Pregnancy Smoking Cessation Program Quality Assurance Monitoring & Evaluation

FINAL REPORT

Produced by JSI Research & Training Institute, Inc.

I

INTRODUCTION

BACKGROUND[1]

The Vermont Department of Health administers cessation, media, community, youth, and evaluation components of the program through a combination of Centers of Disease Control and Prevention (CDC) funds and state dollars contributed by the tobacco industry through the Master Settlement Agreement.

In addition to these three existing program goals (to prevent youth from smoking, reduce adult smoking and reduce secondhand smoke exposure), the CDC recommends including a fourth program goal, addressing health disparities. To that end, the Vermont Department of Health, Tobacco Control Program and its partners performed a comprehensive review of statewide prevalence data, trends and capacity for change. The result was a collaborative plan with an initial focus on two groups of Vermonters: 1.) Those with a lower socioeconomic status; and, 2.) those with mental health and co-occurring substance abuse issues.

These segments of the population have some of the highest smoking rates in the state, and those rates are not decreasing like the other segments of the population.

Low-income women who are pregnant are a smaller segment of the lower socioeconomic status population, which smoke. According to Vermont's Birth Certificate data, the rate of smoking among pregnant women in 2006 was 18%, equal to that of the general population. When using education as a proxy for income, 56% of women with less than a high school degree smoke. The Vermont Department of Health Women, Infants and Children (WIC) nutritional program reach these women through clinics held in the twelve local health offices throughout the state. The WIC goal is to improve health by informing families about good health practices and by providing nutritious foods to eligible Vermonters. Every year, thousands of women, infants and children receive health screenings, nutrition assessments and health education from the Vermont WIC program.

The Vermont Department of Health and their partners developed two plans that address tobacco health disparities: 1.) Bridging the Gap: Addressing Tobacco Related Health Disparities (2007); and, 2.) A Statewide Strategic Plan: Smoking Cessation during Pregnancy Identifying and Eliminating Tobacco Related Disparities in Vermont (2006) which positioned them to implement and evaluate promising programs to the disparate populations.

In spring 2009, Vermont Department of Health, Tobacco Control Program contracted with JSI Research & Training Institute, Inc. to conduct quality assurance monitoring and evaluation of its pilot smoking cessation during pregnancy incentive

[1]The Background statement is taken in its entirety from the Vermont Department of Health, Tobacco Control Program.

program currently operating in the Rutland and Newport district offices. The objective of the incentive program is to support and encourage quitting smoking early and throughout the pregnancy by recruiting women who smoke among the clients seeking WIC nutritional services. In addition, all local health offices are working on systems to improve the ask, advise and refer brief intervention among pregnant women. Linking women who access services locally to the existing smoking cessation services offered through the Vermont Quit Network aligns with the goal to reduce smoking while improving the outcomes for newborns.

The following report details JSI's study approach, findings and conclusions following a literature review, quality assurance monitoring and evaluation activities of the VDH Pregnancy Smoking Cessation Program.

II

LITERATURE REVIEW

The VDH Pregnancy Smoking Cessation Program relies on incentives in the form of cash vouchers which are awarded to pregnant women who quit smoking and remain abstinent throughout their pregnancies. This type of intervention is called "contingency management" (CM) in that receipt of a reward is contingent on objectively verified abstinence from the substance in question, in this case nicotine. Contingency management programs may use positive and/or negative incentives. As one would expect, the positive incentive is a reward for compliant, independently verified behavior. A negative incentive, applied after non compliant behavior or a missed contact is verified, may be a suspension of or reduction in future awards.

To inform the process evaluation and data analysis of the Pregnancy Smoking Cessation Program, JSI conducted a review of relevant literature for the Vermont Department of Health. This report describes the methods and key findings of the literature review. The purpose of the review was to examine the published literature seeking answers to the following questions:

- How effective are incentive-based interventions for health behavior change and for smoking cessation specifically?
- How effective are incentive-based interventions for prenatal smoking cessation versus other evidence-based prenatal smoking cessation interventions?

Answers to these questions are intended to help inform future policy and program decisions to effect reductions in the prevalence of prenatal smoking in Vermont.

To address these questions an extensive literature search was conducted on contingency management (CM), narrowing the purview by excluding research on incentive-based interventions in drug treatment settings. CM is a well-established strategy in these settings, and researchers have built on that foundation as they develop the evidence in other directions; thus, the search for CM interventions for health behavior change (e.g. weight control), smoking cessation and prenatal smoking cessation, specifically evolved. Also included in the review were key findings in the areas of prenatal smoking prevalence, cessation and postpartum relapse. Summaries of these articles along with their abstracts are included in Appendix 1.

Search Methods and Data Abstraction

Because a simple search for CM citations would generate an overwhelming number of items, the following key literature reviews/summaries were used as starting points:

Contingency Management

- Impact of Targeted Financial Incentives On Personal Health Behavior: A Review of the Literature (Sage, 2008),

- Competitions and incentives for smoking cessation (Cochrane, 2009),

Prenatal Smoking Cessation and Relapse

- Treating Tobacco Use and Dependence: 2008 Update. USPHS Clinical Practice Guideline.
- Interventions for promoting smoking cessation during pregnancy (Cochrane, 2004),
- Relapse prevention interventions for smoking cessation (Cochrane, 2009) and
- PRAMS 2000-2005 (CDC, 2009).

Databases MEDLINE, EMBASE and PubMed, and CORK were then used to search for relevant, peer reviewed articles published subsequent to them. Focus attention was directed to articles published after 2007 when the VDH evidence-based Pregnancy Cessation Program protocol was first developed. Three additional literature reviews on CM were identified, along with five later studies to include in this report. Four seminal articles published previously were also included. The most recent searches were conducted in June 2009.

Articles were systematically read with data extracted according to a template developed for the project. Articles were summarized in quick reference tables. The synthesis of themes follows, and summary tables are presented in the following section of the report.

LITERATURE REVIEW

The literature review findings are presented as themes and key points under four headings corresponding to four separate lines of inquiry of the literature review.

Contingency Management Literature Reviews

Five literature reviews focusing on Contingency Management were included, two published in 2009 (Cahill, Volpp), two in 2008 (Sutherland, Sindelar) and one in 2004 (Donatelle). All of the articles focused on behavior change or health outcomes, e.g., weight reduction, physical activity, diet, cholesterol management, medication compliance, medical appointment keeping, smoking cessation and prenatal smoking cessation. Three reviews focused incentive-based interventions in community, workplace and clinical settings (Cahill, Volpp, Sutherland); two (Sindelar, Donatelle) reviewed clinical studies only. Of the five review articles, two (Cahill, Donatelle) focused exclusively on smoking cessation; one of them (Donatelle), on prenatal cessation. All provide valuable commentary on the strengths and limitations of the existing evidence.

Conclusions about the immediate effectiveness of interventions focusing on a range of health behaviors/outcomes (Cahill, Volpp, Sutherland) were mixed—though definitely leaning in a positive direction. Generally, studies included in the reviews demonstrated positive results during the incenting process, however gains made in nearly every study dissipated upon follow up in the post incentive phase.

Sutherland makes note of previous research where behavior change might be classified as simple or complex (simple=completing a health risk assessment; complex=changing dietary patterns to achieve weight loss). He suggests small incentive might be all that is necessary to bring about the desired change in the first case, but that a more sophisticated reward program, incorporating various different incentives over a period of time, might be needed to accomplish the second type of change.

Sutherland and Volpp conclude that CM approaches have been shown to be highly effective in:

1. Worksites. Programs involving financial incentives can contribute to promoting healthy

behaviors, although evidence of long term effects is weak.

2. Clinical settings. There is evidence that patient incentives can increase short term behavior changes: e.g., recommended vaccinations, adherence to appointment keeping

In the area of smoking cessation, the 2009 Cochrane Review, Competitions and incentives for smoking cessation (Cahill), concludes, with 17 studies reviewed (none focusing on prenatal cessation), that there is no significant effect of rewards, competitions or incentives on smoking abstinence at the longest follow up. Cahill notes, however, that several studies identified higher early and medium-term abstinence rates for the intervention groups. Unfortunately, in her analysis, the studies which documented earlier abstinence are not identified.

A 2004 review of the CM literature (Donatelle) offered similar conclusions on incentive-based interventions for smoking cessation and noted, "From these studies, it appears that incentives or CM may have potential for motivating short-term abstinence, particularly in controlled, clinical or outpatient settings with special subsets of the population."

Research using CM to motivate women who are pregnant to quit is in short supply. Donatelle's 2004 review is included here because she highlighted five of her own promising CM research studies in the area of prenatal smoking cessation, one (2000) is discussed in a later section. Three of her small trials, each with different incenting schemes, showed biometrically verified, end-of-pregnancy quit rates ranging from 21% to 32%. At the time of publication Donatelle was PI of a larger randomized controlled trial—also with differing incenting configurations—funded by the Robert Wood Johnson Foundation that was currently enrolling subjects. *The project team was unable to locate any later references to this work other than three PowerPoint presentations on the same preliminary results given in 2004*. The same article highlights a fifth trial by Higgins, et al. that was showing very promising early results in the first two antepartum assessments (CM=40% vs. Non-CM=10%). *Similarly, reference to this research in later peer reviewed journals could not be located.*

Additional themes from the literature reviews include these:

- Positive incentive schedules have been shown to influence behaviors in clinical trials but have not been developed into population-based policies for governments, employers, individuals and families. As previously mentioned, positive incentive is a reward for compliant, independently verified behavior.
- Differing definitions of abstinence from smoking complicate discussion of outcomes (Cahill).
- The threshold level at which quitting behavior is maximized by amount of incentives provided has not been established (Donatelle, Cahill).
- Concerns about CM include cost, cost-effectiveness, financing, fairness and durability of the treatment. Costs and cost-effectiveness are particularly relevant because most addiction treatment is publicly financed and these systems are already financially strapped (Volpp, Sindelar, Donatelle).
- In prenatal settings, published, peer-reviewed findings related to smoking cessation are based on a limited number of trials that have relatively small sample sizes (Sutherland, Donatelle).

Contingency Management and Health Behavior Change Studies

A 2008 article is included detailing a randomized trial of financial incentive–based approaches for weight loss (Volpp). Also included are two additional articles on randomized controlled studies testing CM and Smoking Cessation, both from 2009 (Tevyaw and Volpp).

The outcomes of Volpp's weight loss study mirror the conclusions of Cahill, Volpp and Sutherland in that positive results during the incenting process dissipated upon follow up in the post incentive phase. Of interest, however, is that the two CM arms of the study required subjects to weigh themselves every day (seven days a week) and report those results to a program staff member. It is difficult to parse out whether the CM groups' significantly better results during the incenting phase are due in part to this daily contact, a condition unique to this study.

Tevyaw tested the effect of financial incentives on abstinence from smoking and interest in quitting with non-treatment seeking college students. The study showed that, among these smokers with no apparent motivation to quit, incentives had little effect. While the adoption of the 5As of the trans-theoretical model of behavior change in clinical settings is promoted (and this finding is consistent with it), it is important to keep in mind that in pregnancy, stage of change theory in readiness to stop smoking does not apply (discussed in next section). Thus, the use of incentives with pregnant women who are resistant to change would not contradict these findings.

Volpp's 2009 CM study on smoking compared outcomes between a non-contingent condition where subjects were given information about smoking cessation programs and a contingent condition where subjects were offered the same information along with $100 upon completion of a smoking-cessation program, $250 with cessation within 6 months, and $400 with abstinence for additional 6 mos. after initial cessation. CM showed impressively higher rates of enrollment in a cessation program and completion of that program, higher rates of abstinence within the first 6 months after enrollment and at 9 or 12 months. The effect diminished however at 15 to 18 months, though it remained higher than that of the Non-CM group. In his commentary, Volpp notes, "A 2004 Cochrane Collaboration review of financial incentives for smoking cessation in workplace settings concluded that there was insufficient evidence that these incentives are effective. One reason for this finding may be that many previous studies were not designed with samples that were large enough to detect the differences we observed. A second reason may be that the incentives used in previous studies have generally been small (as little as $10 in some of them)."

Contingency Management and Prenatal Smoking Cessation Studies

Three articles on contingency management and prenatal smoking cessation are included. The first is Donatelle's groundbreaking 2000 randomized controlled trial using social support, financial incentives with community support for high-risk pregnant smokers who were WIC enrollees. The second and third are a 2004 pilot study (Higgins) and a 2008 randomized controlled trial (Heil) on the effects of voucher-based incentives on abstinence from cigarette smoking and (in 2008) fetal growth among pregnant women. It is this research, conducted by the University of Vermont (UVM) with obstetrical patients drawn from Burlington practices, that inspired the rationale and protocol

for the VDH Pregnancy Smoking Cessation Program. Collectively, these three are the only peer-reviewed articles on incentive-based prenatal smoking cessation that could be located. That said, the results of these studies are impressive.

Donatelle's research contrasted usual care alone (information on the importance of smoking and a pregnancy- specific smoking cessation self help kit) with usual care plus bolstered social support, financial incentives and community support. Biochemically verified abstinence at 8 months gestation was 32% and 9% in the contingent and non-contingent groups, respectively. At two months postpartum, biochemically verified abstinence was 21% (CM) and 6% (non-CM). Donatelle emphasizes the importance of community support, particularly in terms of donations of incentives. Incentive vouchers were purchased with funds voluntarily donated by 10 "community partners," healthcare organizations, businesses, and foundations.

Two major limitations are noted. First, is loss to follow up in both the treatment and control groups at each of the follow up assessments: (a) treatment loss to follow up was 32% at eight months gestation, and 36% at two months postpartum; (b) control loss to follow up was 51.5% at eight months gestation, and 52% at two months postpartum. The author asserts that WIC in general has a loss to follow up/no show rate consistent with loss to follow up experienced with the intervention. Second, Donatelle's study design did not allow analysis of whether the combined effect of social support and financial incentives was greater than the sum of either social support or incentives applied independently. Donatelle's Robert Wood Johnson (RWJ) funded randomized controlled trial, described previously, was designed to tease out these distinctions. The results of this research, as far as can be ascertained, were not published in a peer reviewed journal, and a copy of the RWJ end-of-grant report could not be obtained.

