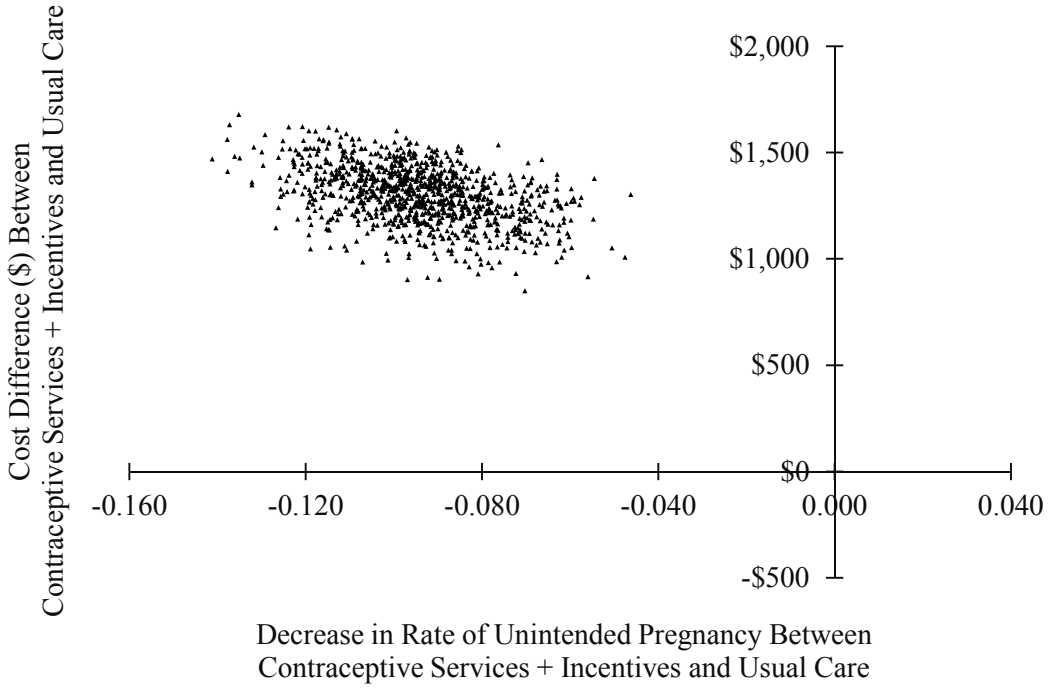
Probabilistic sensitivity analysis assessed both the range of potential outcomes and the probability of each outcome occurring. Scatterplots of the bootstrap estimates of the incremental costs and effectiveness pairs comparing each study condition to the others are presented on the incremental cost-effectiveness plane shown in Figure 5.

Figure 5. *Incremental Cost-Effectiveness Planes*

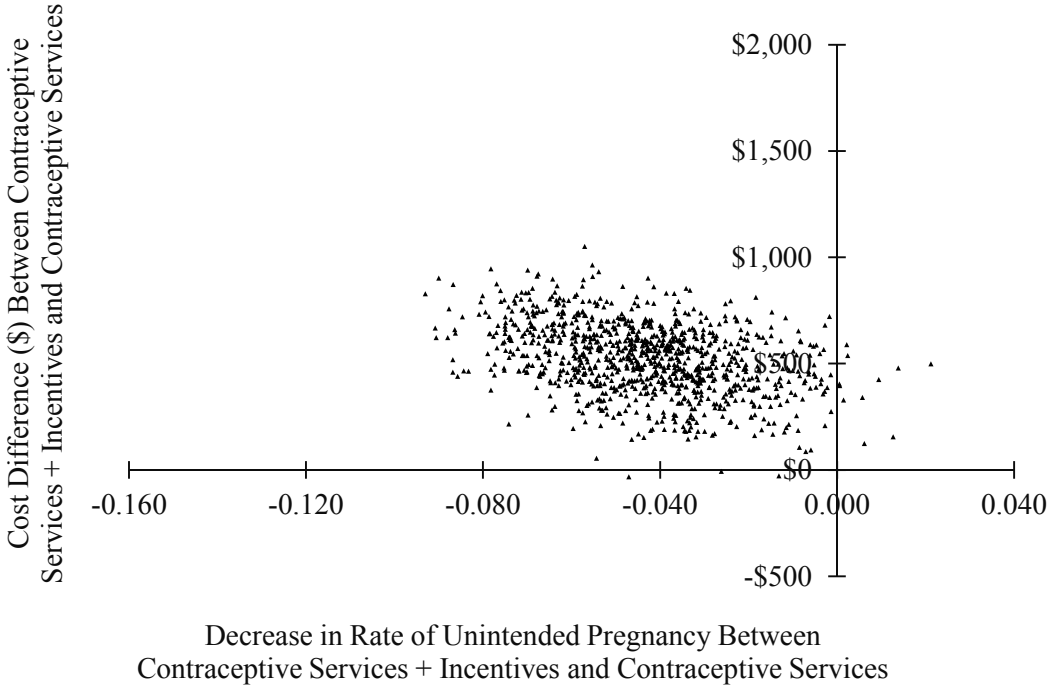
A. Contraceptive Services Compared to Usual Care



