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# Pregnancy and Medical Cost Outcomes of a Self-Help Prenatal Smoking Cessation Program in a HMO

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## Synopsis

*The results of a randomized clinical trial of a prenatal self-help smoking cessation program are reported in terms of the pregnancy and cost outcomes. The study population were the socioeconomically and ethnically diverse members of a large health maintenance organization (HMO) who reported that they were smoking at the time of their first prenatal visit.*

*The intervention consisted predominately of printed materials received through the mail. Compared with the usual care control group, women assigned to the self-help program were more likely to achieve cessation for the majority of their pregnancy (22.2 percent versus 8.6 percent), gave birth to infants weighing on average 57 grams more, and were 45 percent less likely to deliver a low birth weight infant.*

*An economic evaluation of the self-help program was conducted from the perspective of the sponsoring HMO. Based upon the expenditures associated with the neonates' initial hospital episode, the intervention had a benefit-cost ratio of 2.8:1. These findings provide strong evidence to support widespread incorporation of smoking cessation interventions as a standard component of prenatal care.*

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INTRAPREGNANCY SMOKING is associated with intrauterine growth retardation (IUGR), shortened gestation, and perinatal morbidity and mortality (*1*). Women who smoke during pregnancy have from two to four times the chance of delivering a growth retarded infant, with a 32–45 percent absolute risk of IUGR resulting from smoking (*2*). Prematurity rates are nearly 50 percent higher for smokers, and 11–14 percent of all preterm births are attributable to smoking (*3*). Smoking contributes significantly to an estimated 20–40 percent of all low birth weight (LBW) infants (that is, less than 2,500 grams) born in the United States and Canada (*4*). Intrapregnancy smoking also has been correlated with childhood morbidity (*5*). Evidence for a causal connection between intrapregnancy smoking and adverse birth outcomes has been strengthened by results from randomized clinical trials testing the effect of smoking cessation on birth weight (*6, 7*).

Although fewer pregnant women smoke today than in past decades, more than a fifth of pregnant women in the United States smoke throughout pregnancy (*8*). Given the magnitude of the public health problem and the extent of smoking-related research in other populations, it is surprising that few methodologically sound investigations have explored the behavioral impact of cessation interventions targeted to pregnant women.

Notable exceptions are the work of Sexton (*9*) with women referred predominately by private practice physicians and of Windsor and coworkers (*10*) in a public health maternity clinic population. The former study achieved cessation rates of 32 percent over a rate of 7 percent in controls with an intervention that included one personal visit with a health educator at pregnancy intake, monthly telephone calls, and biweekly contact by mail, usually in the form of a newsletter. Windsor found a quit rate of 14 percent versus 2 percent of controls among women who received a pregnancy-specific self-help manual and a 10-minute skills counseling session with a health educator, in addition to 2–3 minutes of counseling about smoking that was part of usual care education during the initial prenatal visit.

The medical costs associated with LBW deliveries are of concern to private insurance carriers, maternal and child health agencies, and health care providers, particularly those practicing in managed care settings. Given supportive evidence that women who quit smoking in pregnancy (even as late as the second trimester) can achieve birth outcomes similar to nonsmokers (*11*), an effective prenatal smoking cessation program could be a successful strategy for cost containment.

Few investigations, however, have focused either on the cost-effectiveness or cost-benefit of prenatal smoking cessation interventions. Windsor and coworkers (*12*) conducted an economic analysis of the intervention cited and found that the pregnancy-specific booklets were more cost-effective than either a generic self-help smoking cessation program or usual care controls. A cost-benefit analysis of a smoking intervention directed to pregnant women by one of the authors, D.H.E., (*13*) found that a self-help home correspondence program yielded a benefit-cost ratio of 2:1. Interpretation of these study findings, however, was limited by lack of random assignment, reliance on self-report of smoking status, and a possible confounding of the effects of the smoking intervention with a concurrent nutrition counseling program. Marks and coworkers, using Office of Technology Assessment data on expenditures associated with neonatal intensive care unit (NICU) hospitalization of LBW infants, have estimated that a typical prenatal smoking cessation program would save nearly $3 for every $1 spent (Marks, J. S., et al.: Cost-effectiveness of smoking cessation in pregnancy. Centers for Disease Control, Division of Prevention and Health Promotion, Atlanta, GA. Unpublished manuscript, 1988).