Donatelle's generation of community support for funding incentives contributes to the sustainability of the program by allowing local organizations to actualize the idea that being smoke-free during pregnancy yields benefits for the entire community. Wider, sustainable dissemination of the intervention would require broader financial support perhaps from insurers or foundations.

UVM's pilot (2004) and, later (2008), randomized controlled trials (n=53, n=77, respectively) showed even greater effects. For both trials, in the CM groups, financial incentives were earned for biochemically verified smoking abstinence; in the non-CM groups the incentives were earned independent of smoking status. All subjects received usual care from their obstetrics providers which usually included being asked about smoking and being advised to quit. Also, all subjects reviewed a pregnancy-specific pamphlet on smoking cessation as part of the study intake. Those not smoking at the end of pregnancy received a pamphlet detailing the benefits of continued abstinence

In the pilot, CM abstinence at the end-of-pregnancy was 37% vs. 9% for non-CM. At 12-weeks postpartum CM abstinence was 33% vs. 0% for non-CM. That effect was sustained through the 24-week postpartum assessment (27% vs. 0%), which was 12 weeks after discontinuation of the voucher program. In the later randomized controlled trial, CM abstinence at the end-of-pregnancy was 41% vs. 10% for non-CM. At 12-weeks postpartum CM abstinence was 24% vs. 3% for non-CM. However, abstinence at the 24-week postpartum assessment, conducted 12 weeks after the discontinuation of the voucher program, was not significantly different (8% versus 3%). Serial ultrasound examinations

indicated significantly greater growth in terms of estimated fetal weight, femur length and abdominal circumference in the CM vs. the non-CM condition.

Prenatal Smoking Cessation and Relapse Prevention Literature Reviews

Treating Tobacco Use and Dependence: 2008 Update. (USPHS) focuses on tobacco treatment in general and includes important information on special populations, including women who are pregnant.Cochrane reviews of the literature on smoking cessation interventions promoting smoking cessation during pregnancy (Lumley) and on relapse prevention interventions for smoking cessation in general (Hajek) are included. Also included is the CDC's Surveillance Summary for the Pregnancy Risk Assessment Monitoring System (PRAMS), 2000-2005 (CDC), with one compelling analysis of the data (Kim). Another analysis of PRAMS data from 1998-2000 (Peterson) focuses on Medicaid coverage for smoking cessation. Finally, an intriguing analysis of Pregnancy Nutrition Surveillance System (PNSS) data focusing on maternal smoking and the timing of WIC enrollment (Yunzal-Butler) is included.

The USPHS 2008 update of the Clinical Practice Guideline (Fiore) reiterates and reinforces the evidence from pervious guidelines that integration of the evidence-based 5A intervention in clinical settings is an effective intervention. Focusing on pregnant women in particular, the guidelines state the following: "Recommendation: Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered person-to-person psychosocial interventions that exceed minimal advice to quit. (Strength of Evidence = A)

Recommendation: Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective tobacco dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. (Strength of Evidence = B)"

The Cochrane review of interventions for promoting smoking cessation during pregnancy (Lumley) published in 2004 showed a significant reduction in smoking in the intervention groups of the 48 trials included. The 36 trials with validated smoking cessation had a similar reduction. Smoking cessation interventions reduced low birthweight and there was an increase in mean birthweight. Lumley concludes that smoking cessation programs in pregnancy reduce the proportion of women who continue to smoke, and reduce low birthweight and preterm birth. He notes that the pooled trials have inadequate power to detect reductions in perinatal mortality or very low birthweight. Of particular relevance to this review Lumley notes that incentive trials singled out as showing larger effect but points out that there have been only two studies.

Lumley notes that data from Solomon 1996 suggest that the transtheoretical model of stages of change in readiness to stop smoking (pre-contemplation, contemplation, preparation and action) may not apply in pregnancy, and that state changes in early pregnancy are not sustained. Pooled analyses showed no evidence for a significant effect with stages of change based interventions, compared with interventions based on other theories. A recent systematic review of smoking cessation concluded that stage-based interventions are no more effective in general than interventions which do not tailor the intervention according to the stage of change (Riemsma 2003).

The 2009 Cochrane review of relapse prevention interventions for smoking cessation (Hajek) focused on studies that explicitly identified a focus on relapse prevention or maintenance in their titles or abstracts. The range of interventions included could be delivered in any format, including group meetings, face-to-face sessions, written or other materials, proactive or reactive telephone support, and pharmacological interventions. The 54 interventions that met the inclusion criteria focused on three types of subjects: people who had quit smoking on their own; people who were undergoing enforced abstinence (e.g. hospitalization, incarceration) or quit smoking due to pregnancy; and smokers participating in treatment programs to assist initial cessation.

The authors failed to detect any significant effects of behavioral interventions for helping smokers who have successfully quit to avoid relapse. Special note is made that the verdict is strongest for interventions that focus on identifying and resolving tempting situations, the focus of most of the studies. Reviewing pharmacotherapy approaches, the authors found that extended treatment with varenicline may prevent relapse; but extended treatment with bupropion is unlikely to have an important effect; and further study of extended treatment with NRT is needed.

In a sub analysis, the authors pooled the results of eight prenatal interventions; the authors could identify no significant benefit at the end of pregnancy. Twelve trials included postpartum follow up, and similarly no significant benefit was found.

The CDC's recently released Surveillance Summary for the Pregnancy Risk Assessment Monitoring System (PRAMS) for the years 2000-2005 finds that all PRAMS states, Vermont included, have met the Healthy People 2010 objective of increasing percentage of pregnant smokers who stop smoking during pregnancy to 30% with a range of 30.2% to 61.0%. With a 2005 rate of 39.2%, Vermont is ranked 6th lowest. The state's quit rate plateaued at 39.1%-39.9% from 2003-2005. The state's prevalence of smoking during pregnancy in 2005 was 16.4, the sixth highest among PRAMS states. On a brighter note, though the percentage is lower than in 2004, the number of Vermont women who relapsed to smoking in 2005 is 44.0, the sixth lowest of the PRAMS states.

The report concludes with a two pronged set of recommendations. (1) States should continue comprehensive tobacco-control efforts (e.g., smoke-free policies and tobacco excise taxes) which reduce smoking before, during, and after pregnancy. (2) Health-care providers should increase efforts to assess the smoking status of their patients and offer effective smoking-cessation interventions to every female or pregnant smoker to whom they provide health-care services.

In a disturbing, yet compelling, analysis of the 2005 PRAMS data, Kim and England concluded that universal implementation of a best-practice, clinic-based prenatal intervention would not substantially reduce smoking prevalence among pregnant women. The authors calculate with maximum efficacy of 5A intervention, smoking prevalence in 3rd trimester would decrease from 16.4% to 14.4%. The authors further darken the picture by citing Hartmann et al. (Obstet Gynecol. 2007;110:765–770) who reported that only one third of prenatal care providers administered the 5 A's to their pregnant patients. That said, an analysis of PRAMS data from 1998-2000 (Peterson) should be repeated with these more current data. Peterson showed that higher levels of Medicaid coverage during prenatal care

for smoking cessation interventions were associated with higher quit rates; 51%, 43%, and 39% of women quit in states with extensive, some, and no coverage, respectively. Vermont's Medicaid program has extensive coverage, though individual counseling for cessation is not covered.

Finally, an analysis of data from eight states participating in the Pregnancy Nutrition Surveillance System (not including Vermont) offers an interesting perspective on the association of the timing of prenatal WIC enrollment and maternal smoking. Women who enroll in WIC in the first trimester of pregnancy are 2.7% more likely to be smoking at intake than women who enroll in the third trimester. Among participants who smoked before pregnancy and at prenatal WIC enrollment, those who enrolled in the first trimester are 4.5% more likely to quit smoking 3 months before delivery and 3.4% more likely to quit by postpartum registration, compared with women who do not enroll in WIC until the third trimester. Smokers who report quitting by the first prenatal WIC visit, first-trimester enrollment is associated with a 2% increase in relapse by postpartum registration. The results differ by race/ ethnicity; white women who enroll early are 3.6% more likely to relapse, while black women are 2.5% less likely to relapse. The authors suggest that while early WIC enrollment is associated with higher quit rates, changes are modest when compared to the results from smoking cessation interventions for pregnant women.

SUMMARY

Effectiveness of contingency management interventions for health behavior change:

CM is firmly established as an effective strategy in the field of drug abuse and is being investigated for its effects on a broad range of health behavior changes.

- Literature review conclusions about the immediate effectiveness of CM on a range of health behaviors/outcomes were mixed—though definitely leaning in a positive direction. Generally, studies included in the reviews demonstrated positive results during the incenting process, though gains in nearly every study dissipated upon follow up in the post incentive phase.
- There is solid evidence that financial incentives can contribute to promoting healthy behaviors in the workplace, although evidence of long term effects is weak. In clinical settings, there is evidence that patient incentives can increase short term behavior changes: e.g., recommended vaccinations, adherence to appointment keeping.
- More complex behaviors may require more sophisticated reward programs, incorporating various different incentives over a period of time.
- A review of the literature on competitions and incentives for smoking cessation found no significant effect of rewards, competitions or incentives on smoking abstinence at the longest follow up. The effect on short-term outcomes is not detailed.

- In prenatal settings published, peer-reviewed findings related to smoking cessation are based on a limited number of trials that have relatively small sample sizes. Loss to treatment is a serious issue. Two large prenatal smoking cessation randomized controlled trials were enrolling subjects in 2004, but their outcomes were not published in peer reviewed journals.

Effectiveness of promoting smoking cessation during pregnancy and postpartum

- Interventions for promoting smoking cessation during pregnancy show a significant reduction in smoking with an absolute difference of six in 100 women continuing to smoke. Smoking cessation interventions reduced low birthweight and preterm birth; there was an increase in mean birthweight.
- Incentive trials have been singled out as showing larger effect over other behavioral interventions, but there have been few studies.
- At the moment there is insufficient evidence to support the use of any specific behavioral intervention for helping smokers who have successfully quit for a short time to avoid relapse. This appears to be true of programs for all groups, including pregnant and postpartum ex-smokers.
- A new analysis of PRAMS data suggests that universal implementation of a best-practice, clinic-based intervention would increase the total number of quitters but would not substantially reduce smoking prevalence among pregnant women.
- Further analysis of PRAMS data may uncover associations between smoking cessation and insurance coverage.
- A recent analysis of PNSS data suggests WIC enrollment is associated with higher quit rates, but changes are modest when compared to the results from smoking cessation interventions for pregnant women.

CONCLUSION

In 2004 Donatelle offered a persuasive perspective in favor of the use incentives in prenatal smoking cessation that continues to resonate today. "As indicated by their continued high rates of smoking, younger, pregnant smokers have not succumbed to significant social pressure to quit and have not been frequent participants in programs such as quit-and-win, workplace interventions, and other public health and workplace programs and services designed to help them quit. The lower a pregnant smoker's socioeconomic status, the more barriers she faces in quitting and remaining abstinent. Some methods for assisting smokers, such as pharmaceutical aides that have proven effective with other populations are not recommended for pregnant women, even though continued smoking poses significant risk for mother and child. If community-based programs have not attracted pregnant smokers; if educational, advertising, and media campaigns have not convinced them of fetal risk; and if typical drug therapies are not a viable option, the challenge is to find a smoking cessation method that is acceptable to this group of women and that motivates them to give up something they enjoy."

The small number of clinical trials using financial incentives for prenatal smoking cessation are impressive in the magnitude of their treatment effects in pregnancy. Further large-scale study is needed to measure the strategy's true effectiveness in promoting abstinence and supporting improved birth outcomes. This potential impact is tempered by the fact that there is presently no evidence on the effectiveness of translating CM successes into population-based programs or policies for governments, employers, individuals and families. Concerns about CM include cost, cost-effectiveness, financing, fairness and durability of the treatment. Costs and cost-effectiveness are particularly relevant because most addiction treatment is publicly financed and these systems are already financially strapped.

III

QUALITATIVE RESEARCH FINDINGS

APPROACH

Newport and Rutland district offices. The purpose of these site visits was to better understand sites' experiences implementing the Pregnancy Smoking Cessation Program (PSCP) as well as to conduct quality assurance monitoring. Site visits were augmented by a review of the literature and analysis of PSCP data collected by each of the pilot sites. The combination of primary and secondary data collection activities were designed to help inform the Department of Health's decision-making process when considering expansion of the PSCP to all district offices and the sites' future self-monitoring.

Newport and Rutland district offices were informed of the site visits two weeks in advance of the initial visit. The project team worked closely with each district office to schedule a time when the majority of key staff involved in the PSCP would be available to meet. To facilitate discussion with staff, a site interview guide was developed based on PSCP Standard Operating Procedures revised by the Department of Health in February 5, 2009. The interview guide addressed each of the key program components: Enrollment Criteria; Process—specifically, how the program is staffed, who performs various program functions such as enrollment, follow-up for missed appointments and CO testing; Educational messages; Documentation; and, Quality Assurance. The guide (Appendix 2) was sent to the district offices via email prior to the scheduled visit.

The initial site visit interview was intended to capture the operationalization of the PSCP in order to develop a comprehensive picture of program related activities, adaptations and challenges. This visit also provided an opportunity for the project team to discuss a limited time study of the PSCP in order to conduct a rudimentary benefit-cost analysis. The time study was not intended to place undue burden on staff, yet it needed to provide insight to the degree to which the program is (or is not) labor intensive and the capacity required of district offices for program implementation and maintenance. Based on suggestions from staff regarding the type of time study instrument and process that would meet the needs of the project, a time study log was developed and provided to each district office (Appendix 3). District offices were asked to record time spent on each program related activity over the course of 4 weeks. At the end of the 4 week time period, a subsequent site visit was conducted to discuss time study results, ask clarifying questions about the PSCP and provide staff a final opportunity to ask questions of the project team. The following presents findings from the site visits, time study and PSCP data analysis.