B. Contraceptive Services + Incentives Compared to Usual Care



C. Contraceptive Services + Incentives Compared to Contraceptive Services



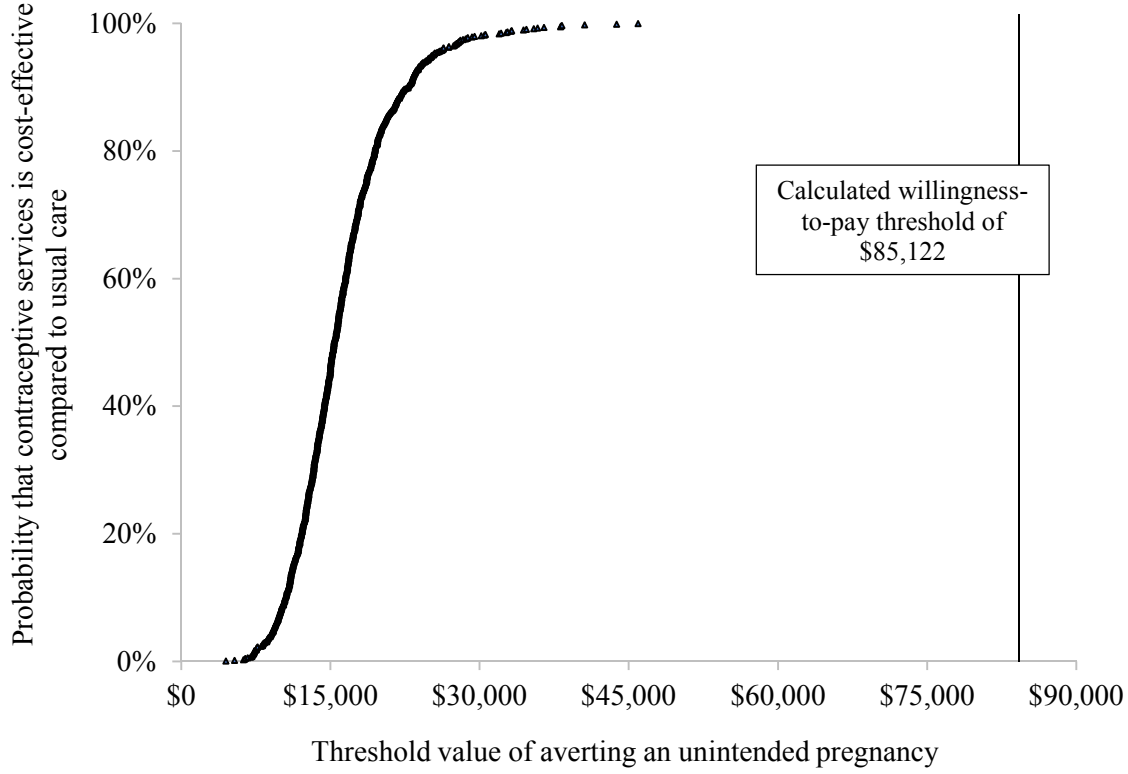
Contraceptive services + incentives compared to contraceptive services (Figure 5C) was the only scatterplot that had data points outside the upper left quadrant, 14 of the 1000 estimates. There was a 0.4% probability (4 of the 1000 bootstrapped estimates) that contraceptive services had a higher cost than contraceptive services + incentives as indicated by the four points in the lower left quadrant of Figure 5C. In addition, there was a 1.0% probability (10 of 1000 bootstrap estimates) that contraceptive services was more effective at reducing the rate of unintended pregnancy than contraceptive services + incentives, as indicated by the 10 points in the upper right quadrant of Figure 5C. However, the overwhelming majority of estimates were located in the upper left quadrant of the

scatterplot, demonstrating that the contraceptive services + incentives intervention had a higher cost and was more effective than the contraceptive services intervention.