*'The intervention was presented as a routine part of prenatal care. All medical care providers were blind to study group assignment. Prenatal patients had no further contact with the intake health educator. No effort was made to modify the usual counseling practices of the medical staff nor the health plan's prenatal education classes and Lamaze instruction.'*

A previous paper (*14*) reported the results of a population-based, prospective randomized clinical trial testing the effects of a prenatal self-help smoking intervention on rates of smoking among women enrolled in a health maintenance organization (HMO). The ethnically diverse study population was composed of all pregnant smokers, regardless of their initial motivation to quit or willingness to receive the program. Statistically significant results were achieved employing the stringent criterion of biochemically confirmed continuous abstinence for the majority of pregnancy. Specifically, 22.2 percent of smokers assigned to the experimental program ($N = 126$) reported to have quit smoking before the 20th week of pregnancy and had abstinence confirmed through delivery, compared with 8.6 percent of controls ($N = 116$). Smoking status was biochemically verified with three urine samples obtained over the course of prenatal care. A quit was defined as no cotinine value greater than 29 nanograms per milliliters (ng per ml) and at least one value less than 10 ng per ml.

This paper presents the pregnancy outcomes and economic evaluation of that trial. Specifically, two questions are addressed.

- Did the experimental and control groups differ on mean birth weight and incidence of LBW deliveries—including both preterm and IUGR infants?

Table 1. Study subjects by experimental status

| Category | Experimental | Control | Total |
|---|---|---|---|
| Initially impaneled prenatal smokers:[1] | 165 | 158 | 323 |
| Abortion | 7 | 11 | 18 |
| Miscarriage | 12 | 13 | 25 |
| Disenrollment from health plan | 20 | 18 | 38 |
| Total prenatal attrition | 39 | 42 | 82 |
| Delivered as plan member:[2] | 126 | 116 | 242 |
| Twin delivery | 3 | 1 | 4 |
| Stillbirth | 2 | 1 | 3 |
| Missing data | 3 | 5 | 8 |
| Live single birth[3] | 118 | 109 | 227 |

[1]Costs of providing the intervention based on this group.
[2]Behavioral evaluation of the self-help program based on this group.
[3]Pregnancy outcomes and economic evaluation based on this group.

• Did the savings in the cost of all institutional and professional charges for newborn care associated with the initial hospitalization episode outweigh the cost of providing the self-help smoking cessation program?. This economic evaluation, therefore, is a cost-benefit analysis from the perspective of the sponsoring HMO.

## Methods

**Sample and design.** Study intake was conducted over a 2-year period from July 1985 through June 1987 among members of Maxicare Health Plans, Inc., a large HMO. All English-speaking women who began prenatal care at one of five health centers of the Hawthorne Community Medical Group, a large multispecialty group affiliated with Maxicare in southern California, were screened for study eligibility.

Patients participated in an individual 45-minute intake conference conducted by a health educator. This mandatory conference marked the formal beginning of prenatal care at the medical group. It consisted of a medical history, an orientation to the group's obstetrical practices, and health education on various prenatal topics. Of the 2,383 women who met the study criteria of being English speaking and less than 18 weeks pregnant at intake, 541 (23 percent) were prepregnancy smokers. Included in the study are the 323 women who reported that they were still smoking seven or more cigarettes per week.

At the conclusion of the conference, the health educator conducted a brief smoking-related interview with the smokers before turning over the preassigned card used to randomize subjects to experimental or control conditions. Of the 323 smokers, 165 were assigned to the experimental group, and 158 to the usual care control group.

**Description of intervention.** In keeping with the standard practice of the medical group, all smokers were given a 2-page pamphlet on the hazards of cigarette smoking during pregnancy and the importance of quitting. The health educator reinforced the written information in a 2-minute discussion. Experimental subjects were then introduced to a serialized cessation program oriented to women and pregnancy. The series was designed to increase motivation and teach behavioral strategies for smoking cessation and relapse prevention. The 4- to 8-page booklets were written at a 9th grade reading level and carried the logos of the health plan and the medical group. The health educator gave a 3-minute overview of the program and its activity assignments, presented Booklet #1, and asked the patient to make a commitment to complete the first activity assignment within the ensuing week. The remaining seven booklets were mailed thereafter at weekly intervals.

