Health Education for Pregnant Smokers: Its Behavioral Impact and Cost Benefit

ABSTRACT

Objectives. A randomized trial (the Birmingham Trial II) was conducted to evaluate the behavioral impact of health education methods among 814 female smokers at four public health maternity clinics.

Methods. Four hundred patients were randomly assigned to an Experimental (E) Group, and 414 were assigned to a Control (C) Group. Self-reports and saliva cotinine tests confirmed smoking status at the first visit, at midpregnancy, and at end of pregnancy.

Results. The E Group exhibited a 14.3% quit rate and the C Group an 8.5% quit rate. A Historical Comparison (C) Group exhibited a 3.0% quit rate. Black E and C Group patients had higher quit rates than White E and C Group patients. A cost-benefit analysis found cost-to-benefit ratios of $1:$6.72 (low estimate) and $1:$17.18 (high estimate) and an estimated savings of $247 296 (low estimate) and $699 240 (high estimate).

Conclusion. Health education methods are efficacious and cost beneficial for pregnant smokers in public health maternity clinics. (*Am J Public Health.* 1993;83:201–206)

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Introduction

Maternal smoking causes infant morbidity and mortality.[1–3] The elimination or reduction of active and passive maternal and fetal exposure to cigarette smoke represents a high national priority for the decade.[4–6] Effective smoking cessation methods among pregnant women, particularly in public health populations, are needed.[3,7–10]

Multiple evaluation studies[11–16] have reported the efficacy of cessation methods for pregnant smokers and have assessed medical cost outcomes.[16] Only one study has evaluated the behavioral impact[12] and cost-effectiveness[17] of cessation methods among pregnant smokers in a public health setting. Cost-benefit analyses of health education methods for that setting are not available.[7]

This report presents the results of the Birmingham Trial II, an evaluation of the behavioral impact and cost benefit of a health education program for pregnant smokers in public health maternity clinics.

Methods

This study was conducted from 1986 to 1991 at the four highest census maternity clinics of the Jefferson County Health Department in Birmingham, Alabama. These clinics represented 85% of the annual cohort. A fifth clinic with a small census did not participate.

A formative evaluation was performed between July 1986 and August 1987 to (1) conduct a prospective, natural history study prior to Trial II to document smoking prevalence and quit rates attributable to routine care and risk information; (2) train the health counselors; and (3) pilot test the intervention, measurement, and data collection methods. All methods were adapted from Trial I, which was conducted at the Jefferson County Health Department from 1982 to 1985.[12]

Screening interviews, conducted at the first prenatal visit from September 1, 1987, to November 30, 1989, identified 4352 patients, of whom 1381 (31.7%) reported smoking at conception. Of that number, 1171 were current smokers (84.8%) and 210 (15.2%) quit before their first visit. A current smoker was defined as "a patient who self-reported during the first prenatal visit at least one puff of one cigarette in the last seven days."[12,14,18] An assessment study using self-reports and salivary cotinine analyses confirmed that 74 (35.2%) of the 210 self-initiated quitters relapsed before delivery.

Of the 1171 smokers screened, 110 (9.4%) were ineligible for one or more reasons: they (1) were not pregnant, (2) were ineligible for care, (3) entered into care late (≥ 32 weeks), (4) did not stay for the first visit, (5) did not return, (6) were Trial I

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This paper was submitted to the Journal February 7, 1992, and accepted with revisions October 14, 1992.

participants, (7) were prisoners, and/or (8) had difficulty reading the baseline questionnaire. Of the 1061 who were eligible, only 67 (6.3%) refused to participate. Thus, 994 smokers were enrolled in Trial II.

Evaluation Design

A prospective randomized, pretest-posttest control group design was implemented to assess midpregnancy and end-of-pregnancy smoking status from self-reports and saliva cotinine tests. At the first visit and after the 994 patients gave their informed consent, a computer-generated system randomly assigned them to two groups: Experimental (E) Group (493 patients) and Control (C) Group (501 patients). After randomization, 93 E Group and 87 C Group patients became ineligible due to withdrawal from public health care, a miscarriage, or an abortion. A total of 814 pregnant smokers—400 E Group and 414 C Group patients—were eligible for follow-up.