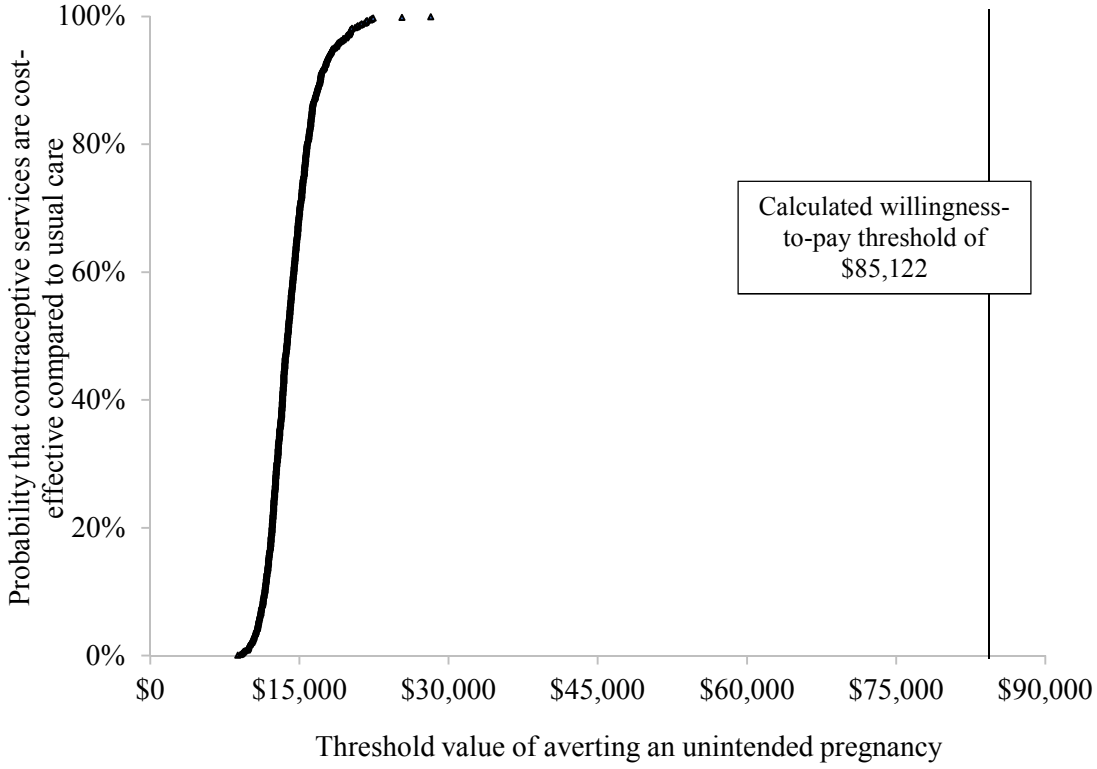
The point estimates of the ICERs were subject to minimal uncertainty as evidenced by the acceptability curves presented in Figure 6. Contraceptive services and contraceptive services + incentives had >99% probability of being cost-effective strategies compared to usual care from a societal perspective (Figure 6A and 6B, respectively). In addition, there was a >99% probability that contraceptive services + incentives was more cost-effective than contraceptive services when the willingness-to-pay threshold was $85,122 (Figure 6C). If the threshold was reduced to ~$27,000 to represent only the perinatal healthcare costs of an infant diagnosed with NAS, there would still be ~90% probability that contraceptive services + incentives was more cost-effective than contraceptive services.

