# Supplementary Online Content

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**eMethods.** Additional Methods

This supplementary material has been provided by the authors to give readers additional information about their work.

## eMethods

### Setting, Recruitment, Eligibility, and Randomization

The opioid treatment program located in Burlington, VT, offers methadone, buprenorphine, and naltrexone. Approximately 40% of patients take their medication in person at the clinic daily; 30% take their medication in person at the clinic 1-3 times a week, with take home doses for other days; and 30% take their medication in person at the clinic 1-2 times a month, with take home doses for other days. The clinic also provides counseling as well as overdose and naloxone education and free HIV and hepatitis testing. In addition, the clinic screens for and treats other co-occurring substance use disorders, including offering medications to treat alcohol use disorder, and provides referrals to other providers for co-occurring medical and mental health issues. This menu of services is very consistent with the services reported by a majority of opioid treatment programs in a recent national survey of nearly 500 programs.[1]

Participants were recruited from the opioid treatment program between May 2015 and September 2018. Flyers advertising the trial were hung around the treatment program and the trial nurse was typically available during dosing hours three days a week to talk with potential participants about the trial, answer any questions, and collect contact information from prospective participants to schedule the screening interview. The screening interview was used to determine trial eligibility based on the following criteria:

- 18 - 44 years old
- premenopausal and no history of tubal ligation or hysterectomy
- have had heterosexual vaginal sex in the past 3 months
- have no plans to become pregnant in the next 6 months
- be at least 8 weeks postpartum
- receiving medication for opioid use disorder (OUD)
- be medically eligible to use prescription contraceptives
- report no recent prescription contraceptive method use
- not be facing imminent incarceration
- speak English

Trial staff enrolled and randomized eligible participants (1:1:1) based on computer-generated stratified randomization sequences in block sizes of six prepared by the trial statistician. Stratification variables were preferred prescription contraception method (pill, patch, or ring vs. injection, intrauterine device (IUD), or implant), age (< 35 vs. 35+), and on whether they had intentions of starting a prescription contraceptive method now or in the near future, smoked, or had a primary/steady partner (all yes/no).

### Economic Evaluation

The purpose of conducting an economic evaluation of a clinical trial is to provide guidance about utilizing a particular intervention, which maximizes a desired health outcome, given various financial constraints. Cost-effectiveness analysis and cost-benefit analysis are commonly used methods to conduct economic evaluations.[2] These approaches are not mutually exclusive as much of the information used in the analyses can be the same. The major difference between these analyses are how the health benefits (i.e., effects) of an intervention are measured. Conventionally, cost-effectiveness analysis assesses the health benefits in terms of changes in health status and quality of life.[3] The recommended and most frequently used measure of effectiveness for cost-effectiveness analysis is the quality-adjusted life-year (QALY).[4] Cost-benefit analysis assesses the health benefits using metrics other than QALYs and measures the benefit in monetary units.[5]

At the time this trial was proposed, there were few if any comprehensive economic evaluations of contraceptive or other family planning interventions in the literature but in recent years, there has been more of an emphasis on using cost-benefit analysis.[e.g., 6,7] As a result, the health benefits of the interventions both in terms of changes in health-related quality of life, consistent with a cost-effectiveness approach, and also in terms of the monetary value of avoiding an unintended pregnancy, consistent with a cost-benefit approach, were examined. Information regarding these analyses are below. First, the health-related quality of life data are presented. Second, the data about the

unintended pregnancy rate for each condition, including a description of the calculations based on documented prescription contraceptive use observed in the trial conditions, are presented. Third, the calculated costs of contraceptive services provided in the interventions and the community are presented. Finally, the calculated cost of an unintended pregnancy from a societal perspective, that is the monetary value of the outcome the interventions aimed to prevent, are presented.

**(a) Measuring health-related quality of life**

To measure if the interventions affected participants' health-related quality of life, the three-level version of the EuroQol EQ-5D (EQ-5D-3L)[8] was administered at the 1-month research assessment. This participant-level preference based health status instrument characterizes health using five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and includes both a visual analogue scale and a descriptive system. By the time participants had completed the 1-month research assessment, women in both intervention conditions (i.e., contraceptive services (CS) and contraceptive services + incentives (CS+)) had had the opportunity to complete 5 follow-up visits; on average (standard deviation, SD) the actual number of visits completed was 2.13 (1.51) for CS and 3.83 (1.67) for CS+.

