Integrating Smoking Cessation into Routine Public Prenatal Care: The Smoking Cessation in Pregnancy Project

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ABSTRACT

Objectives. In 1986, the state health departments of Colorado, Maryland, and Missouri conducted a federally-funded demonstration project to increase smoking cessation among pregnant women receiving prenatal care and services from the Women, Infants, and Children (WIC) program in public clinics.

Methods. Low-intensity interventions were designed to be integrated into routine prenatal care. Clinics were randomly assigned to intervention or control status; pregnant smokers filled out questionnaires and gave urine specimens at enrollment, in the eighth month of pregnancy, and postpartum. Urine cotinine concentrations were determined at CDC by enzyme-linked immunosorbent assay and were used to verify self-reported smoking status.

Results. At the eighth month of pregnancy, self-reported quitting was higher for intervention clinics than control clinics in all three states. However, the cotinine-verified quit rates were not significantly different.

Conclusions. Biochemical verification of self-reported quitting is essential to the evaluation of smoking cessation interventions. Achieving changes in smoking behavior in pregnant women with low-intensity interventions is difficult. (*Am J Public Health.* 1995;85:217–222)

Introduction

The relationship between cigarette smoking and adverse pregnancy outcome is clear.[1–3] In theory, the effects of smoking on the fetus are preventable: if women did not smoke during pregnancy, there would be no health hazard to the fetus. However, the behavior is highly prevalent: in 1989, according to the National Center for Health Statistics, at least 19% of US women smoked during pregnancy.[4] To meet the national health objectives for the year 2000, this proportion must be reduced to 12%.[5] Unfortunately, smoking cessation programs for pregnant women have not achieved very high quit rates.[6–9]

Pregnant women of low socioeconomic status are of particular concern because they have high levels of smoking and their infants are at high risk of being low birthweight.[4,10] Even a program with modest effectiveness could have a substantial public health impact if directed at this group.[11] However, only a few smoking cessation programs have been developed for this population.[9,12,13]

The Smoking Cessation in Pregnancy (SCIP) project was designed for women attending public prenatal clinics and Women, Infants, and Children (WIC) programs. Support was provided through cooperative agreements between the state health departments in Colorado, Maryland, and Missouri and the Centers for Disease Control and Prevention (CDC). These agreements were partially funded by the US Department of Agriculture's Food and Nutrition Service. New smoking cessation intervention programs were developed in each state for implementation by existing clinic staff. The success of the programs was rigorously evaluated by using self-administered questionnaires and biochemical verification of smoking status. In this report, we describe the study design and estimates of the effect of the new interventions on smoking behavior.

Methods

Design of Intervention Programs and Materials

Interventions were designed independently in each state. The process included a literature review, discussions with smoking cessation experts, focus groups conducted with pregnant or postpartum smokers and ex-smokers, input from local clinic staff, and extensive pretesting. The written materials and counseling protocols were unique to each state, although

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common elements were present. All three interventions provided information on the effects of smoking on the fetus, the benefits of quitting, quitting techniques, developing social support, preventing relapse, and limiting exposure to environmental tobacco smoke. All materials were written at a sixth-grade reading level.

The Colorado intervention used in prenatal clinics included a protocol for 1- to 5-minute counseling sessions with the following minimum components: assessment of smoking status, discussion of quitting tips, and a supportive statement by the nurse clinician. A similar but abbreviated protocol was followed at WIC sites. The printed materials included a health care provider's guide to the smoking cessation protocols, eight brochures for pregnant smokers, and a brochure for postpartum women.

The Maryland intervention was a brief, clinic-based counseling program supplemented by self-help materials. The multiple components of the intervention used a five-step approach to quitting that highlighted the stages-of-quitting model.[14]

The Missouri intervention emphasized becoming a lifetime ex-smoker, rather than just quitting for the duration of the pregnancy. The written materials included patient brochures, clinic flip charts, training materials for staff, and chart documentation forms. There was a separate intervention for WIC clients. The intervention included strategies for physicians, nurses, and other clinic staff. The counseling sessions were about 6 minutes long at prenatal clinics and 1 to 2 minutes long at WIC sites.