Formative and Process Evaluation

The formative evaluation (noted above) was conducted at the four clinics with a sample of 269 patients (100 smokers and 169 nonsmokers) recruited from 300 consecutive intakes. A 35% smoking rate (105/300) and a 10% refusal rate (31/300) was observed. The sample of 100 smokers served as a Historical Comparison Group (C Group) to document pretrial baseline prevalence rates and "normal" quit rates from the first visit to childbirth. Clinic nurses and administrators reviewed and field tested data and saliva collection methods with the 269 patients.

Focus group discussions were held with five to eight patients at each clinic to field test the E Group intervention. The intervention was pilot tested to reestablish the feasibility of routinely providing cessation methods and to confirm patient and provider acceptance. Intervention time and barriers to routine use were documented.

A process evaluation system was pilot tested with the 269 patients. Monthly, quarterly, and annual clinic reports were prepared to document implementation levels for intervention components and measurement procedures.

Health Education Methods

The intervention had three components:

Component 1. During the first visit, a trained female health counselor provided the E Group with a standardized cessation skills and risk counseling session of approximately 15 minutes. Patients were taught how to use a 7-day, self-directed cessation guide (Windsor R, Amburgy K, Artz L; Cessation Guide; 1987, unpublished) that has a sixth-grade reading level. The guide and session were modified methods from Trial I.[12] Following completion of Trial II, the guide was revised for dissemination purposes.[19]

During follow-up visits, patients received components 2 and 3:

Component 2. Clinic patient reinforcement methods were provided. A chart reminder form was put in the medical record and a medical letter was sent to patients within 7 days.

Component 3. Social support methods were provided in the form of a buddy letter, a buddy contract, and a buddy tip sheet. Each patient was also sent, quarterly, a one-page "newsletter" with testimonials from successful quitters, additional risk information, and cessation tips.

All 814 patients were urged to quit and given two pamphlets: *Smoking and the Two of You* (American Lung Association), which provides risk and benefit information, and *Where to Find Help If You Want to Stop Smoking*, with a contact name, a phone number, and the cost of local programs.

During a 30-minute group prenatal education class at the first visit, a nurse used 2 minutes to discuss smoking risks and the importance of quitting. No staff participated in continuing education on smoking cessation, and no changes were observed in the staff counseling behavior during the study.

Measurement

Patients completed a one-page screening form, an informed consent, and a self-administered questionnaire to document their smoking status, health beliefs, and commitment to quit. A standardized radioimmunoassay protocol by the Clinical Biochemistry Laboratory of the American Health Foundation was used to test saliva samples.[20] Patients were informed that their saliva would be analyzed.

Smoking status was reassessed by self-reports and cotinine tests at 4 to 8 weeks after the first visit (midpoint observation) and after the 32nd week of gestation (end-point observation). Only one follow-up was performed for patients who started care during the 6th or 7th month of pregnancy. A cotinine value of not more than 30 ng/mL was used as the cutoff to validate self-reports.[14,20-22]

Because a dose-response relationship exists between maternal smoking and intrauterine growth retardation,[7,9] significant reduction rates were documented for all patients.[12] A patient was defined as a "significant reducer" if her follow-up cotinine value was at least 50% less than her baseline value.

Compliance Assessment

Compliance needs to be documented to establish the feasibility of implementation and patient use of all health education methods.[13,14,18,23] E Group patients completed a self-administered questionnaire at the midpoint to document the number of days they used the guide[19] and cessation methods. They had to report use of the guide for 4 or more days and use of five or more cessation methods to be counted as "compliant."