ELIGIBILITY CRITERIA

The protocol indicates that women up to 23 weeks of pregnancy are eligible for enrollment. Both district offices reported very few difficulties with the

23 week eligibility criteria which they attribute to commonly seeing women during their first trimester. At this first encounter, district office staff have the opportunity to inform women of the program and eligibility requirements. For women who are not eligible to participate or not ready to quit, smoking cessation resources and referrals are provided. This information support is also extended to family members. One district office observed that by mid-pregnancy, most women feel that it is not "worth it" to quit. District office staff expressed frustration that they see women early on in pregnancy and then perhaps not until one week past the eligibility criteria of 24 weeks, noting the long interval between visits when a woman might benefit from a subsequent discussion about the program. Women who do enroll but leave the program are described as "falling by the wayside" and those who do not enroll at all are reported to have "cut down" on their smoking during pregnancy and may eventually quit.

PSCP OPERATIONS

District offices were asked to describe how the PSCP is operated, including screening for eligibility, enrollment, counseling and monitoring participants (CO testing and follow up for missed appointments). Each office has a very different approach to these activities.

Newport District Office

In the Newport district office, the certifier of the day (COD) is responsible for any WIC activity including PSCP. Women enrolling for WIC services are asked to complete a WIC Data Collection Form (i.e., health questionnaire) which identifies their smoking status. Once this questionnaire is completed, women who smoke are engaged in a brief intervention following the "5 A's" and information is verified. Based on this information, the COD recommends appropriate smoking cessation resources and services available statewide and locally including the PSCP. Newport staff have pre-packaged the information for women who are interested in quitting smoking to ensure that they receive it immediately to take home. Newport staff state when introducing the program, they first recognize and reinforce the woman's interest in quitting and having a healthy baby. Staff stated that program parameters are explained including the CO testing process, incentives as well as the available support services.

Women, who express interest in the PSCP, are asked to complete an initial visit survey. Newport staff report that some women decide to bring the completed initial survey with them at the first CO testing; however, staff expressed a preference for having women complete the initial survey at the time of first encounter and set a quit date. Women are also encouraged to take advantage of the support services available to them including the Quit Line. Although staff offer to make a fax referral to the Quit Line, many women are not interested in having the fax referral made at that time. Newport staff state that they promote the Quit Line, however have observed women's resistance to this resource, commenting "There is a rugged individual culture here …maybe a lot of women want to quit on their own." Staff also attribute this resistance to women not knowing with whom they are speaking on the Quit Line and where this person is located stating, "If they thought they were calling St. Johnsbury there would be resistance."

Staff view this initial encounter as an important educational opportunity while acknowledging that the majority of the women they see will have numerous quit attempts before actually quitting. Staff's utilization of motivational interviewing during these encounters was described as helping

to "tease out" the resources that would be of most interest to the women. Staff have observed that many women are interested in the online resources.

The WIC enrollment data (WIC Data Collection Form) are immediately entered into a database while the PSCP initial visit survey is entered when returned either at the first encounter or when women return for their first CO test. Data entry is done by one of the certifiers. The Newport district office has an open door policy for clients. Women can come in for CO testing between 7:30 AM and 4:30 PM any business day. Women interested in PSCP are told to return to the district office 5-7 days after they have quit smoking. Staff discuss this time frame with women using a calendar as a tool to "visualize" when a client may be coming in, circling the approximate date. When women return for CO testing, they are engaged in a discussion regarding the reading by the COD. If the CO reading is higher than usual, the discussion may be directed toward possible environmental tobacco exposure. Staff have observed that it is helpful during this interview process to have the woman's partner present to discuss the implications of environmental tobacco exposure and make resources available to the partner. Staff noted that partners express more interest in nicotine replacement than fax referral. Partners do take the information resources and appear to leave with an understanding that they cannot smoke around the woman so that she can take advantage of the incentives.

Interoffice Program Communication & Documentation. Enrolled women are assigned a sixteen digit identification number that is used on the program tracking form. This tracking form, augmented by a notes sheet, is used to facilitate communication among the certifiers regarding women enrolled in PSCP. The notes sheet was added by Newport district office staff as they found the tracking form insufficient in terms of the space necessary to document supplementary information. This supplementary information is not entered into the database. The tracking form and notes sheet are reviewed by the COD in preparation for meeting with enrolled women. The tracking form and notes sheet are kept in a binder that holds all the relevant information that the certifier of the day will need, located in a common drawer accessible to all certifiers. There is also the informal exchange or communication of information. Three certifiers have adjoining pods which facilitates spontaneous questions and answers. Newport staff stated that the current system for the PSCP works well for the office. Staff commented that there are benefits to the women seeing a different certifier as each certifier has a different style but the same message is being conveyed.

Tracking/monitoring women: Follow up phone calls and post card mailings are done weekly by certifiers. Messages will be left on answering machine and post cards communicate a positive message as well as the quit line number. Women have a one week period to come in for their CO testing. If a woman misses a week, Newport staff consider this missed appointment to be a relapse and reset the incentives. Women understand that they have only one opportunity re-start. Staff speak with women to understand why they missed and explain that there is no leeway in the protocol to support multiple missed appointments. Staff work to address barriers the women may identify which interfere with keeping appointments. Newport staff state that they try to make the testing opportunity as accessible as possible, understanding that women may have transportation issues, variable work schedules, sick children, etc. Staff commented, "People fly by the seat of their pants to get by so we have the 'drop-in' option to increase accessibility."

When women come in for CO testing, they are first asked if they have smoked. If the answer is "yes," then women are not tested. Newport staff reported that if this slippage comes up again, they have to make a professional judgment (following the PSCP protocol) and decide if this slippage constitutes a relapse. One staff person commented, "What I listen for is if someone admits to a few puffs to see if they are committed to quitting. Women who have slippage may be followed up for extra support so they do not slip again."

Rutland District Office

Rutland district office collaborates with a smoking cessation counselor from Rutland Regional Medical Center. This counselor staffs the Rutland district office one day per week and works closely with district office staff to coordinate the PSCP. As in Newport, women coming in to the district office for a WIC clinic complete a health questionnaire which includes a tobacco assessment described by Rutland staff as a standard of care. From responses to this questionnaire, tobacco status is determined by the district office certifier. If women are less than 23 weeks pregnant and smoke, the certifier that day talks with women about the program while assessing them for readiness. The MCH Coordinator stated that although not all certifiers have the protocol, she is available should they have questions. In addition, if the smoking cessation counselor is at the district office, she will meet with the women and schedule future appointments. The MCH Coordinator commented that when the smoking cessation counselor is at the district office, her presence creates a "seamless" program.

If interested, women are asked to complete the PSCP initial survey and sign the consent form. Subsequently, a fax referral form is completed by a Rutland staff person. In the Rutland district office there are two versions of fax referral forms: one that says "From WIC" which are those that go to smoking cessation counselor at the hospital while the other fax referral forms go to the Quit Line. Hospital fax referrals occur when the smoking cessation counselor is not on site; Quit Line fax referrals occur when women express interest in this service. The WIC Data Collection Form as well as the PSCP initial survey is entered into databases by district office clerks. Once entered, forms will be put into Maternal and Child Health (MCH) Coordinator's mailbox. The MCH Coordinator keeps a log of the women who enter into the PSCP chronologically.

Rutland district office staff track women's quit date and the incentive they received. The form also captures the "counseling days" (conversations about smoking cessation) prior to her quit date (i.e., when she first enrolls in WIC). Any interaction with an enrolled woman is counted as a WIC interim visit. Some women opt not to enroll but continue to participate in WIC. Once enrolled, retention was described as "pretty good." Rutland staff commented, "Not everyone understands that we want them to come see Susan [the smoking cessation counselor] while they are learning to quit. Some will come and say they have been quit for 10 days and they are immediately CO tested and incentivized." Staff went on to report that many women want to quit on their own and decline enrollment. Staff report that few women choose the Quit Line as their tobacco program.

Interoffice Program Communication & Documentation. Rutland staff described the regular communication that takes place between the MCH Coordinator and the smoking cessation counselor. All interactions that the smoking cessation counselor has with enrolled women are documented and kept in a binder that is shared with the MCH

Coordinator. The smoking cessation counselor maintains a calendar of appointments with notes next to each reporting the woman's status (e.g., waiting for appointment). This calendar of appointments is kept on a clipboard and notes are kept in a binder and are shared between the MCH Coordinator and smoking cessation counselor. For those women who opt for the Quit Line, their names also go into the binder and MCH Coordinator checks on their status via feedback fax or via the Department of Health, Central Office. The MCH Coordinator utilizes a tickler system to ensure regular check-in. Staff commented on the need to check both resources (the PSCP binder and the clipboard) given that some women want to utilize both of these services. However, staff commented on how few women have had a positive experience with the Quit Line.

Tracking/monitoring women: The MCH Coordinator reports that the calendar system is the most helpful tool for tracking the women as key dates are posted such as the 28 week survey and when are they due to deliver. Knowing the delivery date and by collaborating with a hospital affiliated smoking cessation counselor also enables follow up with women post partum when they are still in the hospital. The calendar is also where missed appointments or no-shows are documented. The smoking cessation counselor conducts most of the follow up which includes phone calls and/or a letter/postcard.

PROTOCOL ADAPTATIONS

Both district offices reported following the protocol as written with very few, if any, adaptations. Each office reported the use of additional tools and resources to facilitate a smoother process (e.g., prepackaged information ready for women to take home and system or the notes sheet used by Newport district office to supplement information documented on the tracking form). The Newport district office tracking form also facilitates communication between certifiers. Similarly, the calendar-binder used by Rutland district office facilitates communication between the MCH Coordinator and smoking cessation counselor. The Newport office did report they exclude the 24 hours after quit option. Staff commented that this option to come in for CO testing made it "too easy" to come in for a visit and then keep smoking; therefore, the adaptation they did make was to have women come in after 5-7 days of quitting.

One district office discussed the difficulty of the protocol stating, "It is hard and a learning curve for us. This protocol is not meant to support vulnerable and unstable situations—it is meant for those who are really in the action stage. The protocol is not conducive to someone who is shaky and may waver back and forth. And smoking takes practice and we know that. It is a program that pays them to quit not to practice. That was really hard for us to deal with but I think we are there."

KEY PROGRAM ELEMENTS/ ACTIVITIES

Both district offices identified the incentives as a key program element. When asked, "What if the incentives disappeared?" one district office responded by saying "We need something that gets at the hard core people. We are at the hard core—people who will need something to motivate them—the coping mechanisms are limited. What went over well was the gas and grocery card. If we did not have the incentives we would not have the women coming into the office frequently."

Another key program element identified was flexibility for women to come in when convenient

(e.g., open door policy). Also discussed was training of the staff to ensure "buy-in" to the program and the necessary skill set (specifically identified was motivational interviewing) to know what would motivate behavior change as well as assess readiness to change and the supportive services and resources to enable that change. Newport staff commented on the "toolbox" that they use with clients from discussing stress reduction to deep breathing. Both district offices identified the educational component of the program—informing women of the health implications for the baby and the risk of environmental tobacco exposure. Rutland stated that the WIC environment enables staff to tailor messages to the pregnant woman. District offices report that this educational messaging is extended to family members, friends and the community at large. One district office staff told this story, "There was a woman who worked at Walmart and I knew she was not smoking but her CO readings were ridiculous. She had her truck checked out and her exhaust system was good. She had her house checked out. Turns out she was unloading trucks and the trucks engines were not turned off and she was breathing in all the exhaust. She got the trucks turned off and it benefited everyone. The CO testing is a teachable moment."

PROGRAM CHALLENGES

One district office noted changes in the protocol and the many details that need to be managed, as well as the uncertainty of its tenure commenting, "It was a disadvantage for our community to start and stop. For a statewide program—communities need to know that the program is going to be around for a while." Lastly, the need for program evaluation was identified with one staff person commenting, "For us, we want to see the evaluation component—is it working? Are we on the right path?"

CONSIDERATIONS FOR STATEWIDE IMPLEMENTATION

District offices identified several key factors to consider prior to statewide implementation.

Institutional buy-in. Staff spoke of the need of community wide institutional buy-in—that smoking cessation should be a community priority and incorporated in to all human service provides scope of work.

Training. Staff need to be trained all aspects of the protocol including motivational interviewing, CO testing, data management (specifically entering data into the database), and tracking incentives to ensure consistence (quality assurance).

Quality Assurance Mechanism. District offices need to be provided with technical assistance when establishing quality assurance systems. Rutland and Newport have each established systems for their respective offices including chart audits as a self-monitoring tool. Staff discussed extending the quality assurance mechanism to include a feedback loop that extends to central office. District offices requested that data reports be expanded to include more detailed analysis of the WIC Data Collection Form.

Program Tenure. The program needs to be established for the long term which will ensure buy-in by community partners.

IV

QUANTITATIVE RESEARCH FINDINGS

JSI received a de-identified copy of the PSCP Access data base on May 21, 2009. The data base was converted into SAS 9.1 files for data analysis. Figure 1 describes the volume of program clients contained in the data base. There were 102 clients who at least began the process of the initial interview. Of these, we excluded 12 because they did not meet study criteria: 2 were post-partum, 1 was over 23 weeks pregnant, 1 had very incomplete data, and 2 enrolled after May 8th (no chance to capture a follow-up visit) and 6 were Green Mountain OB/GYN clients. Of the 90 eligible clients, 24 of them did not complete the initial visit – did not provide consent. Of the 66 remaining clients who did complete the initial visit, 36 did not have any follow-up visits. Of the 30 remaining clients, 6 were still in process as of May 21st and the other 24 clients completed their pregnancy (or the 28-32 weeks survey).