The EQ-5D-3L visual analogue scale quantifies the participant's self-reported health state using a 0-100 scale, where the endpoints are labelled, "best imaginable health state" (100) and "worst imaginable health state" (0). The overall average (SD) health state women in this trial reported was 66.03 (17.83); the range was 30 – 100. There were no significant differences in health states reported by women enrolled in usual care (UC), CS, or CS+.

The EQ-5D-3L descriptive system identified participant's self-reported health state by asking participants if they had no problems, some problems, or extreme problems in five different dimensions (i.e., mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). The overall percentages of women who endorsed the severity of each EQ-5D-3L dimension are presented in eTable 1. There were no significant differences in the severity of the five EQ-5D-3L dimensions reported by women enrolled in UC, CS, or CS+.

**eTable 1.**

*Overall percentage of women who endorsed each severity level by EQ-5D-3L dimension*

| | Severity level | | |
|---|---|---|---|
| | "No problems" | "Some problems" | "Extreme problems" |
| Mobility | 78% | 22% | 0% |
| Self-care | 96% | 4% | 0% |
| Usual activities | 72% | 28% | 1% |
| Pain/discomfort | 41% | 51% | 8% |
| Anxiety/depression | 26% | 46% | 28% |

If a difference in health status had been observed between the trial conditions, the EQ-5D-3L data would have been used to identify the number of QALYs gained by each intervention and incremental cost effectiveness ratios (ICERs) would have been calculated.

**(b) Estimated rate of unintended pregnancy based on documented contraceptive use**

Although the health benefits of the interventions did not affect how participants rated their overall health state, as assessed by the EQ-5D-3L, it is well-established that a considerable benefit of using prescription contraception is avoiding an unintended pregnancy.

This trial was not powered to assess differences in the rate of unintended pregnancy between conditions. Therefore, it was necessary to use trial data about documented prescription contraceptive use and model how this use (or non-use) impacted a woman's ability to avoid an unintended pregnancy (i.e., unintended pregnancy risk).

Documented use of 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, patches, and rings were based on verified 6- and 12-month 28-day period prevalence of use and supplemented by participant self-report for the remaining 12-month trial period.

To estimate the probability of an unintended pregnancy for each participant, based on documented contraceptive use (or no method use) during the 12-month trial period, monthly rates of unintended pregnancy associated with each prescription contraceptive method, including no method use, were first derived from nationally representative data about the percentage of women who experienced an unintended pregnancy during the first year of typical use of that contraceptive method.[9,10] A one-year time horizon for contraceptive use was used because of the national data available about the effectiveness of prescription contraception in preventing unintended pregnancy.

Next, each participant's overall probability of unintended pregnancy during the 12-month trial period was derived 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 $s_2 = s_1 (1-r)$.

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, an unintended pregnancy rate of 327 per 1000 women over 12 months was expected. The overall observed rate of unintended pregnancy during the 12-month trial period was 148 per 1000 women (i.e., 19 of the 128 participants with complete data had an unintended pregnancy), approximately half the expected rate from the calculations above based on Trussell et al. and Vaughan et al.[9,10] Possible explanations for this discrepancy may be differences in fertility rates and frequency of sexual activity between women in the general population and women receiving medication for opioid use disorder (MOUD). The literature about fertility rates of women receiving MOUD is extremely limited, but there is one study that suggested the fertility rate of women receiving methadone treatment was only half that of women who did not report opioid use.[11] Data about participants' sexual activity collected during the 12-month trial period indicated that their frequency of sexual activity was approximately 30% less than an established estimate of the general population's frequency.[12] 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 during a 12-month period. To ensure the expected rates of unintended pregnancy associated with each method are reflective of the observed unintended pregnancy rates, the published rates were adjusted. A factor of 0.4585 made the expected rate (0.3273) consistent with the overall observed rate (0.1484) of unintended pregnancies per participant over the 12-month trial period. This adjustment incorporated possible differences in fertility, frequency of sexual activity, and other potentially unique characteristics of women in this trial.