The intervention was presented as a routine part of prenatal care. All medical care providers were blind to study group assignment. Prenatal patients had no further contact with the intake health educator. No effort was made to modify the usual counseling practices of the medical staff nor the health plan's prenatal education classes and Lamaze instruction.

**Cost of intervention.** Intervention costs to the health plan per prenatal patient were based on overhead, personnel time, self-help materials, and postage. Fee-for-service patients of the medical group were charged $25 for the 45-minute intake session or $.55 per minute. The health educator spent an additional 3 minutes on the self-help program, and thus the cost of personnel time and overhead associated with the introduction of the program was estimated to be $1.65.

The cost of the self-help printed materials including a folder to store the booklets, "smoking diary" sheets, "urge diary" sheets, and mailing envelopes was $3.94, based on unit pricing for 2,500 sets of booklets. Development of the booklets including writing, artwork, layout, and design, amortized over 2,500 sets of booklets, was estimated at $1.25. Ten additional minutes of clerical staff time were required to stuff booklets into envelopes, type mailing labels, and mail the booklets. Including salary, fringe, and overhead costs, this additional administrative expense was estimated at $1.67. Finally, postage for mailing 7 booklets at 1985-87 rates was $3.24, resulting in a total program cost of $11.75 per administration.

**Measurement.** Data for these analyses can be categorized as follows: (*a*) maternal baseline information, (*b*) pregnancy outcomes, and (*c*) neonatal medical costs. Baseline information came from the intake conference's medical history, which obtained sociodemographics and pregnancy-related background information. Birth outcomes were derived from chart audits of hospital records. Birth weight and gestational age were used to create the LBW categories: preterm (infants born prior to the 37th completed week of gestation) and IUGR (infants of at least 37 weeks completed gestation, but weighing less than 2,500 grams). All live births not falling into one of these two categories were classified as "other." The other category, although exclusive of LBW deliveries, included several cases of other adverse birth outcomes (for example, respiratory distress syndrome, congenital abnormalities) with several requiring admission to the NICU.

The health plan's costs associated with the delivery were taken from its computerized claims system. This system captured institutional charges to the health plan (for example, nursery, NICU, laboratory, X-ray) and charges from hospital-based providers (neonatologists and radiologists). Additional charges were obtained from the medical group's service summary report, which captured all hospital-based professional charges for services provided by the medical group (in most instances, $92 for a routine examination of a healthy newborn by a pediatrician). Other frequently occurring charges of the medical group providers (primarily pediatricians) included $110 for a stand-by complicated delivery and $45 to treat relatively benign conditions such as jaundice.

The dollar figures provided in the current analysis correspond to the amount paid by the health plan and not the amount billed by the institutional provider. As is customary in the HMO industry, financial arrangements between payor and institutions are lower than fee-for-service medicine (for example, all-inclusive per diem rates, discounts ranging up to 40 percent of the total charges). Although the amount paid by the HMO is not the cost of providing the services, it is closer to the actual cost than a standard fee-for-service charge. The perspective taken in the current evaluation is that of the HMO, and the cost is the amount paid for the service.

**Statistical analysis.** For categorical data, probability values were calculated using the $\chi^2$ statistic. For interval level measures, statistical analyses were performed using analysis of variance and covariance. Values greater than .05 were not considered statistically significant.

## Results

Table 1 outlines the disposition of study subjects from the mother's pregnancy intake visit through the infant's discharge from the hospital. During the prenatal period there was the natural loss of subjects due to miscarriage and abortion, as well as disenrollment from the health plan—a total of 39 (23.6 percent) of the 165 impaneled experimental group and 42 (26.5 percent) of the 158 controls. The remaining 242 subjects who delivered as plan members composed the sample used in the behavioral evaluation of the self-help program.