Drop-outs are defined as those clients who began an initial survey but either did not complete it or had no follow-up visit. The follow-up rate is the number of clients who completed at least one follow-up (the non-drop-outs) divided by the total number of clients (drop-outs + non-drop-outs). Table 1 shows that the follow-up rate was relatively low (or equivalently, the drop-out rate was relatively high); the best follow-up rate, of 50%, was among the 20 clients who initiated enrollment in the 4th quarter of 2008. The number of drop outs was 30 at both Rutland and Newport WIC.

Table 2 provides a comparison of those who dropped out (60) to those who did not (30) on some baseline characteristics from the initial interview. The two groups were similar in their pre-pregnancy smoking (averaging nearly 19 cigarettes/day). Both groups had, on average, cut down on smoking when they found out they were pregnant. However, those who stayed in the program for at least one follow-up had cut down to a greater extent than drop-outs (down to 6.8 cigarettes/day versus 11.3 cigs/day). Those who stayed in the program were more definitive in their desire to quit (85.2% saying so versus 56.4%) and had more confidence in their ability to quit (median score of 9 points vs. 7 points on a 10 point scale). The majority in both groups had friends and family who smoked and three-fourths of both groups lived with a smoker. The majority in both groups were single/never married. The group who stayed with the program had a higher prevalence of finishing high school or having some college (88.8% vs. 65.6%).

The next series of tables focus on the service utilization status of those 24 clients who have completed their pregnancy (or the 28-32 week survey). Note that there are no baseline differences among these clients based on whether they were seen at the Rutland or the Newport programs. Table 3 provides a breakdown of the number of visits and weeks gestation at the initial visit. On average, clients were 10.6 weeks pregnant when

they enrolled. The number of visits ranged from 2 to 11; the median number was 7 visits. Eleven clients (45.8%) had between 9 and 11 visits. The relatively low number of visits for many clients can not be attributed to enrolling late in their pregnancies.

Table 4 provides an analysis of the dollar amount of incentives provided to clients. The amount of incentive clearly increased with increasing number of visits. Those who had 5-7 visits averaged between $162.50 and $250.00 in incentives. As expected, clients who had 9-11 visits had the greatest amount of payouts, ranging on average between $475.00 and $583.30. There were 6 of the 11 clients (55%) with >=9 visits who appear to have received more than the maximum amount of $455 in incentives. These six clients were enrolled prior to a standardized incentive schedule agreed upon and launched by both district offices in February 2009.

Table 4 also describes the number of 5A incentives received. In most cases, the 5As were covered at half or more of the visits. For those with 9-11 visits, the 5As were covered during ~80% to 90% of visits. Table 5 provides a simple comparison of self-reported smoking to CO results during the week 2 visit. For the majority of clients (80%) who reported not smoking, the CO result corroborated their statement (16/20). One of the four did not pass the test and the other three who said they were not smoking did not have a CO test result. None of the self-reported smokers had a CO result. This pattern was similar across subsequent weeks (just smaller numbers of cases).

Tables 6 and 7 describe results from the 28-32 week survey. Of the 24 clients who participated in the program and reached the end of their pregnancy (or completed the 28-32 survey), 19 completed the survey (79.2%). Over half (52.6%) of these clients reported that they were no longer smoking, defined as having not smoked a cigarette in the past 30 days, not even a puff. Among the 9 clients (47.4%) who were still smoking, only 3 of the 9 were currently smoking; the rest had not smoked in the past 7 days. The 3 current smokers were at the Rutland office; the Newport office had no current smokers.

There were no substantive differences in the average number of visits, 5A sessions, or incentive amounts between smokers and not-smokers (Table 7). However, the number of visits, 5As, and incentives tended to be higher on average among those no longer smoking. Most of those still smoking in this small sample were not smoking on the day of the survey (see Table 6) and appear to have made important progress in quitting smoking as well.

The survey also ascertained information on what helped the clients while in the program. Nine respondents (47.4%) reported that health department staff suggested they call the Vermont Quit Line; none of them reported they did so. Nineteen respondents (89.5%) reported that health department staff provided a booklet and/or other materials to help them quit. On a 10 point scale, these materials scored a median of 7 points for helpfulness. In terms of other specific resources clients found helpful for quitting, 3 mentioned hospital programs, 3 mentioned incentives, and 2 mentioned distraction putty.

The overall quit rate for the program was 16.7% (Table 8). The rate was slightly higher in Newport (22.7%) than Rutland (13.2%). The numbers are too small to say that a significant difference exists between the two offices.

Data Quality

By and large the data base was logically designed and relatively easy to use and the data within it was relatively consistent, or accurate, and complete. However, there were a few areas where there could be improvements to either the DB design or to the keying process to improve the accuracy and completeness of the data. The initial visit date was not the same in the initial visit table and the tracking table for 19 clients. It is difficult to know if this difference is due to typos or the initial visit occurring over two days. The 28-32 survey due dates were missing for 20 clients. For 5 women whose due date crossed into the next calendar year, the wrong year was recorded. The tracking table contained a check box to indicate an incentive was distributed. There was also a number box to record the amount of the incentive. For 9 of 29 clients, the incentive box was checked but no amount recorded (there was a note for 1-2 cases that indicated no incentive was available). Finally, in the 28-32 week survey, the quitting questions have a skip pattern that was not consistently followed. There was missing data in the "smoked hours/days/weeks" ago – 5 respondents had missing data in all three fields and a few others had zeros recorded that were difficult to interpret.

FIGURE 1:

Number of Clients Entered into PSCP Database April 1, 2008 – May 21, 2009

102 initial visit records

– 12 not eligible for this analysis (2 Post Partum, 1 blank, 2 May, 2009 dates, 1 >23 Wks, 6 Green Mountain OB/GYN clients)

=> 90 clients

– 24 clients with incomplete initial records

=> 66 clients (consented – enrolled)

– 36 completed initial enrollment visit (incl. consent), but had 0 follow-up visits

=> 30 clients

– 6 clients still in process – delivery dates after 8/1/2009

=> 24 clients completed their pregnancy or the 28-32 week survey and had at least one follow-up visit.

– 5 clients with no 28–32 week survey

=> 19 completed 28–32 week survey and had at least 1 follow-up visit

TABLE 1:
FOLLOW-UP RATES BY CALENDAR DATE OF ENROLLMENT

Quarter & Year of Enrollment	# Drop-outs (no Follow-up visits)	# with at least 1 Follow-up visit	% with at least 1 Follow-up visit*
Q2, 2008	0	2	100%
Q3, 2008	18	9	33%
Q4, 2008	10	10	50%
Q1, 2009	12	5	29%
4/1 – 5/8 2009	15	1	6%
Missing Enroll. Date	5	3	38%
Total	**60**	**30**	33%
Dropouts by Location:			
Rutland	30		
Newport	30		
Total	60		

* Percent is calculated by dividing the number with at least 1 Follow-up visit by the sum of that number and the number of dropouts.

TABLE 2:
COMPARISON OF THE CLIENTS WHO "DROPPED OUT" (DID NOT HAVE > = 1 FOLLOW-UP VISIT) VERSUS THOSE CLIENTS WHO RECEIVED (>=1) FOLLOW-UP SERVICES

Baseline characteristic	Drop-outs (n=60)	Have >=1 F/U (n=30)
Pre-pregnancy average #cigs/day	18.9	18.9
Pregnancy average #cigs/day	11.3	6.8
Pct. Smoke <=30 mins. After wakin	89.1%	73.1%
Avg. age start smoking	15.0	14.5
Definitely plan to quit during pregnancy	56.4% **	85.2% **
Plan to quit next 30 day	76.7%	90.0%
Confidence in quitting (median)	7 pts*	9 pts*
Most friends/family smoke	58.2%	50.0%
Have smokers in home	72.2%	73.1%
Education level < HS HS/GED College	 34.5% 50.9% 14.6%	 11.1% 44.4% 44.4%
Marital Status Single/Never Married Married Sep/Divorced/Widowed/Other	 81.8% 9.1% 9.1%	 74.1% 14.8% 11.1%

* measured on a 10 point scale 1=probably not to 10=definitely.
** note that the median score on this scale for both groups was 10 points.

TABLE 3:
NUMBER OF VISITS (INCLUDING INITIAL VISIT) AMONG PROGRAM PARTICIPANTS WHO COMPLETED >=28 WEEKS OF PREGNANCY

Number of visits	# of clients (n=24)	% of clients	Average # weeks pregnant at initial visit (list of actual # weeks)s
2	2	8.3%	9.0 (7, 11)
3	2	8.3%	11.0 (7, 15)
4	0	0.0%	---
5	4	16.7%	10.5 (5,,7,8,22)
6	2	8.3%	9.0 (7,11)
7	2	8.3%	22.0 (21,23)
8	1	4.2%	9.0 (19)
9	4	16.7%	10.5 (6,8,10,18)
10	4	16.7%	8.0 (5,6,10,11)
11	3	12.5%	5.7 (4,6,7)

Overall, the mean number of visits was 7.2. The mean for Rutland was 6.7 (14 clients) and the mean for Newport was 7.9 (10 clients). Overall, the mean weeks pregnant at the initial visit was 10.6 weeks.

TABLE 4:
THE AVERAGE (ACTUAL) AMOUNT OF INCENTIVE PROVIDED BY THE NUMBER OF VISITS COMPLETED – AMONG PROGRAM PARTICIPANTS WHO COMPLETED >=28 WEEKS OF PREGNANCY

Number of visits	Average incentive amount per client	Actual incentive amounts for each client	Average number of 5A interventions
2	$37.50	$0, $75	1.0
3	$0.00	$0, $0	2.0
4	No clients had 4 visits	----	---
5	$162.50	$0, $200, $200, $250	3.8
6	$287.50	$275, $300	5.0
7	$250.00	$250, $250	6.0
8	$0.00	$0	6.0
9	$475.00	$350, $350, $600, $600	7.00
10	$531.30	$400, $450, $600, $675	9.0
11	$583.3	$250, $750, $750	9.7

The total dollar amount of incentives was $7,575.00. This amount was split, as follows, by site: Rutland $2,700 (14 clients), Newport $4,875 (10 clients).

TABLE 5:
COMPARISON OF SELF-REPORT OF SMOKING VERSUS CO TEST RESULT – 2nd VISIT ONLY AMONG PROGRAM PARTICIPANTS WHO COMPLETED >=28 WEEKS OF PREGNANCY

	CO Result <= 6	CO Result > 6	CO Test Not Done
Self report: not smoking	16	1	3
Self report: smoking	0	0	4

April 1, 2008 – May 21, 2009

TABLE 6:
SMOKING STATUS AMONG PROGRAM PARTICIPANTS WHO COMPLETED >=28 WEEKS OF PREGNANCY

SURVEY DATA AVAILABLE FOR 19 OF 24 PARTICIPATING CLIENTS

Quit Status	Overall	Rutland	Newport
Not smoking = have not smoked a cigarette in the past 30 days, not even a puff	52.6% (10/19)	50.0% (5/10)	55.5% (5/9)
Still smoking	47.4% (9/19)	50.0% (5/10)	44.4% (4/9)
Has not smoked in >= 7 days	31.6% (6/19)	20% (2/10)	44.4% (4/9)
Currently smoking	15.8% (3/19)	30% (3/10)	0.0% (0/9)

TABLE 7:
QUIT RATES (INTENT TO TREAT) FOR PROGRAM PARTICIPANTS WHO COMPLETED >=28 WEEKS OF PREGNANCY

	Quit Rate	Not Smoking/Enrolled*
Overall	16.7%	10/60
Rutland	13.2%	5/38
Newport	22.7%	5/22

* The number enrolled = 60, which is 66 (number of enrolled & consented) less 6, which is the number of clients still in process (4 at Newport, 2 at Rutland). See Figure 1.

** An intent to treat (ITT) quit rate is calculated as the number of quitters divided by the total number enrolled, not just program participants (as in Table 7). The assumption is that those who enrolled but didn't participate didn't quit. The total number enrolled is considered the group "intended to be treated".

TABLE 8:
SERVICE USE BY SMOKING STATUS OF PROGRAM PARTICIPANTS WHO COMPLETED >=28 WEEKS OF PREGNANCY

	Not Smoking (n=10)	Still Smoking (n=9)
Avg. # visits	8.9	6.8
Avg. # 5As	7.7	5.6
Avg. amount of incentive	$397.5	$308.3

V

CONCLUSION

The purpose of this study was to conduct quality assurance monitoring and evaluation of the Pregnancy Smoking Cessation Program, a brief intervention with incentives program targeting women enrolled in the WIC program who are less than or equal to 23 weeks pregnant. The combination of quality assurance monitoring and evaluation provides public health programs an important opportunity to assess impact from several perspectives.

Institute of Medicine's (IOM) "Crossing the Quality Chasm" put forth several properties or domains when defining quality, including effectiveness, efficiency, equity, patient centeredness, safety and timeliness. Although IOM defines quality health care as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge", how quality is assessed or evaluated can be complex. The domains are intended to help answer this question.

Throughout this project, the JSI team has framed the approach to the evaluation of the PSCP with these IOM domains in mind. The following conclusions synthesize the review of the literature, site observations and analysis of program data.

1. ***Effectiveness.*** The PSCP is based on two randomized clinical trials using financial incentives for prenatal smoking cessation. The findings of both are impressive in their reported treatment effects in pregnancy and on birth outcomes. However, the entire body of evidence is limited to these impressive yet very small clinical trials, with only one involving WIC clientele. Large-scale study is needed to measure this strategy's true effectiveness in promoting abstinence and supporting improved birth outcomes. Translating this research to practice on a population-based level might realize enormous benefits to maternal and infant health as well as to society at large. This potential impact is tempered by the fact that there is presently no evidence on the effectiveness of translating CM protocol successes from the research arena into large-scale, population-based programs.