Evaluation Design

In each state, public prenatal clinics were asked to participate in the study. The clinics that agreed to be randomized into the study were stratified by total yearly enrollment (<250 patients and ≥ 250), by experience with a low birthweight prevention program (Colorado), and by percentage of Black and other minority women (Missouri). Within strata, clinics were randomly assigned to deliver the new interventions (intervention status) or to continue providing usual care (control status). Once a clinic was randomized, all women attending it received the same care. In Colorado, 14 clinics (7 intervention/7 control) participated; in Maryland, 28 clinics (14/14) participated; and in Missouri, 22 clinics (11/11) participated.

Selected WIC clinics also participated. In Missouri, all participating WIC clinics used the new interventions. In Colorado, only the WIC clinics associated with prenatal intervention clinics provided the new interventions. In Maryland, there was no participation by WIC in the SCIP study.

All women coming to a clinic for their first prenatal visit were screened for eligibility. Every woman who reported having smoked even a puff of a cigarette within 7 days before screening or within 7 days before she thought she was pregnant was considered to be a smoker and was asked for consent to collect questionnaire data and urine specimens.

Screening and enrollment questionnaires were filled out at the first or second prenatal visit. Follow-up questionnaires were completed at the eighth month of pregnancy (about 32 to 36 weeks) and at the postpartum visit (about 6 to 12 weeks postpartum). The questionnaires covered demographic characteristics, smoking habits, exposure to passive smoke, and other risk factors for low birthweight. Clinic staff also obtained a urine specimen each time a questionnaire was collected. State health department and clinic personnel made attempts, by mail or telephone, to interview women who did not return for their eighth-month or postpartum appointment.

Enrollment began in 1987 or 1988, depending on the state, and lasted about 2 years. Follow-up ended in August 1991.

To assess exposure to the interventions, anonymous opinion forms were collected from a subset of women at their postpartum visit. At the end of the study, state health department personnel solicited comments from providers and patients about the new intervention programs and the program evaluation.

Vital records data were used to obtain information on birth outcome for women lost to follow-up. In Colorado and Missouri, SCIP data were merged with data from birth certificates. In Maryland, SCIP data were merged with data from the state's Maternity Summary Form.

Urine Cotinine Testing

Urine specimens were frozen and shipped in batches to CDC. They were analyzed for cotinine, a nicotine metabolite, by enzyme-linked immunosorbent assay (ELISA).[15] True creatinine was measured with a kinetic Jaffe reaction.[15] We used a regression method to adjust the concentration of urine cotinine for urine creatinine.[16] An active smoking threshold (85 ng/mL adjusted for creatinine) was chosen by visual inspection of the bimodal frequency distribution of values for smokers and nonsmokers.[15]

Women who reported active smoking were considered to be smokers, regardless of their cotinine value.[17] Women who reported not smoking but who had adjusted cotinine levels above the threshold were considered to be smokers. The term "nondisclosure" is used to describe this phenomenon.

Data Analysis

"Enrollment smokers" were women who smoked in the 7 days before enrollment. "Recent quitters" were women who smoked before they thought they were pregnant, but reported not smoking at enrollment. "Self-reported quitters" were enrollment smokers who reported not smoking at the time of their eighth-month visit.