All estimated costs are shown as present value, calculated from birth, adjusted for inflation using the Consumer Price Index, discounted at a rate of 3%, and are reported in 2019 US dollars.

**(c) Contraceptive services cost estimates**

The cost of contraceptive services were calculated as the product of service utilization (from trial records and the assessments completed at 1-, 3-, 6-, and 12-months following randomization) multiplied by the corresponding unit costs (utilizing a micro-costing approach and the literature).[13]

All contraceptive services provided for each participant were tracked during the trial. The unit cost of each contraceptive service was based on staff time, consumables (e.g. contraceptive methods), durable equipment (e.g. blood pressure monitor), and overhead costs to calculate the medical costs of contraceptive services provided in the trial. It was assumed that 13 packs would be required for pills, patch, and ring. The cost of hormonal IUDs, with US Food and Drug Administration (FDA)-approved life spans of 3-5 years depending on product type, and implants, a 3-year product, were amortized based on estimated survival rates of 2.34 and 2.19 years respectively, derived from the observed 12-month survival rate of these methods fit to the 6- and 12-month data assuming an exponential decay function over the approved lifespan.

Any non-medical related costs (e.g., lost time based on the value of minimum wage in Vermont and transportation costs) incurred by each participant were measured with the Brief DATCAP.[14] As expected, these costs were relatively small because the interventions were co-located with an opioid treatment clinic and the trial was sufficiently staffed such that there was no wait time for participants to complete follow-up visits. All contraceptive services visits and research assessments were conducted at this co-located site. The majority of participants scheduled their visits and/or assessments to coincide with their MOUD treatment appointments, however

participants were given the opportunity to schedule their trial-related appointments at any time during the week. After calculating all non-medical related costs, an average cost per condition was calculated.

**(d) Community provider costs**

It was expected that most community-based contraceptive services would be provided to participants in the UC 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. Costs associated with any contraceptive services obtained from community providers included visit and method costs for 12 months of contraception coverage were derived from US HCUP data and the Medicare Reimbursement Fee Schedule as described by Trussell et al.[15,16] and converted to Vermont state equivalents based on CMS estimates of Vermont's per capita healthcare expenditures relative to the national average.[17] Non-healthcare related costs for each condition (e.g., travel expenses and value of participant time) were derived from the mean of the intervention costs minus any incentive-related costs.

**(e) Probablistic sensitivity analysis**

Probabilistic sensitivity analyses were performed using Stata and using nonparametric bootstrapping with 1,000 replications randomly selecting participants of each condition to characterize cost and benefit (i.e., probability of an unintended pregnancy) parameter uncertainty simultaneously (Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC). Statistical uncertainty of the results was estimated by calculating 95% bootstrap confidence intervals (95%CI) around the point estimates, taking the 2.5 and 97.5 percentile values from simulated data in the valid range. Fourteen of the 1,000 replications were excluded where the signs of incremental costs or benefits were reversed. In 3, the incremental cost of CS+ compared to CS was negative and in 11, the incremental benefit of CS+ compared to CS was negative.

**(f) Calculating the cost of an unintended pregnancy from a societal perspective**

For this analysis and as described in more detail below, the cost of an unintended pregnancy among women with OUD was identified from both healthcare and non-healthcare care-related sector perspectives (i.e., societal perspective). To our knowledge, this cost has not been previously estimated.

Using a societal perspective means that all costs and outcomes associated with both healthcare and non-healthcare related sectors (e.g., housing, consumption, education) are considered regardless of who incurs the cost and who obtains the outcome; it is not defined as the cost to society.[3-5] This analysis was not predicated on who would pay for these costs; the objective of this assessment was to identify costs that resulted from unintended pregnancies in this population.

All healthcare costs for the unintended pregnancy cost estimate are provided in eTable 2. Healthcare costs based on national estimates from the literature were used and adjusted to Vermont state equivalents[17] because it was more representative than cost data from the state's only tertiary hospital. We are not aware of any evidence that suggests additional healthcare costs for pregnant women associated specifically with their OUD diagnosis.