The pregnancy outcomes and economic evaluation in this report are based on the 118 experimental and 109

Table 2. Comparison of experimental and usual care groups

| *Category*[1] | *Percent experimental (N = 118)* | *Percent control (N = 109)* |
|---|---|---|
| Sociodemographics: | | |
| White race | 66.9 | 63.3 |
| Black race | 24.7 | 25.7 |
| Other race | 8.4 | 11.0 |
| Education, mean years | 12.7 | 12.4 |
| Age, mean years | 27.0 | 26.4 |
| Marital status, married | 61.9 | 60.6 |
| Pregnancy-related: | | |
| Gravida, 0 | 22.1 | 18.3 |
| Gravida, 1 | 27.1 | 16.5 |
| Gravida, 2 or more | 50.8 | 65.2 |
| Parity, 0 | 50.0 | 40.3 |
| Parity, 1 | 33.1 | 30.3 |
| Parity, 2 or more | 16.9 | 29.4 |
| Miscarriage, 0 | 80.6 | 73.4 |
| Miscarriage, 1 | 16.9 | 18.3 |
| Miscarriage, 2 or more | 2.5 | 8.3 |
| Abortion, 0 | 49.2 | 45.0 |
| Abortion, 1 | 30.5 | 30.3 |
| Abortion, 2 or more | 20.3 | 24.7 |
| Previous IUGR-preterm[2] delivery, yes | 11.0 | 8.3 |
| Week entering prenatal care, mean | 10.5 | 11.2 |

[1]Data reflect characteristics of sample at time of entry into prenatal care.
[2]IUGR = intrauterine growth retardation.

Table 3. Pregnancy outcomes by experimental status

| | *Experimental* | | *Control* | | *Total* | |
|---|---|---|---|---|---|---|
| *Category* | *Number* | *Percent* | *Number* | *Percent* | *Number* | *Percent* |
| Birth weight, mean grams[1] | 3,366 | ... | 3,309 | ... | 3,339 | ... |
| IUGR delivery[2] | 2 | 1.7 | 8 | 7.3 | 10 | 4.4 |
| Preterm delivery | 7 | 5.9 | 7 | 6.4 | 14 | 6.2 |
| Total low birth weight | 9 | 7.6 | 15 | 13.7 | 24 | 10.6 |
| Other delivery | 109 | 92.4 | 94 | 86.3 | 203 | 89.4 |
| Total | 118 | 100.0 | 109 | 100.0 | 227 | 100.0 |

[1]Adjusting on significant covariates, the mean birth weight in the experimental group was 3,370 grams versus 3,305 grams among controls, $P>.05$.
[2]$P<.05$; IUGR = intrauterine growth retardation.

Table 4. Medical costs associated with neonatal care by experimental status

| Outcome | Cost-pregnancy outcome | | Experimental group | | Control group | |
|---|---|---|---|---|---|---|
| | Mean | Standard deviation | Incidence of births | Total cost | Incidence of births | Total cost |
| Intrauterine growth retardation (IUGR) | $1,032 | $ 1,442 | 2 | $ 2,064 | 8 | $ 8,256 |
| Preterm | 6,213 | 10,560 | 7 | 43,491 | 7 | 43,491 |
| Other[1] | 695 | 1,007 | 109 | 75,755 | 94 | 65,330 |
| Total | $1,050 | $ 3,028 | 118 | $121,310 | 109 | $117,077 |
| Average cost per delivery | ... | ... | ... | $ 1,028 | ... | $ 1,074 |

[1]Includes 3 control and 1 experimental group infants who were admitted to the neonatal intensive care unit (NICU) for reasons other than IUGR or preterm. If these other NICU admissions were excluded, the average cost of other deliveries was $586 (standard deviation = $322).

control group women who delivered live single births and whose data were available for analysis. In keeping with the convention of epidemiologic studies that have explored smoking status and pregnancy outcomes (*6, 7*), four sets of twins and three stillbirths were excluded. In eight cases data were missing as a result of the mothers delivering in an out-of-area hospital, having a missing hospital record, or having primary health insurance coverage through another payor.