We used analytic methods appropriate for clustered data because the clinics, not the women, had been randomly assigned to intervention status. For dichotomous outcomes (e.g., quit vs no quit), the clustered Woolf's odds ratio was used as a measure of intervention effect.[18,19] For continuous outcomes, such as changes in mean cotinine level, we used general linear models with a mixture of fixed and random effects.[20,21] We included clinic in the models as a random effect to account for clustering in the design.[22]

To determine whether the interventions had resulted in a reduction in smoking, we compared mean cotinine values at the eighth month for enrollment smokers attending intervention clinics with values for enrollment smokers attending control clinics. General linear models adjusted for factors determined at enrollment: age, race, education, parity, passive smoke exposure, body mass index, WIC status, presence of a husband or partner, caffeine consumption, alcohol consumption, adjusted cotinine level at enrollment (log), and clinic nested within intervention/control status. The following potential interactions with intervention/control status were examined: parity, race, education, cotinine level at enrollment, and passive smoke exposure.

To examine the effect of the interventions on birthweight, we aggregated data from all three states and used general linear models to examine differences in the mean birthweight of singleton, liveborn infants of self-reported enrollment smokers by intervention/control status.

Results

Enrollment and Characteristics

The total numbers of women screened were 5262, 6087, and 4943 in Colorado, Maryland, and Missouri, respectively. In each state, nearly 50% of the women reported smoking. Consent rates for data collection ranged from 66% in Maryland to 79% in Missouri.

Enrollment questionnaire data were available from a total of 5572 women (Table 1). In each state, high proportions of participants were young, had less than 12 years' education, and were White, unmarried, and poor (Table 1). Mean gestational age at entry into prenatal care was 18 to 20 weeks (range: 4 to 32 weeks). Women in Colorado tended to be somewhat lighter smokers than women in the other states. Intervention and control sites were similar at enrollment, indicating that stratification and randomization had been effective (data not shown). In the three states combined, the reasons for loss to follow-up at the eighth month were early termination of pregnancy (7.6%); enrollment after 32 weeks (6.1%); lost, moved, or unable to locate (27.7%); referred to another care provider (2.8%); and refused data collection (1.0%). Loss to follow-up was very similar across intervention and control sites in all three states.

We examined potential biases introduced by nonparticipation or loss to follow-up. In all three states, nonparticipants were less likely than participants to be White and more likely to be recent quitters. The characteristics of women lost to eighth-month follow-up were very similar to those of women for whom questionnaire and urine data were available.

TABLE 1—Smoking Cessation in Pregnancy Project: Characteristics of Participating Women at Enrollment

	Colorado (n = 1741)		Maryland (n = 1936)		Missouri (n = 1895)	
	No.	%	No.	%	No.	%
Age < 20 y	482	27.7	513	26.5	595	31.4
Education < 12 y	647	37.2	815	42.1	884	46.6
Race/ethnicity						
White, non-Hispanic	1361	78.2	1376	71.1	1480	78.1
Hispanic	259	14.9	54	2.8	29	1.5
Black	82	4.7	468	24.2	362	19.1
Other	39	2.2	38	2.0	24	1.3
Unmarried	1127	64.7	1516	78.3	1262	66.6
Receiving WIC services	655	37.6	284	14.7	814	43.0
Nulliparous	803	46.1	881	45.5	778	41.1
Income ≤ $500/mo	579	33.3	529	27.3	760	40.1
Eighth month questionnaire available	1171	67.3	1316	68.0	1354	71.4
Urine specimens available						
At enrollment	1195	68.6	1613	83.3	1529	80.7
At enrollment and eighth month	616	35.4	924	47.7	770	40.6
Amount smoked						
None	341	19.6	219	11.3	249	13.1
< 1 cigarette/d	138	7.9	127	6.6	125	6.6
1–9 cigarettes/d	480	27.6	540	27.9	485	25.6
≥ 10 cigarettes/d	767	44.1	1015	52.4	1034	54.6
Thinks she will quit smoking	529	30.4	647	33.4	592	31.2
Husband or partner smokes[a]	850	70.6	1118	71.6	1028	76.0
Passive smoke exposure						
None	204	11.7	265	13.7	192	10.1
1–8 h/d	759	43.6	742	38.3	727	38.4
> 8 h/d	747	42.9	878	45.4	946	49.9
Mean weeks' gestation at entry into case (SD)	20.3 (7.6)		17.6 (7.4)		18.3 (7.5)	

Note. The sample breakdowns were as follows: Colorado = 865 women attending 7 control clinics, 876 women attending 7 intervention clinics; Maryland = 1242 women attending 14 control clinics, 694 women attending 14 intervention clinics; Missouri = 957 women attending 11 control clinics, 938 women attending 11 intervention clinics.
[a]Among women with a husband or partner.