Furthermore, data analyses of the PSCP database illuminated questions regarding program effectiveness. Analyses indicate that the program is limited in its ability to reach a substantial segment of the population and to retain enrollees. In addition, there is a programmatic financial consequence when women who enroll receive incentives, yet leave (program non-completers) after a period of time. Present quantitative and qualitative analysis cannot explain these statistical observations. Study time limitations and lack of consumer input impedes the ability to create a broader environmental context (e.g., economic, social, cultural) in which the pilot sites are operating and the influence each of these may have on the program and participants.

Recommendation: Given the limitations noted based on the review of the literature and questionable impact that the program has yet to achieve on a population basis, expansion of the pilot statewide is not recommended at this time.

2. ***Efficiency.*** The time study conducted demonstrated that the pilot sites developed and implemented very efficient systems for operationalizing PSCP. The PSCP was well integrated into existing district office systems and culture. District office staff exhibited proficient knowledge of the PSCP protocol which most likely enabled this integration as well as an astute awareness of the office's capacity and sensitivity to client needs. Although the systems are markedly different in each site, both sites average 3.6 hours per week of staff time dedicated to PSCP. This level of efficiency did not compromise equity, patient centeredness; safety; and, timeliness of the services delivered as evidenced by office flexibility (e.g., open-door policy, creating a supportive office/clinic environment), an extremely competent and skilled staff and staff who truly care about the clients.

3. ***Quality.*** As previously discussed in program efficiency, district office staff clearly demonstrated knowledge and understanding of the goal of PSCP and the protocol. Although no observations were conducted of staff/client interactions during program "recruitment", CO testing or follow up, the ease with which staff responded to questions about the protocol and their tenure working with pregnant women who smoke as well as the lack of adaptations to protocol was a strong indication that program fidelity was not being compromised. Quantitative data analyses indicated, however, the program would benefit from more stringent quality assurance monitoring as evidenced by incomplete data fields in the data base and the lack of final disposition for all women approached about the program and/or enrolled.

   Recommendation: Periodic review of the data at set intervals is strongly recommended. Findings from these reviews should be shared with district offices so that adjustments to how and when data is entered can be made and monitored ongoing. Technical assistance should also be made available to district offices seeking to institute their own quality assurance monitoring systems.

The project team's ultimate recommendation not to expand the pilot statewide at this point in time should not reflect poorly upon the district offices' staff knowledge, understanding and skilled integration of program protocols into existing office systems. Many researchers have worked to understand behavior modification and the interventions that would enable positive outcomes. As public health professionals, we are continually confronted by the ever-intensifying social and economic determinants of health that significantly influence behavior. Given the identified population's clear need, further clinical trials of alternative evidence based interventions should be pursued, as should rigorous and controlled research that attempts to translate that evidence into population-based practice.

It was brought to the project team's attention that the state's WIC database could provide additional insight to the population. Although the project team did not have access to these data, it is recommended that a comprehensive analysis, similar to that which was conducted for this study (if one has not been conducted to date), be undertaken. These data, combined with the first hand experience

of district office staff, may identify new directions worth pursing.

In the mid-1990's, the Centers for Disease Control and Prevention (CDC) developed a public health framework for evaluation, one of the ten public health essential services. This framework set forth a "systematic investigation of the merit, worth, or significance" of an identified public health program. The framework further distills the meaning of each of these qualifiers by calling attention to the fact that they may be influenced by values (judgments) as opposed to facts. Therefore, merit, worth and significance are further defined by the terminology quality (i.e., merit), cost-effectiveness (i.e., worth), and importance (i.e., significance) in the framework. The Morbidity Mortality Weekly Review (MMWR) in which this framework was presented states that "If a program is judged to be of merit, other questions might arise regarding whether the program is worth its cost. Also, questions can arise regarding whether even valuable programs contribute important differences. Assigning value and making judgments regarding a program on the basis of evidence requires answering the following questions:

- What will be evaluated? (That is, what is the program and in what context does it exist?)
- What aspects of the program will be considered when judging program performance?
- What standards (i.e., type or level of performance) must be reached for the program to be considered successful?
- What evidence will be used to indicate how the program has performed?
- What conclusions regarding program performance are justified by comparing the available evidence to the selected standards?
- How will the lessons learned from the inquiry be used to improve public health effectiveness?

Recommendation: The Vermont Department of Health should consider these guiding questions from the CDC public health framework for evaluation to help to facilitate exploration of alternative evidence based interventions that may—more expansively and with greater impact—reach the targeted population in the future.

APPENDICES

Contingency Management Literature Reviews and Commentary

Type	Authors Date	Type	
SC	Cahill &Perera 2009 Cochnrane Review	Lit Review CM effects on Quit Rates Relationship between incentives and participation rates	**Results:** • Contests and incentives reviewed. None of the studies demonstrated significantly higher quit rates for the incentives group beyond the six-month assessment. • No clear evidence that different types of incentives were more or less effective. • Recruitment rates can be improved by rewarding participation • Considerable disparities between quit claims validated by CO breath samples (confirming abstinence for a few hours) and those validated by urinary cotinine (days or weeks of abstinence). **Comments:** • Incentives and competitions have not been shown to enhance long-term cessation rates • Early success tending to dissipate when the rewards are no longer offered. **Relevance to this review:** • The use of tangible rewards will always be a trade-off between maximizing participation and attracting smokers who are motivated more by the rewards than by the wish to stop smoking.
CM	Volpp K, et al. 2009	Lit Review on Pay for Performance for Patients (P4P4P) Additional commentary of barriers and facilitators for P4P4P	**Findings:** • Incentive-based approaches have been shown to be highly effective in two areas: (1) increasing the use of preventive services that involve a limited number of visits, and (2) reducing the use of addictive substances. • Eighty-five percent of the U.S. population has employer-sponsored or federal/state health insurance whose premiums bear no relationship to the individual policyholder's behavior. • Many insurers and employers are skeptical about effectiveness of CM. The evidence base is largely limited to short-term follow-up studies of preventive services, although this evidence is arguably stronger than the evidence for P4P for providers. • Many published studies have found no effect of incentives. **Comments:** • The current norm within group-based insurance plans of charging people who engage in high-risk behavior the same premiums as those who engage in unhealthy behavior implicitly encourages unhealthy behavior. There have been few systematic attempts to use price reductions or rewards to encourage healthier behavior. **Relevance to this review:** • Evidence of proven effectiveness and limitations of the existing evidence, reasons for underuse of these approaches, and options for achieving wider use • Many of the patient-targeted incentive programs introduced to date have not used insights gained from behavioral economics on the psychology of human motivation. This makes their success all the more impressive but suggests that more carefully crafted incentive interventions could provide more bang for the same buck.
HB	Sutherland, et al. 2008	Lit Review on worksite and clinical studies of CM Additional commentary	**Findings:** • In worksites, programs involving financial incentives can contribute to promoting healthy behaviors. Evidence of a financial incentive effect on long term weight loss was weak. • In clinical settings, evidence that patient incentives can increase short term behavior changes: e.g., recommended vaccinations, adherence to appointment keeping • In prenatal and postpartum settings findings related to the effects of incentives on adherence to care recommendations are based on a limited number of trials that have relatively small sample sizes. **Comments:** • Those who have limited self-efficacy, low health literacy are likely to need larger incentives. • Income also can be an important factor as it relates to the willingness of individuals to incur the costs of responding to financial incentives.

Type	Authors Date	Type	
			Relevance to this review: • One study of prenatal care in a sample of 104 low-income women found that a taxi voucher had a significant impact on attending the first prenatal visit, but there was no effect of a baby blanket gift when compared with usual care. Notably, only 1 woman of 34 redeemed the taxi voucher, raising questions about the mechanism that led to the significant result. • Another study of 205 Medicaid-eligible women found no effect of a $5 gift certificate or a $5 gift certificate plus $100 raffle ticket, compared with usual care, on prenatal and postnatal care visits (Kane et al., 2004).
HB	Sindelar 2008	Lit Review & Commentary CM and Health Economics	**Findings:** **Comments:** **Relevance to this Review:** • Concerns about CM include cost, cost-effectiveness, financing, fairness and durability of the treatment. Costs and cost-effectiveness are particularly relevant because most addiction treatment is publicly financed and these systems are already financially strapped. • Issue of fairness arises as the government would be paying some people to abstain from drugs, while others abstain but do not get paid. • Positive incentive schedules have been shown to influence behaviors in clinical trials but have not been developed into population-based policies for governments, employers, individuals and families.
PSC	Donatelle, et al. 2004	Review of author's work and work in progress Review of literature on CM for health behavior change	**Findings:** • 5 prenatal smoking cessation studies, two in progress. End of pregnancy results on three completed studies range from 19% to 32%. Abstinence verified by salivary cotinine. • Author posits that CM may have potential for motivating short-term abstinence, particularly in controlled, clinical or outpatient settings with special subsets of the population. **Comments:** • Author provides a detailed summary of previous research using CM for smoking cessation. The results are mixed, though generally positive. Most studies are small, with results not biochemically verified. • Author's own groundbreaking work in incentive-based prenatal smoking cessation with short term abstinence showed great promise. **Relevance for this review:** • Author's research noted above was never published in a peer reviewed journal. Unable to locate any reference to this work since presentations on preliminary results were given in 2004.

Contingency Management and Health Behavior Change

Type	Authors Date	Study Design Setting Subjects N=	Study Groups • CM • Non-CM Length	Intervention Features	Outcomes Studied	Results	Comments
HB	Volpp et al. 2008	Randomized Controlled Trial VA Medical Center Veterans between ages of 30 and 70 with BMI 30-40 N=57	• CM1: 16 week weight loss monitoring program, monthly weigh ins, daily lottery-based financial incentive plan • CM2: 16 week weight loss monitoring program, monthly weigh ins, deposit contract plan • Non-CM: 16 week weight loss monitoring program, monthly weigh ins. Length: • 12 months	• Weight loss goal for all was 16 lbs. • All participants received $20 at monthly weigh-ins, reducing loss to follow up • CM groups had daily opportunities for small incentives and daily contact with the program.	• Weight loss after 16 weeks • Weight loss after 7 months • Meeting or exceeding weight loss goal.	Mean weight loss greater in CM groups (CM1=13.1 lbs.; CM2=14.0 lbs.)than in Non-CM (3.9 lbs.) Meeting goal greater in CM groups (CM1=52.6%; CM2=47.4%) over NonCM (10.5%) Losing 20+ lbs. greater in CM groups (CM1=36.8 lbs.; CM2=26.3) over Non-CM (5.3) Between 16 weeks and 7 mos. CM groups gained weight, though CM groups weighted significantly less then at the beginning of study.	• Given study group consisted of Veterans, most subjects were male. **Relevance to this review:** • Smaller more frequent incentives may be effective • Authors note that participants are motivated by past rewards and prospects of new ones. **Relevance to this review:** Difficult to parse out whether the daily contact with the program had an influence on outcome over and above the incentives.
SC	Tevyaw, et al. 2009	Randomized Controlled Trial University Non-treatment-seeking daily smokers who are college students N=110	• CM + motivational therapy • CM + relaxation control (REL) • Non-CM + motivational therapy • Non-CM + REL Length: 3 weeks with 6 mo. Follow up	• 2x2 design • Expired carbon monoxide (CO) samples were collected twice daily for 3 weeks. • All participants received $5 for submitting each sample. • Contingent condition incentives: escalating $ based on lowered CO (week 1) and abstinence (weeks 2-3)	• CO levels at 1 wk. • CO levels + abstinence at 2-3 wks • Interest in quitting post treatment	• Compared with NR, CM resulted in significantly lower CO levels and greater total and consecutive abstinence during the intervention. • Those in the CM and MET groups reported greater interest in quitting posttreatment • Rates of confirmed abstinence at 6 mo.	• Interest in quitting smoking not assessed at baseline • Hypothesis that the combination of CM and MET would produce differentially better smoking outcomes was not supported **Relevance to this review:** Incentives have little effect on smokers who are not interested in

Type	Authors Date	Study Design Setting Subjects N=	Study Groups • CM • Non-CM Length	Intervention Features	Outcomes Studied	Results	Comments
				• REL treatment has been shown to have effects equal to no treatment		follow-up very low(4%) • Did not differ by group.	quitting.
SC	Volpp, et al. 2009	Randomized Controlled Trial Workplace Smokers	• CM + Information about smoking cessation programs • Non-CM Information about smoking cessation programs only Length: • 9-12 mos with followup at 15-18 mos	• Contingent condition incentives: $100 with completion of a smoking-cessation program, $250 with cessation within 6 mos. , $400 with abstinence for additional 6 mos. after initial cessation • Smoking status for all subjects confirmed by biochemical test.	• Cessation 9 or 12 months after enrollment, depending on whether initial cessation was reported at 3 or 6 months. • Cessation at 15 or 18 months after enrollment. • Secondary end points: cessation within the first 6 mos. after enrollment and rates of participation in and completion of smoking-cessation programs.	• Contingent condition had significantly higher cessation rates at 9 or 12 months, • higher rates of enrollment in a cessation program completion of a program • higher rates of cessation within the first 6 months after enrollment.	• Unable to determine unintended consequences (e.g. employee initiating smoking to get incentives) • Selection bias. • Relapse rates at 15-18 months higher than one would expect from the literature. **Relevance to this review:** Unable to generalize to employees who are members of minority racial groups or to pregnant women or patients in clinical settings

