

Voucher-Based Reinforcement Therapy for Drug-Dependent Pregnant Women

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Summary

Opioid and other drug abuse during pregnancy is a leading preventable cause of fetal and neonatal morbidity and mortality. Given the limited availability of safe and effective pharmacotherapies for this population, additional interventions that address drug use and other behaviors are sorely needed. One of the most robust interventions for increasing drug abstinence is voucher-based reinforcement therapy (VBRT). The present report reviews the growing literature on VBRT interventions to promote opioid and other drug abstinence in pregnant substance abusers. Overall, results suggest that VBRT interventions can foster drug abstinence and other therapeutic behaviors in this special population.

Key Words: Reinforcement therapy - Pregnancy - Drug Dependence

Opioid and other drug abuse by pregnant women is a leading preventable cause of fetal and neonatal morbidity and mortality. While less than 5% of pregnant women self-report recent illicit drug use ⁽⁴¹⁾, results from large-scale meconium screening suggest rates at least twice that high in samples in the U.S. ⁽²⁷⁾, as well as abroad ^(31, 36, 46).

Both licit and illicit substance abuse during pregnancy increase obstetric risk, including early pregnancy loss, placental insufficiency, premature birth, low birth weight, congenital defect, and neonatal death ^(4, 7, 13, 33, 50). Prenatal substance exposure

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may also manifest itself postpartum in the form of poor cognitive skills, mental retardation, and conduct disorders^(33, 45, 50). The adverse consequences of substance abuse during pregnancy are also costly in direct economic terms. It has been estimated that the lifetime cost of caring for a child prenatally exposed to tobacco, alcohol, or other drugs is between \$750,000 and \$1.4 million⁽³⁰⁾.

For opioid-dependent pregnant women, methadone maintenance has long been recommended⁽¹²⁾ and buprenorphine is currently being evaluated as a potentially efficacious medication for perinatal addiction treatment⁽²²⁾. Though clearly beneficial, pharmacological treatments are not without consequence; infants born to agonist-maintained mothers may exhibit neonatal abstinence syndrome (NAS), a generalized disorder that includes dysfunction of the autonomic and central nervous systems, gastrointestinal and respiratory tracts^(e.g., 14) and often requires treatment with pharmacologic agents. In addition, agonist maintenance therapies for opioid dependence are rarely sufficient by themselves to manage the multitude of problems faced by opioid-dependent pregnant women. Regarding other drugs of abuse, efficacious pharmacological treatments either have not been approved (e.g., cocaine)⁽⁴⁴⁾, or their safety and efficacy during pregnancy have yet to be determined (e.g., nicotine replacement therapy)⁽⁸⁾. Given the limited availability of safe and effective pharmacotherapies for managing pregnant substance abusers, additional interventions aimed at eliminating drug and alcohol use and improving treatment attendance are sorely needed.

One of the most robust interventions for promoting drug abstinence among non-pregnant drug abusers is a behavioral treatment called contingency management. Contingency management involves systematic delivery of reinforcing or punishing consequences contingent on the occurrence of a target response, and the withholding of those consequences in the absence of the target response⁽¹⁹⁾. The CM intervention that has garnered the most research attention is voucher-based reinforcement therapy (VBRT) wherein patients receive vouchers or related monetary-based incentives exchangeable for retail items contingent on recent drug abstinence. A recent meta-analysis of 30 controlled studies of VBRT targeting drug abstinence reported that VBRT reliably and significantly improved treatment outcomes compared to control conditions⁽²⁸⁾. Across studies, three characteristics of the VBRT interventions were found to moderate the magnitude of the outcome. The first was the number of drugs targeted, meaning studies that targeted abstinence from a single drug (e.g., opioid abstinence) generally had better outcomes than studies that simultaneously targeted opioid and cocaine abstinence or polydrug abstinence. The second characteristic was voucher magnitude, meaning that studies using vouchers with greater monetary value (i.e., values of \$5.00 and above per day) generally had better outcomes. The third characteristic was the immediacy of the voucher delivery, such that studies that delivered the voucher immediately after verifying abstinence (i.e., same clinic visit) rather than later generally had better outcomes. Overall, this report provided quantitative evidence supporting the efficacy of VBRT for the treatment of substance use disorders as well as practically useful information to those considering the use of VBRT.