Effect of the Interventions on Smoking Behavior

In all three states, enrollment smokers attending intervention clinics were more likely to report quitting smoking by the eighth month than were enrollment smokers attending control clinics (Table 2). However, the cotinine-verified quit rates were not significantly different between intervention and control sites in any state. In aggregated data from all three states, the odds ratio for quitting was 1.0.

The majority of recent quitters did not resume smoking by the eighth month, although the verified rates of cessation maintenance were somewhat lower than the self-reported rates (data not shown).

In aggregated three-state data, the crude verified quit rates differed among subgroups of women (Table 3). The interventions had a statistically significant effect only among women who stated at enrollment that they did not think they would quit smoking during their pregnancy. For this subgroup, the quit rates were very small.

Creatinine-adjusted urine cotinine values ranged from 0 ng/mL to 27 000 ng/mL. Cotinine values tended to be highest for women in Missouri and lowest for women in Colorado. At the eighth month, the mean adjusted cotinine values were 23 ng/mL for verified quitters, 1142 ng/mL for women who did not disclose their smoking, and 1985 ng/mL for continuing smokers.

In Colorado and Maryland, the interventions had no impact on mean cotinine values at the eighth month. In Missouri,

TABLE 2—Smoking Cessation in Pregnancy Project: Self-Reported and Verified Quit Rates among Enrollment Smokers at the Eighth Month of Pregnancy

	Self-Reported					Verified				
	No. Who Quit	No. Enrollment Smokers	%	OR	95% Confidence Limits	No. Who Quit	No. Enrollment Smokers	%	OR	95% Confidence Limits
Colorado										
Control	48	467	10.3	...	...	26	284	9.2	...	...
Intervention	65	468	13.9	1.6	1.0, 2.7	19	233	8.2	1.0	0.31, 3.3
Maryland										
Control	73	743	9.8	...	...	28	546	5.1	...	...
Intervention	49	416	11.8	1.1	0.18, 7.3	22	307	7.2	1.2	0.01, 86.0
Missouri										
Control	47	557	8.4	...	...	15	347	4.3	...	...
Intervention	76	583	13.0	1.6	0.89, 3.1	13	348	3.7	0.88	0.19, 4.1
All										
Control	168	1767	9.5	...	...	69	1177	5.9	...	...
Intervention	190	1467	13.0	1.4	1.2, 1.9	54	888	6.1	1.0	0.69, 1.6

Note. Enrollment smokers are women who smoked in the 7 days before enrollment. OR = clustered Woolf's odds ratio; CI = confidence interval. The intracluster correlation coefficients averaged .003. The design effects were about 1.4 for clinics with 100 or more smokers and about 1.0 for clinics with fewer than 100 smokers.

women with more than 12 years' education who attended intervention clinics had significantly lower mean cotinine values than control subjects (intervention mean = 700 ng/mL vs control mean = 1802 ng/mL; $P = .0042$).

Rates of nondisclosure varied by time of data collection, state, race, and intervention status. The overall rates of nondisclosure were 28% at enrollment and 35% at the eighth month. The nondisclosure rate was 32% among self-reported quitters attending control clinics, compared with 49% among self-reported quitters attending intervention clinics.

The crude rates of low birthweight (<2500 g) were 10.3%, 10.2%, and 9.1% for Colorado, Maryland, and Missouri, respectively. In the aggregated data, the new interventions had no effect on infant birthweight. The crude mean birthweights were 3433 g for verified quitters and 3201 g for continuing smokers.