Figure 6. *Cost-Effectiveness Acceptability Curves*

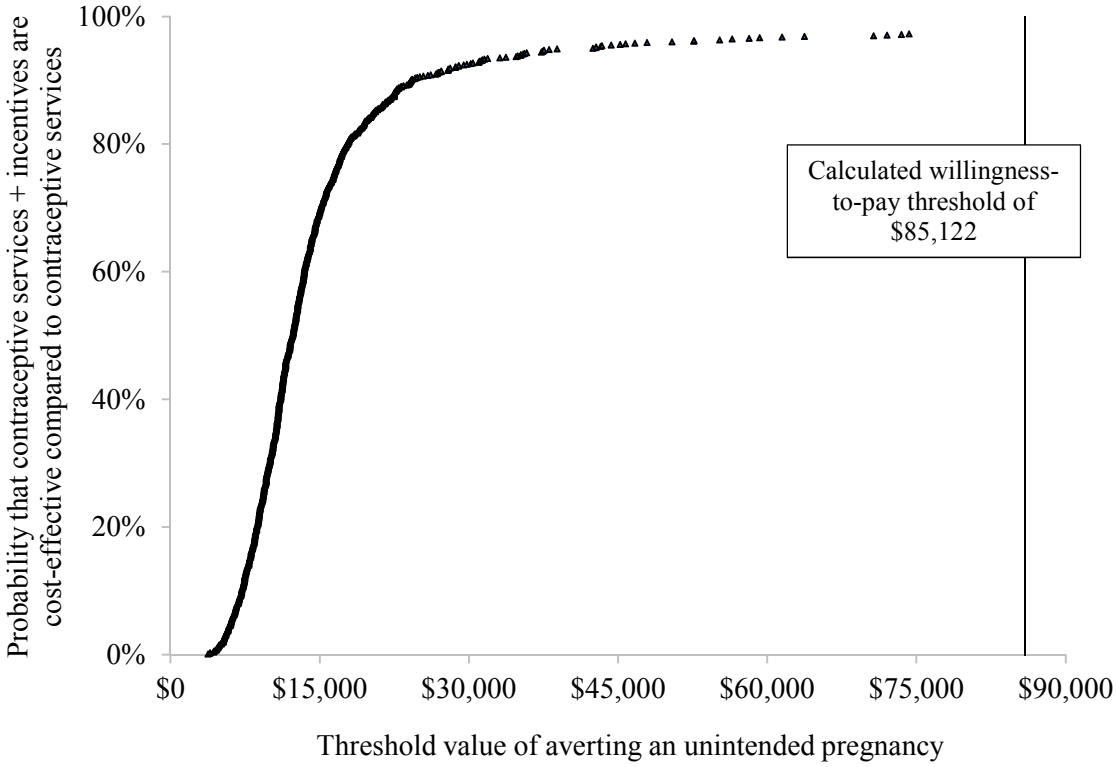
A. Contraceptive Services Compared to Usual Care



B. Contraceptive Services + Incentives Compared to Usual Care



C. Contraceptive Services + Incentives Compared to Contraceptive Services



Discussion

Results from the BCII trial demonstrated that both novel contraceptive services interventions co-located with an OUD treatment facility increased the initiation and ongoing use of prescription contraception among women receiving mOUD and at risk of unintended pregnancy. However, there is little chance that these interventions would be widely adopted in community settings without a demonstration of their economic value. While the overarching aim of healthcare services is to better patient health and well-being, payers like health insurance companies and governmental entities also consider cost-effectiveness when making decisions about covered services. In fact, one could argue that a substantial level of financial return is necessary in order for these payers to consider paying for more effective healthcare services. Without this, there is little incentive for these payers to alter their current payment structures.

To my knowledge, this study offers the first comprehensive economic analysis of contraceptive services interventions for women in treatment for SUDs and subsequent demonstration of their economic value. Compared to usual care, the estimated economic values of avoiding an unintended pregnancy with the contraceptive services intervention and the contraceptive services + incentives intervention are $15,223 and $13,852, respectively. These are both well below the willingness-to-pay threshold of $85,122 per unintended pregnancy and results of the sensitivity analysis demonstrate that both interventions have >99% probability of being cost-effective compared to the usual care condition. Even when the willingness-to-pay threshold is considered from the more limited view of just the perinatal healthcare costs of an infant diagnosed with NAS (i.e., ~$27,000), the probability that these interventions are more cost-effective than usual care remains very

high (>90%). Therefore, we can be very confident that these interventions are an economically superior option to ASAM's current policy recommendation of screening reproductive-age women for pregnancy intention at SUD intake and referring them to contraceptive and other family planning services within the community.