Table 2 contrasts the experimental and control groups on sociodemographic variables and pregnancy-related background characteristics. No statistically significant differences were observed. The sample was approximately two-thirds white, one-quarter black, with the large majority (approximately 80 percent) in their 20s and having at least a high school education. More than half were married at pregnancy intake. One-fifth reported a previous miscarriage and one-quarter reported having had two or more abortions. Approximately one-tenth of the sample reported having delivered a preterm or IUGR infant in the past. Four-fifths of the women began prenatal care for the current pregnancy in the first trimester.

• Question No. 1—Did the groups differ in pregnancy outcomes? These comparisons are provided in table 3. Women in the experimental group gave birth to infants who on average were 57 grams heavier and experienced nearly half the incidence of LBW deliveries (7.6 percent versus 13.7 percent), although neither contrast was statistically significant. A statistically significant difference was detected with respect to IUGR deliveries (1.7 percent of experimental women versus 7.3 percent in controls, $P < .05$).

• Question No. 2—Did program savings exceed program costs? Analysis of the comparison of actual neonatal expenditures for infants born to experimental and control women revealed large standard deviations in both groups and the presence of an extreme outlier in the control group (that is, a preterm infant that generated medical costs in excess of $40,000). To obtain a more stable estimate of the economic impact of the intervention, the costs of each of the three birth outcome categories were standardized with data from the total sample (that is, $6,213 for a preterm delivery, $1,032 for an IUGR delivery, and $695 for an other delivery). These costs were then applied to the incidence rate of the birth outcome categories in each group. This method yielded an average cost per delivery of $1,028 in the experimental group and $1,074 in controls (table 4). Multiplying the $46 differential per delivery by the 118 women in the experimental group yielded a total difference of $5,428. Given that 165 experimental group women were exposed to the self-help program at $11.75 per administration, the total intervention cost was $1,939, producing a net benefit of $3,489 and a benefit-cost ratio of 2.8:1.

To corroborate the above benefit-cost ratio, results were simulated for a HMO with a membership of 100,000. Specifically, the study's net quit rate of 13.6 percent (22.2 percent in the experimental group versus 8.6 percent among controls) was applied to a recent estimate of smokers' neonatal costs per delivery relative to nonsmokers. Oster and coworkers (*15*) concluded that infants born to smokers in the United States generate an additional $288 (1983 dollars) in neonatal costs. This estimate was revised to $366 (1987 dollars), using a 6.2 percent per year increase in the medical consumer price index, to correspond to the timeframe of the current study.

Table 5 provides the results of the simulation. Assuming a 25 percent smoking rate in the target population of 2,400 pregnant women per year, 600 prepregnancy smokers would be identified at their first prenatal visit. Based on experience from the current trial, 40 percent of the prepregnancy smokers would be expected to have quit on their own prior to seeking prenatal care (*16*). As such, 360 women would be current smokers at pregnancy intake and receive the program at a total cost of $4,230.

Assuming that 25 percent of the initial cohort would be lost over the course of pregnancy (miscarriage, abortion, disenrollment), 270 women would be expected to deliver as health plan members. Applying the net quit rate of 13.6 percent generates an additional 36.7 quits over the course of 1 year. Using the $366 cost differential per delivery discussed earlier, the 36.7 additional quits would yield savings of $13,432, a net benefit of $9,202 to the HMO and a benefit-cost ratio of 3.17:1.

Table 5. Economic evaluation of smoking cessation program implemented in a HMO of 100,000 members

| *Variable* | *Amount* |
|---|---|
| Pregnancy intake per year | 2,400 |
| Prepregnancy smokers identified at beginning of prenatal care | 600 |
| Prepregnancy smokers still smoking at intake | 360 |
| Cost of providing self-help intervention (360 × $11.75) | $4,230 |
| Deliveries as health plan member | 270 |
| Additional quits resulting from intervention (270 × 13.6 percent) | 36.7 |
| Cost saving derived from intervention (36.7 × $366)[1] | $13,432 |
| Net benefit | $9,202 |
| Benefit-cost ratio | 3.17:1 |

[1]The use of the $366 cost differential for this analysis assumes that women who quit early in pregnancy have pregnancy outcomes comparable to those of nonsmokers. In the current study a $360 differential in neonatal costs was found between infants born to quitters versus continuing smokers.