Process Evaluation

In all three states, the clinic staff were enthusiastic about the new interventions but found the data collection to be tedious and time-consuming. The majority of patients at intervention clinics who responded to the postpartum anonymous evaluation reported having received antismoking materials and counseling. However, many patients at control clinics also reported having received (non-SCIP) materials and counseling, which indicated that the usual prenatal care included exposure to smoking cessation messages. Details of the process evaluation will be presented in a future publication.

Discussion

Three states implemented similar low-intensity smoking cessation programs for pregnant women with very similar results. Women attending intervention clinics were more likely than those attending control clinics to report having quit smoking by the eighth month of pregnancy. However, the cotinine-verified quit rates were not significantly different; no effect was seen on infant birthweight. Rates of nondisclosure were very high. Our study was unusual because we evaluated the effect of incorporating a low-intensity smoking cessation program into the routine care delivered by existing staff in public prenatal and WIC clinics.

Methodologic Considerations

Because we did not expect such high levels of nondisclosure, we did not collect urine specimens on women who said they were nonsmokers at screening. Thus, the reported smoking prevalence of 50% is almost certainly an underestimate.

The mean time from entry into care to eighth month follow-up was 16 weeks. This short interval provided limited opportunity for the patients to be exposed to the new interventions and for them to quit smoking. Changing an addictive behavior probably requires more time.[14]

We were able to determine verified quit rates among only a subset of enrolled women because of difficulties in obtaining urine specimens. If we had considered women lost to follow-up to be continuing smokers, our quit rates would have been lower than those reported, but comparably so in intervention and control sites.

In all three states, project staff felt that the use of the existing staff both to deliver the new interventions and to collect data affected the study negatively. Clinic staff were often overwhelmed by the amount of time required to process questionnaires and urine specimens from each SCIP participant. As a result, the state coordinators reported that the intervention protocols did not appear to have been fully implemented and that the motivation to promote smoking cessation counseling varied among staff members.

A particular strength of our study was its focus on the real world of public prenatal care. The interventions were delivered by existing clinic staff who were already busy. The programs were designed so that they required minimal additional resources to implement. Our results give an indication of how difficult it can be to successfully integrate such a program into the current system of public care.

TABLE 3—Smoking Cessation in Pregnancy Project: Verified Quit Rates, by Selected Characteristics (Aggregated Three-State Data)

	% Quit	
	Control	Intervention
All enrollment smokers	5.9	6.1
Age, y		
<20	9.4	8.5
20–29	4.9	5.1
≥30	3.5	4.4
Education, y		
<12	6.1	5.2
12	5.4	5.4
>12	6.8	11.2
Race/ethnicity		
White, non-Hispanic	4.8	6.0
Hispanic	18.0	11.1
Black	7.3	5.3
Passive smoke exposure		
0–2 h/d	11.8	11.0
3–8 h/d	7.0	6.2
>8 h/d	3.2	4.4
Amount smoked		
0.5–9 cigarettes/d	10.4	10.1
≥10 cigarettes/d	2.0	2.3
No. of previous live births		
0	8.1	8.4
≥1	4.4	4.2
Thinks she will quit		
Yes	11.8	8.8
No*	1.4	2.6

*P = .023.

Other Studies

Windsor et al. recently reported positive results in one of the few other studies of smoking cessation to focus on public prenatal care patients.[9] The cotinine-validated quit rate was 14.3% among women receiving the new intervention, compared with 8.5% among controls. This intervention differed from ours in that it relied on specially trained health educators to provide counseling and used a self-help guide with supplemental mailings. The involvement of a person who does not have other clinical responsibilities may be a key to the success of that intervention.

Other smoking cessation programs for pregnant women have focused on private patients and have been more resource-intensive.[7,8,23,24] In these studies, the validated cessation rates have ranged from 10% to 32%. Thus, under the best possible circumstances, the results from programs directed at pregnant women compare favorably with those of programs directed at other smokers.