Results of this study also suggest that investing in provision of these interventions is not only cost-effective but would also generate substantial societal cost savings. Given the estimated $85,122 cost of an unintended pregnancy women with OUD, every dollar spent on contraceptive services or contraceptive services + incentives would result in $5.59 ($85,122/$15,223) or $6.14 ($85,122/$13,852) in societal cost savings, respectively, compared to usual care. Previous studies have overwhelmingly concluded that contraceptive use and family planning services results in considerable cost savings in the general population (Cleland et al., 2011; Frost et al., 2014; Sonfield, Hasstedt, Kavanaugh, & Anderson, 2013). These results demonstrate that interventions that increase contraceptive use among women receiving mOUD also yield substantial societal cost savings.

Beyond comparing the intervention conditions to usual care, this study also quantified the financial impact of adding incentives to contraceptive services by calculating the ICER of contraceptive services + incentives compared to contraceptive services without incentives. Adding incentives to contraceptive services increased the overall cost per participant, but also decreased the risk of unintended pregnancy compared to contraceptive services without incentives. Overall, every dollar spent on contraceptive services + incentives yielded $6.96 ($85,122/$12,225) in societal cost savings compared to contraceptive services without incentives. This value is independent of the estimated

societal cost savings described in the previous paragraph because those values represented cost savings relative to usual care. This is an unusual observation in the treatment development literature (Hunink et al., 2014). Typically, when you are trying to increase the efficacy of an intervention, additional costs are incurred that are not proportional to the benefits gained and therefore no cost savings are observed, but this was not the case when incentives were added to contraceptive services. Using incentives to promote attendance at contraceptive services appointments had a more favorable economic outcome than not using incentives.

Given these results, any opposition to the use of incentives with contraceptive services would seem negligible. However, despite their known efficacy, incentive programs have not been widely disseminated in non-research-based settings. Ethical and financial concerns are often cited as major impediments to incentive use; but a systematic review about the acceptability of using incentive programs to promote a wide range of healthy behaviors concluded that the majority of the literature criticizing incentive programs on these grounds was not empirically based (Giles, Robalino, Sniehotta, Adams, & McColl, 2015). Empirically-based research has demonstrated that using incentives appears most acceptable in situations when they are shown to be both effective and cost effective (Marteau, Ashcroft, & Oliver, 2009; Schmidt, 2008) and when they reduce barriers to care (Madison, Volpp, & Halpern, 2011; Mitchell et al., 2013; Parke, Ashcroft, Brown, Marteau, & Seale, 2013). The health and economic outcomes of the BCII trial address all three of these factors and provide important evidence that can be used to advocate for the reimbursement of healthcare costs associated with using the contraceptive services + incentive intervention in community-based settings.

It should be noted that, while contraceptive services + incentives generates societal cost savings compared to contraceptive services without incentives and should be the first-line intervention, I recognize that there may be instances where the additional upfront cost of the contraceptive services + incentives intervention (an additional $525 per woman beyond the cost of providing contraceptive services) might make it unfeasible (e.g., federal family planning block grant of a fixed amount). In these situations, implementing the contraceptive services intervention with no incentives would still generate very favorable health and economic outcomes relative to usual care. Said differently, contraceptive services without incentives should be put into practice in situations where contraceptive services + incentives is not feasible.

In assessing the cost-effectiveness of the BCII trial interventions, this analysis generated other novel findings that are contributions to the literature. This study provides the first comprehensive estimate of the healthcare and non-healthcare related (i.e., societal) costs of an unintended pregnancy among women with OUD. Assigning a monetary value to an unintended pregnancy in this population is useful because it facilitates decision making about potential utilization of interventions that reduce unintended pregnancy risk. Previously, the only costs considered in the context of unintended pregnancies among women with OUD have been based on estimates of the immediate healthcare costs of an opioid-exposed neonate, but it is important to recognize that not every unintended pregnancy results in a live birth and that there are many costs beyond the immediate postnatal period for live births that do occur.