While the majority of the studies reviewed in that meta-analysis were performed with non-pregnant substance abusers, a small number focused on pregnant substance abusers and they also reported favorable outcomes. This prompted us to review the extant literature on VBRT interventions to promote drug abstinence in pregnant women with substance abuse disorders. Included in our review are the two reports covered in that meta-analysis, but also nine additional reports that did not meet the various criteria for inclusion in the meta-analysis. The results of our qualitative review were also presented at the 2006 EUROPAD Conference in Bratislava, Slovak Republic as part of a symposium on new approaches in the treatment of opioid dependency during pregnancy. While we certainly include studies targeting opioid-dependent pregnant women in the present report, we did not limit ourselves to this drug class. The meta-analysis described above found that the three moderating characteristics of VBRT interventions (number of targets, reinforcer magnitude, and immediacy of reinforcement) are more critical to the success of this approach than the particular drug(s) targeted. Overall, our review of the growing scientific literature on the efficacy of VBRT with substance-abusing pregnant women suggests likewise that this intervention has equal potential to benefit opioid- and other drug-dependent pregnant women.

VBRT Interventions Targeting Drug Abstinence in Pregnant Women

Cocaine

The first successful use of VBRT in this population targeted cocaine use by pregnant women. In the early 1990s, the need for cocaine treatment in the general population had increased sharply and there was particular concern about cocaine use by pregnant women and the fate of children who had been exposed to cocaine in utero^(32, 34, 35). Our group demonstrated the efficacy of voucher-based incentives combined with psychosocial counseling for treating cocaine dependence in non-pregnant populations⁽¹⁵⁻¹⁷⁾. Following these reports, Elk and colleagues⁽¹¹⁾ examined the use of incentives to promote cocaine abstinence in pregnant women using a multiple-baseline across participants design. During the baseline phase (average duration = 2 weeks), urine samples were collected thrice weekly and tested for cocaine and all participants were expected to attend weekly prenatal care visits. No explicit contingencies were placed on either behavior. During the intervention phase (average duration = 10 weeks), all participants received \$10 each time their urine sample results indicated a significant decrease ($\geq 15\%$) in cocaine metabolite levels relative to her prior sample or \$12 for each sample that was cocaine-negative. A participant could also earn a \$15 bonus each week if (1) all three urine samples met the criteria above and (2) she attended her weekly prenatal care visit. Incentives earned at one visit were paid out at the participant's next visit. On average, participants submitted twice as many cocaine-negative urine samples during the intervention phase compared to the baseline phase (52% vs. 25%). Attendance at prenatal care visits was also increased during the intervention phase. These results provided the first evidence of the efficacy of VBRT in pregnant substance abusers.

Smoking

One of the most promising targets of VBRT interventions to date is smoking during pregnancy and postpartum. The majority of trials examining the efficacy of smoking cessation interventions have not resulted in significant differences in end-of-pregnancy quit rates in experimental compared to control conditions, with quit rates often below 20%⁽²⁾. Three published reports have examined the efficacy of VBRT to promote smoking cessation during pregnancy and postpartum. The seminal study on the use of incentives with pregnant and postpartum smokers examined the efficacy of this approach among pregnant and postpartum women residing in a residential treatment program for other types of substance abuse⁽²⁶⁾. Carbon monoxide (CO) levels were measured daily for approximately 8 weeks. Each day that a participant's CO level indicated smoking abstinence, she earned a credit that could be accumulated and redeemed for program privileges (e.g., extra phone or pass time) or prizes donated by community businesses (e.g., jewelry, children's toys, hair cuts, etc.). Women who received incentives had lower mean daily CO levels compared to participants in another residential substance abuse treatment program for pregnant and postpartum women in the same area who simply provided daily CO samples, but did not receive any incentives (3.07 vs. 12.42, respectively). This study provided compelling evidence that smoking is sensitive to VBRT interventions.

A second report describes a more rigorous randomized trial involving low-income pregnant smokers⁽⁹⁾. Women were randomly assigned to VBRT or usual-care control conditions. In the VBRT condition, they received a monthly \$50 voucher contingent on biochemically-verified smoking abstinence throughout pregnancy and for two months postpartum. Additionally, women in the VBRT condition included a "Social Supporter" in treatment (i.e., a female non-smoker with whom the subject had a positive association) who also received vouchers when the subject was abstinent (i.e., a \$50 voucher in the first and last months and a \$25 voucher in each intervening month). Abstinence rates were significantly greater in the VBRT compared to the control condition at the end of pregnancy (34% vs. 9%, respectively) and the end of the voucher program at 2-months postpartum (22% vs. 6%, respectively). These results provided additional evidence that the low quit rates typically observed among low-income, pregnant smokers are not inevitable and that relapse rates postpartum are modifiable.