Contingency Management and Prenatal Smoking Cessation

Type	Authors Date	Study Design • Setting • Subjects • N=	Study Groups • CM • Non-CM Length	Intervention Features	Outcomes Studied	Results	Comments
PSC	Heil, et al, 2008	Randomized Controlled Trial University Clinic Smokers entering prenatal care	• CM Vouchers earned for biochemically verified smoking abstinence • Non-CM Vouchers earned independent of smoking status.	• Contingent condition incentives: voucher given beginning at $6.25 with $1.25 added per no-smoking status visit to $45 max. Reset protocol for testing positive for smoking. • Non-contingent incentives: $15 per visit antepartum; $20; postpartum	• Smoking outcomes evaluated using urine-toxicology testing and self-report. • Fetal growth outcomes evaluated using serial ultrasound examinations performed during third trimester.	Contingent condition had significantly higher point-prevalence abstinence at the end-of-pregnancy and at the 12-week postpartum assessment. Serial ultrasound results indicated significantly greater growth in terms of estimated fetal weight, femur length and abdominal circumference	**Relevance to this Review:** • Low rate of enrollment in study (45% of those eligible) • No formal cost analysis • Postpartum abstinence is significantly higher than that seen in other studies.
PSC	Higgins, et al. 2004	Pilot, only some subjects randomized. University clinic Smokers entering prenatal care N=53	• CM Vouchers earned for biochemically verified smoking abstinence • Non-CM Vouchers earned independent of smoking status. Length: 24 weeks postpartum		• Smoking outcomes evaluated using CO, urine-toxicology testing and self-report.	• Contingent condition had significantly higher point-prevalence abstinence at the end-of-pregnancy and at the 12 and 24 week postpartum assessments. • Those randomized to contingent group had abstinence levels at 25% vs. 0% of those randomized to non-contingent group.	• Study had more intensive monitoring and higher incentive value than previous studies. **Relevance to this review:** First of two studies upon which the Pregnancy Smoking Cessation Program was based.
PSC	Donatelle, et al. 2000 WIC clinics	Randomized Controlled Trial WIC clinics WIC clients who are >28 weeks	• CM: Ususal care plus incentives for subject and a "significant other supporter"	• Participants completed written surveys and salivary specimen collections, analysed for cotinine regardless of smoking status, at each of three	Biochemically verified abstinence at 8 months gestation and 2 months postpartum.	Eight month gestation quit rate CM 32% Non CM 9% Two month postpartum quit rate CM 21% Non CM 6%	• Incentive vouchers were purchased with funds voluntarily donated from healthcare organizations, businesses, and

Type	Authors Date	**Study Design** • **Setting** • **Subjects** • **N=**	**Study Groups** • **CM** • **Non-CM** **Length**	**Intervention Features**	**Outcomes Studied**	**Results**	**Comments**
		pregnant and smoke. N=220	• Usual care	assessments: baseline, eight months gestation, and two months postpartum. All participants received a participation voucher (value of $5.00) at each assessment. • All subjects telephoned monthly. On self-report of not smoking, subject visited clinic for saliva specimen collection. • With abstinence, treatment subjects received $50 voucher as did their Social Supporter.			foundations who held the belief that being smoke free during pregnancy carries a tremendous health, social, and cost benefit. **Relevance to this review:** • Sustainability of intervention and method of funding incentives over time and equally across the state are dubious. • While WIC was an excellent conduit to this population, staff tended to be "stretched thin" and they had limited time to engage in research tasks. • WIC in general has a loss to follow up/no show rate consistent with loss to follow up experienced with intervention.

Prenatal Smoking Cessation and Relapse Prevention

	Author Date	Type	
PSC	Lumley, et al. 2004 Cochrane Review	Lit. Review of Interventions for promoting smoking cessation during pregnancy	**Findings:** • Even with substantial variation in the intensity of the intervention and the extent of reminders and reinforcement through pregnancy, there was an increase in the median intensity of both 'usual care' and interventions over time. • Smoking cessation interventions reduced low birthweight (RR 0.81, 95% CI 0.70 to 0.94) and preterm birth (RR 0.84, 95% CI 0.72 to 0.98), and there was a 33 g (95% CI 11 g to 55 g) increase in mean birthweight. • Only one group of the trials (those including a social support and a reward component) showed a significantly larger effect (pooled RR 0.77, 95% CI 0.72 to 0.82). Their results were consistent but comprised only two trials. • There were no statistically significant differences in very low birthweight, stillbirths, perinatal or neonatal mortality but these analyses had very limited power. • Pooled analyses showed no evidence for a significant effect with stages of change based interventions, compared with interventions based on other theories. **Comments** • 64 trials included **Relevance to the Review** • Smoking cessation programs in pregnancy reduce the proportion of women who continue to smoke, and reduce low birthweight and preterm birth. • Incentive trials pointed out as showing larger effect, but author points out that there have been only two studies.
PSC	Kim & England 2009	PRAMS analysis	**Findings:** • Universal implementation of a best-practice, clinic-based intervention would increase the total number of quitters but would not substantially reduce smoking prevalence among pregnant women. **Comments:** • Uses RR from Cochrane Review 2004 • Estimate of the rate of spontaneous quitting (23%) was based on national data from1990, and the rate may have increased since then. However, this estimate is consistent with recent studies conducted in health care settings in which rates of spontaneous quitting ranged from 23% to 29%. **Relevance to this review:** • With maximum efficacy of 5A intervention, smoking prevalence in 3rd trimester would decrease from 16.4% to 14.4% • However, Kim notes that Hartmann et al. (Obstet Gynecol. 2007 ;110:765–770) recently reported that only one third of prenatal care providers administered the 5 A's to their pregnant patients.
PSC	CDC 2009 Pregnancy Risk Assessment Monitoring System (PRAMS)	CDC Surveillance Summary 2000-2005	**Findings:** • All PRAMS states have met HP2010 objective of increasing percentage of pregnant smokers who stop smoking during pregnancy to 30%. • None of the sites achieved the HP 2010 objective of reducing the prevalence of prenatal smoking to 1%. • For the majority of sites, smoking rates did not change over time before, during, or after pregnancy **Comments:** • Vermont data spans 2003-3005; not included in analyses which span 2000-2005 • There are 31 PRAMS states **Relevance to this review:** • The results indicate that efforts to reduce smoking prevalence among female smokers before pregnancy have not been effective; however, efforts targeting pregnant women have met some success as rates have declined during pregnancy and after delivery. • Health-care providers should increase efforts to assess the smoking status of their patients and offer effective smoking-cessation interventions to every female or pregnant smoker to whom they provide health-care services. • States can reduce smoking before, during, and after pregnancy through sustained and comprehensive tobacco-control efforts

	Author Date	Type	
			(e.g., smoke-free policies and tobacco excise taxes).
PSC	Yunzal-Butler, 2009 Pregnancy Nutrition Surveillance System (PNSS)	PNSS data from 8 states. Varied time spans, 1995-2004	**Findings:** • Women who enroll in WIC in the first trimester of pregnancy are 2.7% points more likely to be smoking at intake than women who enroll in the third trimester. • Among participants who smoked before pregnancy and at prenatal WIC enrollment, those who enrolled in the first trimester are 4.5% points more likely to quit smoking 3 months before delivery and 3.4% points more likely to quit by postpartum registration, compared with women who do not enroll in WIC until the third trimester. • Smokers who report quitting by the first prenatal WIC visit, first-trimester enrollment is associated with a 2% point increase in relapse by postpartum registration. **Comments:** • These results differ by race/ ethnicity; white women who enroll early are 3.6% points more likely to relapse, while black women are 2.5% points less likely to relapse. **Relevance to this review:** • Early WIC enrollment is associated with higher quit rates, although changes are modest when compared to the results from smoking cessation interventions for pregnant women.
PSC	Peterson, et al. 2006	PRAMS analysis 1998-2000 PSC coverage by Medicaid	**Findings:** • Higher levels of coverage during prenatal care for smoking cessation interventions were associated with higher quit rates; 51%, 43%, and 39% of women quit in states with extensive, some, and no coverage, respectively. • Maintenance of cessation after delivery was associated with extensive levels of Medicaid. 48% of women maintained cessation in states with extensive coverage compared to 37% of women in states with no coverage. **Comments:** Vermont Medicaid has extensive coverage **Relevance to this Review:** Suggests increased promotion of cessation by Medicaid providers could increase quit rates significantly.

Cahill K, Perera R. Competitions and incentives for smoking cessation (Review). Cochrane Database of Systematic Reviews 2009, Issue 3. Art. No.: CD004307.

BACKGROUND: Material or financial incentives may be used in an attempt to reinforce behaviour change, including smoking cessation. They have been widely used in workplace smoking cessation programmes, and to a lesser extent within community programmes. Quit and Win contests are the subject of a companion review. OBJECTIVES: To determine whether competitions and incentives lead to higher long-term quit rates. We also set out to examine the relationship between incentives and participation rates. SEARCH STRATEGY: We searched the Cochrane Tobacco Addiction Group Specialized Register, with additional searches of MEDLINE, EMBASE, CINAHL and PsycINFO. Search terms included incentive*, competition*, contest*, reward*, prize*, contingent payment*, deposit contract*. The most recent searches were in December 2007. SELECTION CRITERIA: We considered randomized controlled trials, allocating individuals, workplaces, groups within workplaces, or communities to experimental or control conditions. We also considered controlled studies with baseline and post-intervention measures. Data collection and analysis Data were extracted by one author and checked by the second. We contacted study authors for additional data where necessary. The main outcome measure was abstinence from smoking at least six months from the start of the intervention. We used the most rigorous definition of abstinence in each trial, and biochemically validated rates where available. Where possible we performed meta-analysis using a generic inverse variance model, grouped by timed endpoints, but not pooled across the subgroups. MAIN RESULTS: Seventeen studies met our inclusion criteria. None of the studies demonstrated significantly higher quit rates for the incentives group than for the control group beyond the six-month assessment. There was no clear evidence that participants who committed their own money to the programme did better than those who did not, or that different types of incentives were more or less effective. There is some evidence that although cessation rates have not been shown to differ significantly, recruitment rates can be improved by rewarding participation, which may be expected to deliver higher absolute numbers of successful quitters. Cost effectiveness analysis is not appropriate to this review, since the efficacy of the intervention has not been demonstrated. AUTHORS' CONCLUSIONS: Incentives and competitions have not been shown to enhance long-term cessation rates, with early success tending to dissipate when the rewards are no longer offered. Rewarding participation and compliance in contests and cessation programmes may have more potential to deliver higher absolute numbers of quitters. CM Review

Centers for Disease Control and Prevention. Trends in Smoking Before, During, and After Pregnancy — Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 31 Sites, 2000–2005a. Surveillance Summaries, May 29, 2009. MMWR 2009;58(No. SS-4).

PROBLEM: Smoking among nonpregnant women contributes to reduced fertility, and smoking during pregnancy is associated with delivery of preterm infants, low infant birthweight, and increased infant mortality. After delivery, exposure to secondhand smoke can increase an infant's risk for respiratory tract infections and for dying of sudden infant death syndrome. During 2000–2004, an estimated 174,000 women in the United States died annually from smoking-attributable causes, and an estimated 776 infants died an-

nually from causes attributed to maternal smoking during pregnancy.Reporting Period Covered: 2000–2005. DESCRIPTION OF SYSTEM: The Pregnancy Risk Assessment Monitoring System (PRAMS) was initiated in 1987 and is an ongoing state- and population-based surveillance system designed to monitor selected maternal behaviors and experiences that occur before, during, and after pregnancy among women who deliver live-born infants in the United States. Self-reported questionnaire data are linked to selected birth certificate data and are weighted to represent all women delivering live infants in the state. Self-reported smoking data were obtained from the PRAMS questionnaire and birth certificates. This report provides data on trends (aggregated and site-specific estimates) of smoking before, during, and after pregnancy and describes characteristics of female smokers during these periods. RESULTS: For the study period 2000–2005, data from 31 PRAMS sites (Alabama, Alaska, Arkansas, Colorado, Florida, Georgia, Hawaii, Illinois, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Jersey, New Mexico, New York, New York City, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Utah, Vermont, Washington, and West Virginia) were included in this report. All 31 sites have met the Healthy People 2010 (HP 2010) objective of increasing the percentage of pregnant smokers who stop smoking during pregnancy to 30%; site-specific quit rates in 2005 ranged from 30.2% to 61.0%. However, none of the sites achieved the HP 2010 objective of reducing the prevalence of prenatal smoking to 1%; site-specific prevalence of smoking during pregnancy in 2005 ranged from 5.2% to 35.7%. During 2000–2005, two sites (New Mexico and Utah) experienced decreasing rates for smoking before, during, and after pregnancy, and two sites (Illinois and New Jersey) experienced decreasing rates during pregnancy only. Three sites (Louisiana, Ohio, and West Virginia) had increases in the rates for smoking before, during, and after pregnancy, and Arkansas had increases in rates before pregnancy only. For the majority of sites, smoking rates did not change over time before, during, or after pregnancy. For 16 sites (Alaska, Arkansas, Colorado, Florida, Hawaii, Illinois, Maine, Nebraska, New Mexico, New York [excluding New York City], North Carolina, Oklahoma, South Carolina, Utah, Washington, and West Virginia) for which data were available for the entire 6-year study period, the prevalence of smoking before pregnancy remained unchanged, with approximately one in five women (from 22.3% in 2000 to 21.5% in 2005) reporting smoking before pregnancy. The prevalence of smoking during pregnancy declined ($p = 0.01$) from 15.2% in 2000 to 13.8% in 2005, and the prevalence of smoking after delivery declined ($p = 0.04$) from 18.1% in 2000 to 16.4% in 2005. INTERPRETATION: The results indicate that efforts to reduce smoking prevalence among female smokers before pregnancy have not been effective; however, efforts targeting pregnant women have met some success as rates have declined during pregnancy and after delivery. Current tobacco-control efforts and smoking-cessation efforts targeting pregnant women are not sufficient to reach the HP 2010 objective of reducing prevalence of smoking during pregnancy. PUBLIC HEALTH ACTION: The data provided in this report are important for developing, monitoring, and evaluating state tobacco-control policies and programs to reduce smoking among female and pregnant smokers. States can reduce smoking before, during, and after pregnancy through sustained and comprehensive tobacco-control efforts (e.g., smoke-free policies and tobacco excise taxes). Health-care providers should increase efforts to assess the smoking status of their patients and offer effective smoking-cessation interventions to every female or pregnant smoker to whom they provide health-care services.