Cost Estimation

Before health education methods are used routinely, a cost analysis should be performed. The cost to deliver the intervention was personnel time and materials. Because an agency perspective was used in our cost analyses,[17,24,25] patient time, facilities cost, and intervention development costs were not used in our estimates. Although a health counselor provided the intervention, a nurse would be the usual provider. A salary of $30 000 plus a fringe benefit rate of 20% was used to estimate staff cost ($36 000 per year/2080 hours = $17.31 per hour). Personnel costs for routine use of the 15-minute intervention including reinforcement would be about $4.33 per patient ($17.31 × 0.25). Although the guide cost approximately $5.00 per patient, large volume printing (2000 to 5000 copies) reduced the cost to about $1.20 per patient. Materials, reproduction, and labor costs were about $0.40. Thus, total cost was $6.00 per patient.

Two minutes were spent at the first visit to provide the C Group with risk information and materials. That, plus brief contacts at follow-up visits, which may have served as reinforcement, produced a total of 5 minutes, so total cost amounted to about $1.50 per patient ($17.31 × 0.083).

Cost Benefit Analyses of Statewide Dissemination

Smoking population attributable risk for low birthweight has been documented at 20% to 35%.[2,3,7,18,26] The low estimate of this risk was used to estimate the impact of intervention dissemination on the incidence of low birthweight in Alabama in 1990.

The benefit of dissemination, defined as the estimated number of low-birth-

weight infants preventable by cessation, was based on the Office of Technology Assessment's estimates of the net incremental health care costs of a low-birthweight birth: $9000 (low estimate) and $23 000 (high estimate).[8] These estimates include three components: (1) hospitalization and physician costs at birth, (2) rehospitalization costs in the first year of life (hospital costs only), and (3) long-term health care costs of treating a low-birthweight infant.[8] These estimates, including Office of Technology Assessment discounting, were adjusted to 1990 dollars by the inflation rates of the consumer price index–medical care component of the Bureau of Labor statistics: 5.8% (1987), 6.9% (1988), 8.5% (1989), and 9.6% (1990). The discounted, inflation-adjusted, low estimate of $12 104 and high estimate of $30 935 were used in our cost calculations.

Results

Data in Table 1 confirm E and C Group equivalence. The C Group (comparison group) pregnant smokers were comparable to the E and C Groups. The refusals were similar to the study participants.

At baseline, about 45% of the patients had low (≤ 99 ng/mL) and 40% had moderate (100 to 199 ng/mL) levels of cotinine. No E vs C Group or Black vs White differences in mean baseline cotinine values were observed.

Process Evaluation

Process evaluation data from monthly, quarterly, and annual clinic reports confirmed the following E Group exposure rates by health education component: Component 1, 100%; Component 2, 88%; and Component 3, 100%. Thus, the intervention was successfully provided by nine different counselors to 400 patients over a 27-month period.

Patient Compliance Rates

Data confirmed that 63% of the E Group reported use of the guide. This rate was comparable to the E Group compliance rate of Trial I: 65%.[23] Eighty-two percent of the E Group and 60% of the C Group reported a quit attempt.

Behavioral Impact

The impact of the health education methods is reported in Table 2. Only patients who self-reported quitting at their first and follow-up visits and who had a cotinine value of not more than 30 ng/mL were counted as quitters. Approximately 15% of the 814 patients were lost to follow-up; all were counted as failures. The baseline characteristics of failures and participants were not significantly different.

TABLE 1—Comparability of Study Groups by Baseline Variables

	C Group (n = 100)	E Group (n = 400)	C Group (n = 414)	Total (n = 814)	Refused (n = 67)
Mean age, y	23.8	24.1	24.7	24.6	27.5
Mean education, y	12.1	12.4	12.2	12.4	13.7
Mean estimated gestational age[a]	3.8	3.9	4.1	4.0	4.1
Race: % Black	52	50	54	52	49
Cotinine (ng/mL)					
Mean	121	117	109	114	N/A
SD	103	100	91	96	N/A

[a]At entry into care (units = months).