In our effort to further extend this approach, we conducted a pilot study with low-income women who were still smoking upon entering prenatal care⁽¹⁸⁾. Participants were initially assigned to either contingent or non-contingent voucher conditions as consecutive admissions and later randomly. Vouchers were available antepartum and through 12 weeks postpartum, and earned for biochemically-verified smoking abstinence in the contingent condition and independent of smoking status in the non-contingent condition. Biochemically-verified, 7-day point-prevalence abstinence was significantly greater in the contingent than the non-contingent condition at the end-of-pregnancy (37% vs. 9%, respectively), 12-week postpartum (33% vs. 0%, respectively), and 24-week postpartum (27% vs. 0%, respectively) assessments. Note that the 24-week assessment

occurred 12 weeks after vouchers were discontinued. Total mean voucher earnings across antepartum and postpartum were $\$397 \pm 414$ and $\$313 \pm 142$ in the contingent and non-contingent conditions. The magnitude of these treatment effects were consistent with those reported by Donatelle et al. ⁽⁹⁾ and exceeded levels typically observed with low-income pregnant and recently postpartum smokers. Additionally, the maintenance of significant treatment effects through 24-weeks postpartum extended the duration of treatment effects beyond any reported previously in this population. We have recently replicated these results in a fully randomized trial (Heil et al., in preparation).

Overall, these results combined with those of the prior reports suggest that smoking during pregnancy and the early postpartum period is a promising target for VBRT research and dissemination.

Opioids

One of the most powerful and innovative demonstrations of the efficacy of VBRT to date is the work of Silverman and colleagues and their Therapeutic Workplace intervention developed for opioid-dependent pregnant and postpartum women. In the Therapeutic Workplace, patients are hired and paid to work in a model work program. Salary is linked to abstinence by requiring patients to provide objective evidence of abstinence (i.e., a drug-free urine) to gain entrance to the workplace. Therefore, patients work and earn salary only when abstinent. In addition, the daily salary increases as the patient's duration of sustained abstinence and workplace attendance increases. In the Workplace, patients participate in intensive job skills training until they meet strict criteria of sustained abstinence, workplace attendance, job skills and professional demeanor. Once these criteria are achieved, patients can be hired as employees in an income-producing Therapeutic Workplace business, Hopkins Data Services ⁽⁴⁰⁾. This approach aims to address a fundamental difficulty that many substance-abusing women face; that is, the gap that exists between their occupational interests and their actual academic abilities ⁽³⁷⁾. In addition, because employment can be sustained for years, this approach offers the possible advantage of maintaining high-magnitude salary-based abstinence reinforcement over extended periods of time.

In the first evaluation of this intervention ⁽³⁸⁾, forty women were randomly assigned to either the Therapeutic Workplace group or to a usual care control group. All participants were methadone-maintained pregnant and postpartum women, only 10% of whom reported periods of full-time employment in the three years prior to study entry. Urine samples were collected thrice weekly during the 24-week intervention in both groups and participants were compensated \$3.50 for each sample. In the Therapeutic Workplace group, urine samples that were negative for opiates and cocaine allowed the participant to enter the workplace that day. In the workplace, patients participated in basic skills education and job skills training in 3-hour work shifts. On the first day a participant provided a negative urine sample and completed a 3-hour work shift, she earned a \$7 voucher. Vouchers increased in value by \$.50 for each consecutive successful day, to a maximum of \$27. A drug-positive sample or failure to provide a sample reset the voucher value back to \$7. After a reset, nine consecutive days of abstinence

and workplace attendance returned the voucher value back to the pre-reset value. The majority of a participant's earning potential came from these contingencies promoting abstinence and attendance, but modest incentives were also available for productivity, punctuality, and professional behavior.

The results of the initial evaluation of the Therapeutic Workplace's effects on abstinence and attendance were quite promising. Over the course of the intervention, Therapeutic Workplace participants provided nearly twice as many cocaine- and opiate-negative urine samples compared to the usual care control condition (59% vs. 33%, respectively). On average, 45% of the Therapeutic Workplace participants attended the workplace on a given day. In total, Therapeutic Workplace participants earned an average of \$1,013 (range = \$0 to \$3,126) over the 6-month intervention period.

The Therapeutic Workplace participants were repeatedly offered re-enrollment in 6-month blocks to examine the long-term effects of the intervention. A second article by Silverman and colleagues⁽³⁹⁾ reported abstinence outcomes based on urine samples collected at monthly assessments between months 18 and 36. Relative to the usual care control group, cocaine and opiate abstinence was significantly higher in Therapeutic Workplace participants (28% vs. 54% and 37% vs. 60%, respectively). In addition, Therapeutic Workplace participants were six times more likely to show evidence of continuous cocaine and opiate abstinence over this extended assessment period than the usual care group (30% vs. 5%, respectively). Across the entire 36-month intervention period, Therapeutic Workplace participants attended the workplace on 43% of the 780 workdays and had earned an average of \$10.73 each workday in vouchers. Together, these two reports provide a unique demonstration of the ability of VBRT to produce long-term changes in drug use in an especially recalcitrant population.