## Discussion

Findings from this study indicate that the behavior change stimulated by a prenatal smoking cessation program had a favorable impact on pregnancy outcomes and generated cost savings for the HMO. Compared with controls, women in the experimental group gave birth to infants who on average were 57 grams heavier, an outcome that falls midway between the results of two other randomized clinical trials—92 grams reported by Sexton and Hebel (*6*) and 34 grams from the MacArthur and coworkers' (*7*) investigation. The differences among the three studies in birth weight outcomes is consistent with the relative success of the interventions in assisting experimental subjects to quit smoking. The 92-gram differential between experimental and control subjects in the Sexton and Hebel study corresponds to a net quit rate of 23 percent, compared with 13.6 percent in this study and 3 percent in the MacArthur investigation.

In addition to birth weight, this study examined the more clinically relevant pregnancy outcome—incidence of LBW deliveries. Experimental subjects were found to have a rate 45 percent lower than controls. Consistent with previous studies, the impact of smoking on LBW was found to be more pronounced in the category of IUGR as opposed to premature deliveries. Importantly, however, although prematurity rates were similar, 5.9 percent in the experimental group versus 6.4 percent in controls, this minor difference is consistent with available epidemiologic data on the relative risk of intrapregnancy smoking on prematurity. Specifically, there is evidence of an approximate 50 percent increase in prematurity rates among smokers relative to nonsmokers (*17*). If all the women in the experimental group had quit smoking, one would have expected a prematurity rate of approximately 4 percent or a net reduction of 2 percent to 2.5 percent. As such, the .5 percent observed differential is consistent with the experimental group's net quit rate advantage of 13.6 percent.

Study data revealed that prematurity had a major impact on cost savings derived from the intervention. Importantly, although the groups differed in the incidence of IUGR deliveries to a much greater extent than was observed for prematurity, the slight .5 percent differential in prematurity rates between groups contributed more to the overall cost savings. This is because the average cost per delivery of premature infants was six times that of IUGR deliveries. These data illustrate how even a modest decline in prematurity rates will translate into major savings, given the extremely high health care expenditures associated with this adverse pregnancy outcome. To put the numbers in perspective, one preterm birth averted at the cost of $6,213 could pay for the self-help program for more than 500 smokers. Given the effectiveness of the intervention for increasing quit rates during pregnancy and the supportive epidemiologic evidence linking smoking with an increased incidence in prematurity, there was good reason to believe that the self-help program would yield cost savings to the HMO. This conclusion was supported by an evaluation of the neonatal medical costs associated with the treatment of infants born to study subjects, as well as a simulation that used national data.

The economic evaluation revealed that the HMO saved approximately $3 for every $1 spent on the self-help smoking cessation program. This 3:1 benefit-cost ratio is most likely conservative in that it takes into account only the effect of maternal smoking on IUGR and prematurity and not on other adverse pregnancy outcomes (*15*). Further, economic analyses were based only on costs of the neonates' initial hospitalization episode and therefore excluded long-term care costs associated with increased childhood morbidity of LBW infants. For example, Marks and coworkers (unpublished) raise their cost saving estimate from 3:1 to 5:1 when these additional medical expenditures are factored into the equation.

Prenatal smoking cessation programs also could be

*'... data from the medical group's service summary report revealed that among routine deliveries, those infants born to mothers who smoked during pregnancy generated $48 in outpatient care for respiratory conditions during the first 6 months of life, compared with $34 among those whose mothers had quit smoking during pregnancy.'*

expected to yield financial savings among infants who were not LBW or admitted to the NICU. For example, data from the medical group's service summary report revealed that among routine deliveries, those infants born to mothers who smoked during pregnancy generated $48 in outpatient care for respiratory conditions during the first 6 months of life, compared with $34 among those whose mothers had quit smoking during pregnancy.

Also, no estimate was made of anticipated outpatient and inpatient cost savings associated with pregnancy-specific maternal health benefits derived from a prenatal smoking cessation program including reduced incidence of miscarriage, stillbirths, pre-eclampsia, and so forth. Further, potential savings from maternal health benefits derived from cessation maintained beyond pregnancy were not estimated.