TABLE 2—Quit Rates by Race and Study Group

	E Group Quit Rate		C Group Quit Rate		C Group Quit Rate		95% Confidence Interval	
Race	%	n	%	n	%	n	(E–C)	*P*
Black	18.1*	210	10.7**	242	N/A		(0.8, 13.9)	.03
White	10.0*	190	5.2**	172	N/A		(–0.6, 10.2)	.08
Total	14.3	400	8.5	414	3.0	100	(1.4, 10.1)	.01

*P = .03; **P = .07 (for group comparisons).

As noted in Table 2, the E Group had significantly higher quit rates than the C and C Groups. The intervention increased quit rates by 7.4% among Black E Group patients (P = .03) and by 4.9% among White E Group patients (P = .08). In both the E and C groups, Black patients had substantially higher quit rates than White patients. Data in Table 3 confirm that cessation occurred among both the E and C groups with low to moderate cotinine levels. The E Group had a significantly higher relapse rate (14%) than the C Group (8%) (P = .001).

Analyses of baseline variables—age, education, estimated gestational age, race, and cotinine value—to document cessation predictors revealed that E Group participation, baseline cotinine, and race were significant.

As noted in Table 4, White E Group patients had a significantly higher reduction rate than Black E Group patients (P = .05) or White C Group patients (P = .05). Although not statistically significant (P = .07), the E Group had a 27% higher reduction rate than the C Group. Of the women who quit or significantly reduced, a 200-g and a 92-g difference, respectively, was observed when birthweights were compared with those of

TABLE 3—Quit Rates by Level of Baseline Cotinine Values

Baseline Cotinine (ng/mL)	E Group, % (n = 57)	C Group, % (n = 35)
Low (≤ 99)	89	83
Moderate (100–199)	9	14
High (≥ 200)	2	3

smokers.[27] Including the quitters and significant reducers, the "behavior change rate" was 31.0% in the E Group vs 20.8% in the C Group (P = .001).

Sensitivity, specificity, and the positive predictive value of the cotinine test to validate end-of-pregnancy self-reports of smoking status were 86%, 74%, and 93%, respectively. A comparison of self-reports with cotinine values of at least 31 ng/mL confirmed a total deception rate of 28%: 32% for E Group patients and 17% for C Group patients. No differences in deception rates were observed between Black and White patients in either group.

Estimated Behavioral Impact of Statewide Dissemination

The E, C, and C Group differences in quit rates were 6% (E–C) and 11% (E–C). However, the E and C Group quit rates in

TABLE 4—Significant Reduction Rates, by Race and Study Group[a]

Race	E Group %	E Group n	C Group %	C Group n	95% Confidence Interval	P
Black	12.9	210	11.6	242	(–4.8, 7.3)	.68
White	21.1	190	13.4	172	(0.0, 15.4)	.05
Total	16.8	400	12.3	414	(–0.4, 9.3)	.07

[a]Patients who quit were not counted as significant reducers.

Trial II (E = 14%, C = 3%) were comparable to those in Trial I (E = 14%, C = 2%).[12] Both trials were conducted at the same Jefferson County Health Department sites among cohorts equivalent by socioeconomic status, age, education, estimated gestational age, cotinine values, and percent Black. However, only Component 1 was provided in Trial I. *The addition of 5 minutes for Components 2 and 3 in Trial II did not produce a higher quit rate.* Thus, behavioral impact and cost benefit were estimated on the basis of time (10 minutes), Component 1 alone, and the average E–C or C Group quit rate difference of 12% (Trial I = 12%, Trial II = 11%).

Although a 12% difference may be possible at many clinics, it may be an estimate of intervention *efficacy* (best estimate) on smoking behavior. Accordingly, the 12% quit rate *difference* was attenuated to 8% to reflect intervention *effectiveness* (typical estimate) in routine use by nurses. If the intervention had been provided to the estimated 4800 smokers (0.30 × 16 000 patients) in the 1990 Alabama public health cohort, an additional 384 quitters (0.08 × 4800) might have been produced.