A second novel finding from this study is the estimate of the percent of women receiving mOUD and using contraception (or no method use) who will experience an

unintended pregnancy during a 12-month period. My results suggest that among women receiving mOUD, the rate of experiencing an unintended pregnancy during a 12-month period is approximately half the rate of women in the general population. This is consistent with a very crude estimate reported by Morrison, Ruben, & Beeching (1995). There are several possible explanations for this difference. A number of studies have assessed menstrual cycle functioning among women receiving mOUD and documented high rates of irregularities or problems (Dürsteler-MacFarland et al., 2010; Gronbladh & Ohlund, 2011; Haber et al., 2017; Santen, Sofsky, Bilic, & Lippert, 1975; Schmittner, Schroeder, Epstein, & Preston, 2005). In the general population, assuming a regular menstrual cycle, it is estimated that the probability of a single act of intercourse occurring within a woman's fertile window, the only time she can become pregnant, is only 25%. Given the irregularities in menstrual cycle functioning reported by women receiving mOUD, it is likely that 25% is an overestimate and that women in this population are less at risk of getting pregnant after a single act of intercourse compared to women in the general population. Data about participants' daily sexual activity collected during the BCII trial also indicates that the frequency of sexual activity among trial participants was approximately 30% less than an established estimate from the general population (Trussell, Koenig, Ellertson, & Stewart, 1997). Less frequent sexual activity reduces the number of opportunities to become pregnant and could therefore also be contributing to the reduced rates of unintended pregnancy risk among women receiving mOUD.

This CEA has several strengths. First, the usual care condition reflects ASAM's most recent recommendation of referring reproductive-age women for contraceptive and other family planning services at SUD treatment intake (American Society of Addition

Medicine, 2017), thereby serving as an apt representation of current services to which to compare the BCII trial interventions. Second, this study provided very detailed information about the cost inputs for each trial condition. For example, all individual items and the related costs for each type of contraceptive visit provided in the trial were identified, down to the cost of a single pump of hand sanitizer, and any changes in the type of contraceptive method each participant used during the trial were documented and incorporated into the effectiveness analysis. Given that the costs of contraceptive methods and family planning services vary across the US, others can use this very thorough cataloging as a template where they can substitute their local costs to generate estimates for their area. In addition, the contraceptive visit costs are not specific to women receiving mOUD and could be used to produce cost estimates for other populations. Third, the components of the societal cost estimate of an unintended pregnancy were purposely presented by healthcare and non-healthcare related inputs to facilitate analysis from other perspectives or with different thresholds. For example, if an insurance company was trying to identify the medical costs associated with an unintended pregnancy, it would not include education and childcare costs for a child that resulted from a live birth. Thus, my results allow various decision makers to use different thresholds that reflect their particular perspective to interpret the cost-effectiveness of the BCII trial interventions.

There are some limitations to this study. This analysis was restricted to a relatively short time horizon because the BCII trial period was only 12 months long. With a longer time horizon, ha

Another limitation of the present study is the absence of potential opportunity costs of unintended pregnancies for women with OUD from the societal cost estimate of an

unintended pregnancy in this population. To date, a specific value has not been assigned to the opportunity costs of an unintended pregnancy for women in the general population, let alone women with SUDs, due to the inherent complexities of trying to quantify these costs. Many unintended pregnancies exacerbate social inequality and poor socioeconomic outcomes, especially among women who become pregnant at a young age. This is certainly pertinent to participants in the BCII trial, who reported at intake that they first became pregnant at age 19, with 89% of these pregnancies unintended and 58% ending in live births. Research by Graham and others have suggested that pregnancy and motherhood at a young age have a disruptive, long-term effect on various socio-economic indicators (Graham, 2009, 2010; Sawhill, Karpilow, & Venator, 2014). For example, having an unintended pregnancy at a young age is associated with lower educational attainment, lower income as an adult, and a lower likelihood of marriage (Ng & Kaye, 2013). In contrast, research suggests that when women are supported in planning their pregnancies, their lifetime career earnings, hours worked, and educational attainment increase (Miller, 2011; Petrilli, 2015). Research has also identified that preventing unintended pregnancies has some positive impacts on the circumstances into which a child is born and the trajectory of that child's life (Sawhill et al., 2014). Quantification of these opportunity costs would provide an even more comprehensive estimate of the costs of an unintended pregnancy among women with OUD, from a societal perspective, but doing so would not change the conclusion of the current economic analysis that both interventions are highly cost-effective and cost saving.

Conclusion

The present study is the first to estimate the economic value of contraceptive services for women in SUD treatment and the added value of incentivizing attendance at these services. Compared to usual care, both BCII trial interventions reduced the risk of unintended pregnancy and generated societal cost savings. Adding incentives to contraceptive services resulted in a larger reduction in unintended pregnancy risk and a more favorable economic outcome compared to contraceptive services with no incentives. This rigorous economic analysis supports implementing these interventions in community-based treatment settings.

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