Donatelle R, Hudson d, et al. Incentives in smoking cessation: Status of the field and implications for research and practice with pregnant smokers. Nicotine Tob Res 2004 6: S163-S179.

The article reviews the rationale and empirical evidence for the use of incentive and contingency management strategies for smoking cessation. Plausible theoretical rationales exist for the application of these strategies to smoking cessation, and a great deal of research with illicit drug users in laboratory or controlled treatment settings suggests such strategies can be effective. Contingency management methods have been effective in modifying smoking behavior in volunteers not seeking cessation assistance in highly controlled settings. Incentives have been used primarily as a component of worksite interventions, in community-wide quit-and-win programs, in quasi-experimental and experimental trials, and more recently with low-income pregnant women. Worksite studies have rarely been designed to isolate the impact of incentives. Nevertheless, they appear to be useful in these settings especially in increasing participation and increasing awareness about the deleterious effects of smoking. Quit-and-win programs are used widely in the United States and internationally and appear to attract many participants and produce modest quit rates. The quality of the evaluations of quit-and-win programs varies considerably, and none has employed rigorous control or comparison groups to sufficiently identify the effect of incentives. Recent controlled studies have yielded promising results with pregnant smokers, and larger trials are in progress. Key methodological issues in mounting and evaluating incentive interventions, particularly during pregnancy are discussed, along with the practical and ethical issues arising from the use of incentives. CM Smoking Review

Donatelle R, Prows S, et al. Randomised controlled trial using social support and financial incentives for high risk pregnant smokers: Significant Other Supporter (SOS) program. Tob Control 2000 9(Suppl III):iii67–iii69.

Smoking cessation interventions have posed significant challenges for health professionals, particularly when directed at high risk, low income, pregnant smokers. Typical quit rates for pregnant women who receive publicly financed obstetrical care have rarely exceeded 12–16%. As many as 70% of women who quit smoking during pregnancy relapse within one year of delivery. Two areas that have received particular attention as possible adjuncts to behaviour change are the use of reinforcements and social supports. Reinforcement in the form of incentives/rewards for positive behaviours has been controversial as an intervention strategy. Some argue that the overjustification effect" of external rewards may cause subjects to lose internal motivation to modify behaviour over the long term. However, results of several studies, including two meta-analyses on reinforcement, provide compelling evidence that positive reinforcement provides positive behavioural changes. A second area of study that has been explored in the behaviour change research is the role of social support in motivating and sustaining selected behaviour change. Recent studies have empirically linked tobacco quit rates with daily interaction with a supportive "other," preferably one who did not smoke. The primary objective of our intervention was to determine whether the combination of bolstered social support and financial incentives had an effect in significantly reducing smoking behaviour among low income, high risk, pregnant and postpartum women who participate in Oregon's Women, Infants, and Children (WIC) program. CM Prenatal Smoking

Hajek P, Stead LF, et al. Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: CD003999.

BACKGROUND: A number of treatments can help smokers make a successful quit attempt, but many initially successful quitters relapse over time. Several interventions were proposed to help prevent relapse. OBJECTIVES: To assess whether specific interventions for relapse prevention reduce the proportion of recent quitters who return to smoking. SEARCH STRATEGY: We searched the Cochrane Tobacco Addiction Group trials register in August 2008 for studies mentioning relapse prevention or maintenance in title, abstracts or keywords. Selection criteria Randomized or quasi-randomized controlled trials of relapse prevention interventions with a minimum follow up of six months. We included smokers who quit on their own, or were undergoing enforced abstinence, or who were participating in treatment programmes. We included trials that compared relapse prevention interventions to a no intervention control, or that compared a cessation programme with additional relapse prevention components to a cessation programme alone. DATA COLLECTION AND ANALYSIS: Studies were screened and data extracted by one author and checked by a second. Disagreements were resolved by discussion or referral to a third author. MAIN RESULTS: Fifty-four studies met inclusion criteria, but were heterogeneous in terms of populations and interventions. We considered 36 studies that randomized abstainers separately from studies that randomized participants prior to their quit date. Looking at studies of behavioural interventions which randomised abstainers, we detected no benefit of brief and skills-based' relapse prevention methods for women who had quit smoking due to pregnancy, or for smokers undergoing a period of enforced abstinence during hospitalisation or military training. We also failed to detect significant effects of behavioural interventions in trials in unselected Relapse prevention interventions for smoking groups of smokers who had quit on their own or with a formal programme. Amongst trials randomising smokers prior to their quit date and evaluating the effect of additional relapse prevention components we also found no evidence of benefit of behavioural interventions in any subgroup. Overall, providing training in skills thought to be needed for relapse avoidance did not reduce relapse, but most studies did not use experimental designs best suited to the task, and had limited power to detect expected small differences between interventions. For pharmacological interventions, extended treatment with varenicline significantly reduced relapse in one trial (risk ratio 1.18, 95% confidence interval 1.03 to 1.36). Pooling of five studies of extended treatment with bupropion failed to detect a significant effect (risk ratio 1.17; 95% confidence interval 0.99 to 1.39). Two small trials of oral nicotine replacement treatment (NRT) failed to detect an effect but treatment compliance was low and in two other trials of oral NRT randomizing short-term abstainers there was a significant effect of intervention. AUTHORS' CONCLUSIONS: At the moment there is insufficient evidence to support the use of any specific behavioural intervention for helping smokers who have successfully quit for a short time to avoid relapse. The verdict is strongest for interventions focusing on identifying and resolving tempting situations, as most studies were concerned with these. There is little research available regarding other behavioural approaches. Extended treatment with varenicline may prevent relapse. Extended treatment with bupropion is unlikely to have a clinically important effect. Studies of extended treatment with nicotine replacement are needed. RESULTS OF REVIEW FOR PREGNANT AND POSTPARTUM EX-SMOKERS: In pooling the results of eight trials of interventions in pregnancy we did not demonstrate a significant benefit at the end of pregnancy (n = 1523, risk ratio [RR]

1.04; 95% confidence interval [CI] 0.98 to 1.11, I2 = 0%, Analysis 1.1). Twelve studies included follow up during the postpartum period. We also failed to detect any significant benefit among this group of studies, overall or in subgroups according to timing of intervention (n = 3273, RR 1.07; 95% CI 0.98 to 1.18, I2 = 0%, Analysis 1.2). One further study that we could not include in the meta-analysis did not detect any significant effect of intervention on spontaneous quitters at delivery; the postpartum non smoking rate was higher in the usual care group (Pbert 2004). RELAPSE Review

Heil S, Higgins S, et al. Effects of voucher-based incentives on abstinence from cigarette smoking and fetal growth among pregnant women. Addiction 2008 103:1009–1018.

AIMS: This study examined whether voucher-based reinforcement therapy (VBRT) contingent upon smoking abstinence during pregnancy is an effective method for decreasing maternal smoking during pregnancy and improving fetal growth. Design, setting and participants A two-condition, parallel-groups, randomized controlled trial was conducted in a university-based research clinic. A total of 82 smokers entering prenatal care participated in the trial. Intervention Participants were assigned randomly to either contingent or non-contingent voucher conditions. Vouchers exchangeable for retail items were available during pregnancy and for 12 weeks postpartum. In the contingent condition, vouchers were earned for biochemically verified smoking abstinence; in the non-contingent condition, vouchers were earned independent of smoking status. Measurements Smoking outcomes were evaluated using urine-toxicology testing and self-report. Fetal growth outcomes were evaluated using serial ultrasound examinations performed during the third trimester. Findings Contingent vouchers significantly increased point-prevalence abstinence at the end-of-pregnancy (41% versus 10%) and at the 12-week postpartum assessment (24% versus 3%). Serial ultrasound examinations indicated significantly greater growth in terms of estimated fetal weight, femur length and abdominal circumference in the contingent compared to the non-contingent conditions. Conclusions These results provide further evidence that VBRT has a substantive contribution to make to efforts to decrease maternal smoking during pregnancy and provide new evidence of positive effects on fetal health. CM Prenatal Smoking

Higgins S, Heil S, et al. A pilot study on voucher-based incentives to promote abstinence from cigarette smoking during pregnancy and postpartum. Nicotine Tob Res 2004 6:1015-1020.

We report results from a pilot study examining the use of vouchers redeemable for retail items as incentives for smoking cessation during pregnancy and postpartum. Of 100 study-eligible women who were still smoking upon entering prenatal care, 58 were recruited from university-based and community obstetric practices to participate in a smoking cessation study. Participants were assigned to either contingent or noncontingent voucher conditions. Vouchers were available during pregnancy and for 12 weeks postpartum. In the contingent condition, vouchers were earned for biochemically verified smoking abstinence. In the noncontingent condition, vouchers were earned independent of smoking status. Abstinence monitoring and associated voucher delivery was conducted daily during the initial 5 days of the cessation effort, gradually decreased to every other week antepartum, increased to once weekly during the initial 4 weeks

postpartum, and then decreased again to every other week for the remaining 8 weeks of the postpartum intervention period. Contingent vouchers increased 7-day point-prevalence abstinence at the end-of-pregnancy (37% vs. 9%) and 12-week postpartum (33% vs. 0%) assessments. That effect as sustained through the 24-week postpartum assessment (27% vs. 0%), which was 12 weeks after discontinuation of the voucher program. Total mean voucher earnings across antepartum and postpartum were US$397 (SD~US$414) and US$313 (SD~$142) in the contingent and noncontingent conditions, respectively. The magnitude of these treatment effects exceed levels typically observed with pregnant and recently postpartum smokers, and the maintenance of effects through 24 weeks postpartum extends the duration beyond those reported previously. CM Prenatal Smoking

J. Sindelar, "Paying for Performance: The Power of Incentives over Habits," Health Economics 2008 17:449-451.

New evidence suggests that individuals do not always make rational decisions, especially with regard to health habits. Smoking, misuse of alcohol, overeating and illicit drug use are leading causes of morbidity and mortality. Thus, influencing health habits is critical for improving overall health and well-being. This editorial argues that economists should take a more active role in shaping individuals' health habits. Two recent innovations in economic theory pave the way. One change is that some economists now view rationality as bounded and willpower in short supply. Another, related to the first, is a more accepting perspective on paternalism, authorizing economists to help individuals make better choices when the neoclassical model breaks down. Findings from psychology offer incentive-based approaches; specifically, contingency management (CM). Economists could use this approach as a basis for developing public and private policies. CM Editorial

Kim SY, England L. The Contribution of Clinic-Based Interventions to Reduce Prenatal Smoking Prevalence Among US Women. Am J Public Health. 2009 99:893–898.

OBJECTIVES: We sought to estimate the effect of universal implementation of a clinic-based, psychosocial smoking cessation intervention for pregnant women. METHODS: We used data from US birth certificates (2005) and the Pregnancy Risk Assessment Monitoring System (2004) to estimate the number of women smoking at conception. To calculate the number of women eligible to receive the cessation intervention, we used estimates from the literature of the percentage of women who quit spontaneously (23%), entered prenatal care before the third trimester (96.5%), and disclosed smoking to their provider (75%). We used the pooled relative risk (RR) for continued smoking from the 2004 Cochrane Review as our measure of the intervention's effectiveness (RR=0.94). RESULTS: We estimated that 944,240 women smoked at conception. Of these, 23.0% quit spontaneously, 6.3% quit with usual care, and an additional 3.3% quit because of the intervention, leaving 67.4% smoking throughout pregnancy. The calculated smoking prevalence in late pregnancy decreased from 16.4% to 15.6% because of the intervention. Conclusions: Universal implementation of a best-practice, clinic-based intervention would increase the total number of quitters but would not substantially reduce smoking prevalence among pregnant women. PRAMS Review

Lumley J, Oliver S, et al. Interventions for promoting smoking cessation during pregnancy. Cochrane Database of Systematic Reviews 2004, Issue 4. Art. No.: CD001055.

BACKGROUND: Smoking remains one of the few potentially preventable factors associated with low birthweight, preterm birth and perinatal death. OBJECTIVES: To assess the effects of smoking cessation programs implemented during pregnancy on the health of the fetus, infant, mother, and family. SEARCH STRATEGY: We searched the Cochrane Pregnancy and Childbirth Group trials register and the Cochrane Tobacco Addiction Group trials register (July 2003), MEDLINE (January 2002 to July 2003), EMBASE (January 2002 to July 2003), PsychLIT (January 2002 to July 2003), CINAHL (January 2002 to July 2003), and AUSTHEALTH (January 2002 to 2003). We contacted trial authors to locate additional unpublished data. We handsearched references of identified trials and recent obstetric journals. SELECTION CRITERIA: Randomised and quasi-randomised trials of smoking cessation programs implemented during pregnancy. Data collection and analysis Four reviewers assessed trial quality and extracted data independently. MAIN RESULTS: This review included 64 trials. Fifty-one randomised controlled trials (20,931 women) and six cluster-randomised trials (over 7500 women) provided data on smoking cessation and/or perinatal outcomes.Despite substantial variation in the intensity of the intervention and the extent of reminders and reinforcement through pregnancy, there was an increase in the median intensity of both 'usual care' and interventions over time. There was a significant reduction in smoking in the intervention groups of the 48 trials included: (relative risk (RR) 0.94, 95% confidence interval (CI) 0.93 to 0.95), an absolute difference of six in 100 women continuing to smoke. The 36 trials with validated smoking cessation had a similar reduction (RR 0.94, 95% CI 0.92 to 0.95). Smoking cessation interventions reduced low birthweight (RR 0.81, 95% CI 0.70 to 0.94) and preterm birth (RR 0.84, 95% CI 0.72 to 0.98), and there was a 33 g (95% CI 11 g to 55 g) increase in mean birthweight. There were no statistically significant differences in very low birthweight, stillbirths, perinatal or neonatal mortality but these analyses had very limited power. One intervention strategy, rewards plus social support (two trials), resulted in a significantly greater smoking reduction than other strategies (RR 0.77, 95% CI 0.72 to 0.82). Five trials of smoking relapse prevention (over 800 women) showed no statistically significant reduction in relapse. AUTHORS' CONCLUSIONS: Smoking cessation programs in pregnancy reduce the proportion of women who continue to smoke, and reduce low birthweight and preterm birth. The pooled trials have inadequate power to detect reductions in perinatal mortality or very low birthweight. PSC Review

Peterson, et al. Medicaid reimbursement for prenatal smoking intervention influences quitting and cessation Tobacco Control 2006;15:30–34.