Our finding of high rates of nondisclosure among women receiving interventions is consistent with previous studies of nonpregnant persons.[17,25] Some persons may react to smoking cessation counseling by giving the desired response to questions at followup.[17] In the only other study that calculated nondisclosure rates among pregnant women, the rates were comparable to ours.[9]

Interpretations

The SCIP programs were designed to require minimal resources to implement. However, the target population for these programs was women who were poor, were unmarried, and had little education. To expect major behavioral change among these women in response to a minimal, low-intensity intervention may have been unrealistic.

The cessation rates seen in the SCIP intervention clinics are probably what should be expected from a minimal intervention. The control cessation rates were already somewhat higher than those expected under a control condition in which the subjects received no smoking cessation assistance. This may explain why we saw no difference between the new interventions and usual care.

Recommendations

In planning a new program for pregnant smokers, establishing baseline rates of verified smoking and nondisclosure may be helpful. Otherwise, a large proportion of the potential target population may be missed.

For their results to be credible, studies of smoking cessation programs developed for pregnant women must include laboratory verification of self-reported nonsmoking. Efforts should be directed at developing methods to validate abstinence in simpler, less expensive ways than the complex procedures for urine shipment and laboratory analyses involved in this study.

Because of the relatively short duration of pregnancy and the difficulty of achieving smoking cessation, future investigators may wish to focus on changes in stage of behavior as the outcome.[14] If interventions were evaluated from this perspective, changes might be seen that are missed by concentrating on smoking cessation. Progress through behavior stages may eventually result in cessation. For a pregnant woman, this may mean that future fetuses would be unexposed to cigarette smoke.

Public health officials should consider broad approaches to dealing with the problem of smoking during pregnancy. Intensive efforts to prevent initiation of smoking among teenagers could decrease the number of women of reproductive age who are smokers. Repeated exposure to anti-smoking messages delivered at the community level, as well as through family planning, prenatal care, WIC, and well-child clinics, could enhance smoking cessation. Only limited success should be expected from low-intensity programs confined to public clinics. □

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International Symposium on Lead in the Americas to Be Held in Mexico

The Institute of Medicine of the US National Academy of Sciences, with the Ministry of Health, National Institute of Public Health, and National Academy of Medicine of Mexico, announces an international symposium and workshops on the subject of lead toxicity, to be held in Cuernavaca, Mexico, May 8–10, 1995. The objectives of the meeting are to identify principal pathways of lead exposure in the Americas and to develop recommendations for controlling exposures and preventing disease.

The focus of the meeting will be lead exposure as a public health problem in the countries of North and Latin America and the Caribbean. Presentations will discuss the distribution and ranges of lead levels in human populations, pathways of human exposure to lead, and case studies of efforts to reduce environmental or occupational exposure to lead.

Persons wishing to attend the symposium and workshop are encouraged to preregister by March 31, 1995. The registration fee before March 31 is US$100; on-site registration will be US$200. A course on lead screening and environmental sampling for lead surveillance will also be offered during the symposium. There is space available for 30 participants, and the cost of the course is US$300.

Payments should be made to the Instituto Nacional de Salud Pública, Lead in the Americas bank account no. 0046984-3 de Bancomer S.A. de C.V., branch (surcursal) Plan de Ayala No. 2010, Cuernavaca Morelos, Mexico; tel 91.73.225184. The registration fee may be deposited directly into the account by money order, bank wire, or cash deposit. For further information regarding registration, please contact Dr Mauricio Hernández-Avila, MD, ScD, Director, Centro de Investigaciones en Salud Pública, Instituto Nacional de Salud Pública, Av. Universidad 655, Col. Sta. Maria Ahuacatitlán, Cuernavaca, Morelos, C.P. 62508 México; fax 52.73.11.11.48.