Importantly, all analyses were calculated exclusively from the perspective of direct cost savings to the HMO. Of note, more than 10 percent of the women who received the self-help program from the HMO changed insurance carriers prior to the completion of pregnancy. Any benefits derived from the program for those women were lost to the sponsoring HMO. Finally, indirect benefits (for example, earnings from longer life expectancies, fewer work days missed by parents caring for their sick infants) as well as indirect costs (for example, time costs for participants exposed to the program) were not considered in any analyses.

In examining the costs associated with the intervention, it is noted that over half of the $11.75 cost per administration is associated with the personal introduction by the health educator and the postage and administrative time for mailings over a 2-month period. Although it would cost less to have a paraprofessional give a smoker a single manual at the time of the first prenatal visit, we believe this mode of program implementation would be far less effective and would thereby act to lower the benefit-cost ratio (*14*).

Although data from this study strongly suggest that the self-help intervention yielded cost savings to the HMO, the question arises whether alternative or complementary strategies could generate further cost savings. A self-help program can be expected to be effective primarily with persons who are at least somewhat motivated to quit smoking. Heightened personal interaction or counseling, such as that used in the Sexton and Hebel trial, is probably necessary to increase substantially the quit rate above that achieved in the current trial. Since other studies have demonstrated that pregnant women do not attend group smoking cessation classes (*10, 18*), programs based on counseling the individual woman are the most promising. While there is little doubt that labor-intensive interventions would generate somewhat higher quit rates, they may not yield more favorable benefit-cost ratios.

The physician, of course, is the most influential provider in obstetrical care. To date, rigorously designed trials have not measured the impact of physician counseling on prenatal smoking cessation rates. The results of studies in primary care settings demonstrate only modest effectiveness of provider-based interventions (*19*). However, even under ideal conditions of trained physicians committed to behavioral counseling, approximately 5 minutes of physician time is as costly as the entire self-help intervention implemented in this trial (*20*).

Importantly, we are not suggesting that prenatal medical care providers be excluded from smoking cessation intervention. In conjunction with a program that taught behavioral skills, if physicians and nurse practitioners briefly reinforced a cessation message at the first visit ("It's important for you to stop smoking. It is dangerous for you and your baby. I want you to use the program that we have provided you.") and provided monitoring at subsequent visits ("How are you doing with quitting smoking?"), quit rates could be improved and such intervention could be justified from a cost-benefit standpoint.

In closing, it is important to consider the limitations of the study. Although diverse, the study population did not include welfare recipients, and there is some evidence that a self-help smoking cessation intervention directed to low-income women may not yield as high a net quit rate as reported in the current study. Further, the study was conducted in a HMO setting. The cost of providing the intervention and the cost outcomes may not easily generalize to persons insured through traditional indemnity plans and receiving care from solo, fee-for-service practitioners.

The relatively few women in the sample is another limitation of this investigation. Power calculations for the experiment were based on the ability to detect group differences in smoking cessation rates. A sample size in excess of 10,000 subjects would be required to detect group differences in all pregnancy outcomes of interest. As a result, although substantive differences were detected between the experimental group and controls for both pregnancy and cost outcomes, several comparisons, most notably, differences in the incidence of prematurity, failed to achieve statistical significance.

Although the sample size was less than optimal, we do not believe this limitation compromised the major conclusions of the study. First, the mean birth weight differential between study groups was consistent with numerous epidemiologic studies and the findings from two other prenatal smoking cessation trials (*6, 7*). Second, the benefit-cost ratio based on data from this study was similar to a simulated estimate that used a national data source (*15*).

In a time of concern for cost containment, prevention and lifestyle modification are receiving greater attention. Unfortunately, the modest effectiveness of state-of-the-art behavioral programs and the long latency period associated with risk factor exposure and disease endpoints make it difficult to demonstrate that behavioral risk factor interventions are cost beneficial. This is particularly true when indirect benefits are not included in the model. Data from this trial demonstrate that prenatal smoking cessation programs can yield savings from the perspective of the program sponsor, and the results suggest that widespread implementation of these programs may be a worthwhile investment for society.

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