Background: 40% of births in the USA are covered by Medicaid and smoking is prevalent among recipients. The objective of this study was to evaluate the association between levels of Medicaid coverage for prenatal smoking cessation interventions on quitting during pregnancy and maintaining cessation after delivery. Methods: Population based survey study of 7513 post-partum women from 15 states who: participated in Pregnancy Risk Assessment Monitoring System (PRAMS) during 1998–2000; smoked at the beginning of their pregnancy; and had Medicaid coverage. Participating states were categorised into three levels of Medicaid coverage for smoking cessation interventions during prenatal care: extensive (pharma-

cotherapies and counselling); some (pharmacotherapies or counselling); or none. Quit rates among women who smoked before pregnancy and rates of maintaining cessation were examined. Results: Higher levels of coverage during prenatal care for smoking cessation interventions were associated with higher quit rates; 51%, 43%, and 39% of women quit in states with extensive, some, and no coverage, respectively. Compared to women in states with no coverage, women in states with extensive coverage had 1.6 times the odds of quitting smoking (odds ratio (OR) 1.58, 95% confidence interval (CI) 1.00 to 2.49). Maintenance of cessation after delivery was associated with extensive levels of Medicaid coverage; 48% of women maintained cessation in states with extensive coverage compared to 37% of women in states with no coverage. Compared to women in states with no coverage, women with extensive coverage had 1.6 times the odds of maintaining cessation (OR 1.63, 95% CI 1.04 to 2.56). Conclusions: Prenatal Medicaid coverage for both pharmacotherapies and counselling is associated with higher rates of quitting and continued cessation. This suggests policymakers can promote cessation by broadening smoking cessation services in Medicaid prenatal coverage.

Sutherland K, Christianson J, et al. Impact of Targeted Financial Incentives On Personal Health Behavior: A Review of the Literature. Med Care Res Rev 2008 65: 36S-78S.

Over the past decade, there has been a substantial increase in the use of financial incentives by private employers and public programs to encourage healthy behaviors, wellness activities, and use of preventive services. The research evidence regarding the effectiveness of this approach is reviewed, summarizing relevant findings from literature reviews and from recent evaluations. The article concludes that financial incentives, even relatively small incentives, can influence individuals' health-related behaviors. However, the findings regarding health promotion and wellness are based primarily on analyses of a limited number of private sector initiatives, whereas the evidence regarding preventive services is based on evaluations of initiatives sponsored predominantly by public programs and directed at low-income populations. In either case, there are several important limitations in the ability of the published findings to provide clear guidance for public program administrators or private purchasers seeking to design and implement effective incentive programs. CM Review Health

Tevyaw T, Colby S, et al. Contingency management and motivational enhancement: A randomized clinical trial for college student smokers. Nicotine Tob Res 2009 11:739-749.

INTRODUCTION: The efficacy of contingency-management (CM) and motivational enhancement therapy (MET) for college student smoking cessation was examined. METHODS: Nontreatment-seeking daily smokers (N = 110) were randomly assigned to 3 weeks of CM versus noncontingent reinforcement (NR) and to three individual sessions of MET versus a relaxation control in a 2 _ 2 experimental design. Expired carbon monoxide (CO) samples were collected twice daily for 3 weeks. Participants earned U.S.$5 for providing each sample; additionally, those randomized to CM earned escalating monetary rewards based on CO reductions (Week 1) and smoking abstinence (Weeks 2 – 3). RESULTS: Compared with NR, CM resulted in significantly lower CO levels and greater total and consecutive abstinence during the intervention. Those in the CM and MET groups reported greater interest in quitting smoking posttreat-

ment, but rates of confirmed abstinence at follow-up were very low (4% at 6-month follow-up) and did not differ by group. DISCUSSION: Findings support the short-term efficacy of CM for reducing smoking among college students. Future research should explore enhancements to CM in this population, including a longer intervention period and the recruitment of smokers who are motivated to quit. CM

Volpp K, John L, et al. Financial Incentive–Based Approaches for Weight Loss: A Randomized Trial. JAMA 2008 300:2631-2637.

CONTEXT: Identifying effective obesity treatment is both a clinical challenge and a public health priority due to the health consequences of obesity. OECTIVE: To determine whether common decision errors identified by behavioral economists such as prospect theory, loss aversion, and regret could be used to design an effective weight loss intervention. DESIGN, SETTING, AND PARTICIPANTS: Fifty-seven healthy participants aged 30-70 years with a body mass index of 30-40 were randomized to 3 weight loss plans: monthly weigh-ins, a lottery incentive program, or a deposit contract that allowed for participant matching, with a weight loss goal of 1 lb (0.45 kg) a week for 16 weeks. Participants were recruited May-August 2007 at the Philadelphia VA Medical Center in Pennsylvania and were followed up through June 2008. MAIN OUTCOME MEASURES: Weight loss after 16 weeks. RESULTS: The incentive groups lost significantly more weight than the control group (mean, 3.9 lb). Compared with the control group, the lottery group lost a mean of 13.1 lb (95% confidence interval [CI] of the difference in means, 1.95-16.40; P=.02) and the deposit contract group lost a mean of 14.0 lb (95% CI of the difference in means, 3.69-16.43; P =.006). About half of those in both incentive groups met the 16-lb target weight loss: 47.4% (95% CI, 24.5%-71.1%) in the deposit contract group and 52.6% (95% CI, 28.9%-75.6%) in the lottery group, whereas 10.5% (95% CI, 1.3%- 33.1%; P=.01) in the control group met the 16-lb target. Although the net weight loss between enrollment in the study and at the end of 7 months was larger in the incentive groups (9.2 lb; t=1.21; 95% CI, _3.20 to 12.66; P=.23, in the lottery group and 6.2 lb; t=0.52; 95% CI, _5.17 to 8.75; P=.61 in the deposit contract group) than in the control group (4.4 lb), these differences were not statistically significant. However, incentive participants weighed significantly less at 7 months than at the study start (P=.01 for the lottery group; P=.03 for the deposit contract group) whereas controls did not. CONCLUSIONS: The use of economic incentives produced significant weight loss during the 16 weeks of intervention that was not fully sustained. The longer-term use of incentives should be evaluated. CM Weight

Volpp K, Pauly M, et al. P4P4P: An Agenda For Research On Pay-For-Performance For Patients. Health Affairs 2009 28:206–214.

Unhealthy behavior is a major cause of poor health outcomes and high health care costs. In this paper we describe an agenda for research to guide broader use of patient-targeted financial incentives, either in conjunction with provider-targeted financial incentives (pay-for-performance, or P4P) or in clinical contexts where provider-targeted approaches are unlikely to be effective. We discuss evidence of proven effectiveness and limitations of the existing evidence, reasons for underuse of these approaches, and options for achieving wider use. Patient-targeted incentives have great potential, and systematic testing will help determine how they can best be used to improve population health. CM Review

Volpp K, Troxel A, et al. A Randomized, Controlled Trial of Financial Incentives for Smoking Cessation. N Engl J Med 2009 360:699-709.

BACKGROUND: Smoking is the leading preventable cause of premature death in the United States. Previous studies of financial incentives for smoking cessation in work settings have not shown that such incentives have significant effects on cessation rates, but these studies have had limited power, and the incentives used may have been insufficient. METHODS: In this study, 878 employees of a multinational company based in the United States were randomly assigned to receive information about smoking-cessation programs (442 employees) or to receive information about programs plus financial incentives (436 employees). The financial incentives were $100 for completion of a smoking-cessation program, $250 for cessation of smoking within 6 months after study enrollment, as confirmed by a biochemical test, and $400 for abstinence for an additional 6 months after the initial cessation, as confirmed by a biochemical test. Individual participants were stratified according to work site, heavy or nonheavy smoking, and income. The primary end point was smoking cessation 9 or 12 months after enrollment, depending on whether initial cessation was reported at 3 or 6 months. Secondary end points were smoking cessation within the first 6 months after enrollment and rates of participation in and completion of smoking-cessation programs. RESULTS: The incentive group had significantly higher rates of smoking cessation than did the information-only group 9 or 12 months after enrollment (14.7% vs. 5.0%, P<0.001) and 15 or 18 months after enrollment (9.4% vs. 3.6%, P<0.001). Incentive-group participants also had significantly higher rates of enrollment in a smoking-cessation program (15.4% vs. 5.4%, P<0.001), completion of a smoking-cessation program (10.8% vs. 2.5%, P<0.001), and smoking cessation within the first 6 months after enrollment (20.9% vs. 11.8%, P<0.001). CONCLUSIONS: In this study of employees of one large company, financial incentives for smoking cessation significantly increased the rates of smoking cessation. CM Smoking

Yunzal-Butler C, Joyce T, Racine A. Maternal Smoking and the Timing of WIC Enrollment. Matern Child Health J, Feb 2009.

OBJECTIVE: To investigate the association between the timing of enrollment in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and smoking among prenatal WIC participants. METHODS: We use WIC data from eight states participating in the Pregnancy Nutrition Surveillance System (PNSS). We adjust the association between the timing of WIC participation and smoking behavior with a rich set of maternal characteristics. RESULTS: Women who enroll in WIC in the first trimester of pregnancy are 2.7% points more likely to be smoking at intake than women who enroll in the third trimester. Among participants who smoked before pregnancy and at prenatal WIC enrollment, those who enrolled in the first trimester are 4.5% points more likely to quit smoking 3 months before delivery and 3.4% points more likely to quit by postpartum registration, compared with women who do not enroll in WIC until the third trimester. However, among pregravid smokers who report quitting by the first prenatal WIC visit, first-trimester enrollment is associated with a 2% point increase in relapse by postpartum registration. These results differ by race/ ethnicity; white women who enroll early are 3.6% points more likely to relapse, while black women are 2.5% points less likely to relapse. CONCLUSIONS: Early WIC enrollment is associated with higher quit rates, although changes are modest when compared to the results from smoking cessation interventions for pregnant women. Given the prevalence of prenatal smoking among WIC participants, efforts to intensify WIC's role in smoking cessation through more frequent, and more focused counseling should be encouraged. WIC

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March 25, 2009

Dear Rutland and Newport District Office staff,

The following document is the Draft Site Visit Interview Guide that we will be using during our conversations with you next week. As you may be aware, the purpose of these site visits is to better understand your experiences implementing the Pregnancy Smoking Cessation Program as well as to conduct quality assurance monitoring. Both of these activities will help inform the Vermont Department of Health's decision-making process when considering expansion of the Program to other district offices and future self-monitoring.

JSI believes in a participatory and completely transparent approach to evaluation. We believe this approach will allow us to get a clearer picture of the program and will inform your efforts to self-monitor the program on an ongoing basis. We hope that you see these site visits as an opportunity to ask us questions and share with us any insights you may have to program operations, efficiencies, inefficiencies and effectiveness. We truly welcome your input.

Thank you in advance for your support of this process. We look forward to seeing you next week.

Sincerely,

Naomi Clemmons and Janet Van Ness

Eligibility Criteria

1. The protocol indicates that women up to 23 weeks of pregnancy are eligible for enrollment. Has your office experienced any challenges to these criteria?

    a. If yes, please describe.
    b. If yes, how were these challenges handled?

Process

2. Who within this district office screens, enrolls, counsels and monitors women?
    a. If multiple staff are responsible, please describe how these efforts are coordinated in terms of:
        - Communication about a woman's progress (e.g., relapse, slippage, etc.)
        - Tracking women's appointments and missed appointments

3. Describe the basic process that you follow when discussing the Pregnancy Smoking Cessation Program to a potential client?

4. Have you had to make any adaptations to the protocol? For example, have you had to make adaptations to the:

    a. Enrollment criteria
    b. Educational messages
    c. Initial/ Enrollment visit (including the 5 As)
    d. Incentives—intervals, CO monitoring, relapsing behavior, resetting incentives
    e. Incentive tracking
    f. Weekly CO Test Visits
    g. Other adaptations

5. What have you identified as the critical components or activities of the Program?

6. Describe your system for managing the flow and protocol steps?

7. Are there any aspects of the protocol that you find inconvenient or interrupt work flow?

Documentation

8. How is information during each encounter with a client documented?
    a. When is it transcribed into the database?

9. How do you document and monitor appointments and missed appointments?

    a. How are missed appointments handled?
    b. Do you follow up with clients who have missed appointments? How?

10. How is "slippage" documented?

11. How is "relapsing behavior" documented?

12. How is abstinence documented?

Quality Assurance

13. What do you think the elements (i.e., indicators) would be for Program success?

14. What is necessary for the Program to be successful? For example, staff qualifications, flexible hours, etc.

15. If the Program were to be implemented in other district offices, are there any changes or systems you would recommend?

    a. For example, would an orientation or informal training be helpful? Ongoing technical assistance? Conference calls with other offices implementing the program?

16. How important do you think the incentives are to the program?

Smoking Cessation During Pregnancy
Time Study Log

CLIENT	RECRUITMENT	ENROLLMENT	EDUCATIONAL MESSAGE	CO TEST	DATA ENTRY	FOLLOW-UP	OTHER*	TIME SPENT
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

*Other: Examples for this category include staff meetings, staff consultations, administrative, etc. Can also be used for general comments.

DISTRICT OFFICE: **STAFF POSITION:**