Consistent with previous literature, the overall cost of an unintended pregnancy that resulted in a live birth was reduced to take into account the likelihood of an unintended pregnancy being mistimed (42% of unintended pregnancies observed in the 12-month trial period were reported mistimed); the full cost of these births should not be considered avoidable as it is assumed they will occur at some point in the future.[18]

An unintended pregnancy can have substantially different healthcare costs depending on whether it results in a spontaneous abortion, therapeutic abortion, ectopic pregnancy, or live birth. Therefore, the unintended pregnancy cost calculations were weighted to reflect the proportion of each unintended pregnancy outcome that were observed during the 12-month trial period (42% live birth, 32% therapeutic abortion, 21% miscarriage, and 5% ectopic pregnancy).

The additional healthcare costs associated with a live birth included the estimated average healthcare costs incurred by a neonate diagnosed with neonatal abstinence syndrome (NAS) from birth to age eight[19] and the estimated average healthcare costs per child, ages 9-18.[20] It was assumed that all opioid-exposed infants received a NAS diagnosis. However, it was not assumed that all infants diagnosed with NAS received pharmacological treatment,

the healthcare service that drives the substantial costs of NAS monitoring and treatment. Nationally representative data[19] were used estimate the need for pharmacological treatment and related costs.

The differences in healthcare costs by age 9 between children diagnosed with NAS vs. not appear negligible; thus the average healthcare costs for children 9-18 years old are based on children not diagnosed with NAS.[20] Hospital charges were converted to costs using the US HealthCare Cost and Utilization Project (HCUP) Kids' Inpatient Database-specific cost-to-charge ratios, based on hospital accounting reports from the Centers for Medicare and Medicaid Services (CMS).[21] US national healthcare cost estimates were converted to Vermont state equivalents based on CMS estimates of Vermont's per capita healthcare expenditures relative to the national average.[17]

**eTable 2**.
*Estimated average cost of an unintended pregnancy among women with opioid use disorder 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 |
| 9-18 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 - 18 yrs.) | $15,521/yr. | Kolbe & Kieran, 2017 | $32,717 |
| 3. Family expenditures (0-18 yrs.) | $10,018/yr. | Lino et al., 2017 | $26,999 |
| ***Additional average costs, per child, incurred by children with neonatal abstinence syndrome (NAS)*** | | | |
| 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 cost | | | |
| - Healthcare perspective | | | $20,915 |
| - Societal perspective (healthcare and non-healthcare related) | | | $85,122 |

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 US$59,200,[22] the USDA characterization that best matched the circumstances of trial participants. These national estimates were converted to Vermont equivalents based on the CMS estimate of Vermont's per capita income relative to the national average.[17] Non-healthcare related costs of a live birth also included the average Vermont-specific costs of childcare and educational services, ages 6 weeks – 18 years.[23,24] Childcare costs were assumed to exist only for those participants that reported employment (36%). Educational costs were adjusted to account for the additional costs of special education services that children with a history of NAS are more likely to incur.[25] To minimize concerns that the cost-benefit analysis incorporated societal disparities in earnings by race or gender, the distributions of these groups were not restricted when the economic cost of raising a child was estimated.[26]

An 18-year time horizon for this analysis was used because that is the period for which a child is minor and can be considered the responsibility of a parent(s). While there is a productive contribution to society over the remainder of the person's life, there are also complementary societal inputs (e.g., education) and societal resource uses (e.g. lifetime consumption); to a large extent these two elements would tend to offset one another.[27]

Unintended pregnancy can also have substantial opportunity costs for women. However, to date, a specific value has not been assigned to the any of these costs for women in the general population, let alone women with opioid or other substance use disorders, 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 this 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.[28-30] 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.[31] In contrast, research suggests that when women are supported in planning their pregnancies, their lifetime career earnings, hours worked, and educational attainment increase.[32,33] 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 only increase the estimated cost of an unintended pregnancy among women with OUD.

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