Reports with Negative Outcomes

While the results of the studies described above appear quite promising, there are a similar number of studies with substance-abusing pregnant women where the results indicated no advantage of the VBRT intervention^(5, 6, 10, 23, 25). As described previously, our group's examination of moderators of the efficacy of VBRT interventions found that studies with single drug targets, relatively larger magnitude reinforcers, and immediate voucher delivery were associated with better outcomes. Consistent with these findings, it appears that many of the studies with negative results simultaneously targeted multiple drugs^(5, 6, 23, 25), had relatively low magnitude reinforcers^(5, 6) and/or the immediacy of voucher delivery could not be determined, suggesting that it was delayed^(5, 6).

Studies Targeting Outcome Measures Other Than Abstinence

In addition to the 11 studies using VBRT to target drug abstinence, our search of the literature also identified six studies targeting other outcomes. Three of the six^(23, 24, 43) were a series of studies targeting treatment attendance at the Center for Addiction and Pregnancy in Baltimore, MD⁽²¹⁾. Treatment attendance is related to positive treatment outcome and dropout is associated with relapse and adverse effects on the mother

and the baby^(20, 29, 42). Thus, improving treatment attendance is another mechanism by which maternal and fetal/neonatal outcomes may be enhanced. The remaining 3 studies⁽⁴⁷⁻⁴⁹⁾ targeting other outcomes all took place in the context of the Therapeutic Workplace intervention described above and were efforts to modify other types of behavior relevant to employment settings, such as on-time attendance. Overall, the results of all six studies were favorable and suggest that VBRT can facilitate other therapeutic changes. However, given the small number of reports currently in this literature, additional experimental studies are needed to more fully flesh out this area. Nevertheless, we see no reason to expect that the same variables shown to be significant moderators in interventions targeting drug abstinence would not extend to studies on attendance and other behaviors.

Disseminating Use of VBRT Interventions During Pregnancy

Overall, the results of studies to date on the use of VBRT in the treatment of pregnant and postpartum women with substance use disorders suggest that VBRT significantly improves treatment outcomes in this population. Replications and extensions of the studies reviewed here, including trials by other groups of investigators, are needed to further strengthen this literature. However, the data are sufficiently compelling and the consequences of continued substance abuse during pregnancy sufficiently dire that dissemination of VBRT interventions for pregnant substance abusers appears warranted at this time. One potential challenge facing dissemination of VBRT interventions with this population outside of the research clinic is the cost. However, pregnant women are likely a population where cost is less of an issue for at least two reasons. First, while most people find the idea of a pregnant woman using drugs disturbing and difficult to understand, they are also sympathetic to the fact that the fetus is potentially being harmed. As a result, communities may be more willing to support VBRT interventions targeting substance abuse by a pregnant woman to protect the health of the fetus. One form of support already documented in this literature is donation of goods and services to be used as incentives. In the reports by Ker et al.⁽²⁶⁾ and Donatelle et al.⁽⁹⁾ described above, incentives for their smoking cessation interventions were provided by or purchased with funds donated by community agencies. Amass and Kamein⁽¹⁾ previously reported results from successful donation solicitation programs to supply incentives for VBRT interventions for substance abusing pregnant and parenting women and their methods can serve as a guide for similar campaigns.

A second reason that the cost of VBRT interventions may be less of an issue when those interventions are directed at substance-abusing pregnant women is that cost-benefit analyses are relatively easily calculated and compelling in this population. For example, Svikis et al.⁽⁴²⁾ calculated the average cost of initial neonatal hospital stays following delivery in women who abused opioids, cocaine, and other drugs during pregnancy, but did not receive substance abuse treatment. The mean cost was \$12,183. Assuming a conservative 5% increase (e.g.,³) in health care costs each year since 1992

when these data were collected, that figure has nearly doubled to \$24,039. Further, these are conservative cost estimates in that they are limited to only those costs associated with admission to neonatal intensive care units (NICU), suggesting that the true costs are significantly higher. Thus, the economic benefit of reducing or eliminating substance abuse by pregnant women using VBRT interventions would appear to be quite economical and justifiable.

Summary

This review merits several comments and conclusions regarding the use of VBRT interventions to promote opioid and other drug abstinence and other behavior change in pregnant and postpartum women with substance abuse disorders. The overarching point to be noted is that the evidence to date suggests that VBRT significantly improves treatment outcomes in this population. Consistent with research in non-pregnant populations, studies with single drug targets, relatively larger magnitude reinforcement, and/or immediate voucher delivery tended to have positive outcomes. As such, this review provides evidence supporting the efficacy of this approach and suggests that dissemination efforts are warranted. To that end, this review also highlights a number of the innovative settings and funding strategies that researchers in this area have examined, including models such as the Therapeutic Workplace and creative and practical demonstrations of how VBRT programs can be funded outside of the research clinic. Future research replicating and extending these findings will provide additional evidence to further develop the use of this promising intervention in this truly special population.

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