Estimated Impact of Statewide Dissemination on the Low-Birthweight Rate

A low-birthweight rate of about 12% to 13% has been observed among the Alabama cohort for several years, resulting in about 2000 low-birthweight infants each year (0.125 × 16 000). Based on the low estimate of smoking population attributable risk for low birthweight (0.20),[1–3,18,26] about 400 smoking-attributable low-birthweight infants (0.20 × 2000) were born to the 1990 cohort. If the 8% difference to estimate the intervention's potential to reduce the incidence of smoking-attributable low birthweight had been used, an estimated 32 fewer infants (0.08 × 400) might have been born with low birthweight.

Estimated Cost Benefit of Statewide Dissemination

Based on the Office of Technology Assessment's discounted, inflation-adjusted estimates of excess health care costs (low estimate = $12 104; high estimate = $30 935),[8] the 32 smoking-attributable low-birthweight infants cost an excess of between $387 328 and $989 920.

Because data from Trials I and II confirmed that Component 1, delivered during a 10-minute session, produced the impact, the total cost per patient can be reduced from $6.00 to $4.50 (as time is reduced from 15 to 10 minutes). Because our cost-benefit estimates of dissemination is expressed as a net cost difference (economic benefit minus cost) among all 4800 women who might have received the intervention and not just among quitters, dissemination costs for the estimated 4800 pregnant smokers would thus be approximately $21 600 per year.

The cost-benefit ratio low estimate is $1:$17.93 and high estimate is $1:$45.83. The net benefit minus cost difference is $365 728 (low estimate) and $968 320 (high estimate) in favor of the intervention.

Sensitivity Analysis

Sensitivity analyses need to be performed in an assessment of the cost benefit of new prevention methods.[24,25] We examined the sensitivity of our estimates using changes in two parameters: intervention cost and estimated economic benefit. We varied the intervention cost from $4.50 (low estimate) to $9.00 (high estimate). We varied the health benefit by reducing the smoking population attributable risk from 0.20 to 0.15, thereby further reducing the estimated number of preventable low birthweights from 32 (low estimate) to 24 (very low estimate).

Data from evaluation studies confirmed that a quit rate difference (E–C Group) of 6% to 12% is achievable. Because we used a difference of 8% (low estimate), this parameter is likely to reflect the rate achievable in public health practice and is unlikely to vary substantially. However, costs for personnel and materials to routinely provide the intervention will vary. If we increase the intervention costs moderately by 50% from $4.50 to $6.75 ($6.75 × 4800 = $32 400), the cost-benefit ratio becomes $1:$11.95 (low estimate) and $1:$30.55 (high estimate). If costs were increased by 100% ($9.00 × 4800 = $43 200), the cost-benefit ratio becomes $1:$8.97 (low estimate) and $1:$22.91 (high estimate). The net difference between benefit and cost favors the intervention: $344 128 (low estimate) and $946 720 (high estimate).

If we increase the intervention cost by 100% and decrease the benefit by 25%, the cost-benefit ratio low estimate becomes $1:$6.72 (24 × $12 104/$43 200) and high estimate becomes $1:$17.18 (24 × $30 935/$43 200). Thus, for each $1 spent on cessation methods, $7 to $17 in medical costs might be saved. The net difference between the economic benefit and excess cost favors the intervention: the low estimate is $247 296 and the high estimate is $699 240.

Thus, variations in estimates of behavioral impact, smoking population attributable risk, excess health care costs, or discount rates do not affect the conclusions about the cost benefit and potential net savings of the intervention. The estimated cost-benefit ratios from this study, and thus the net economic benefits, are much higher than the cost-benefit ratio of $1:$3.40 for prenatal care from the Institute of Medicine.[7]

Discussion

This evaluation recruited 94% of a cohort of pregnant smokers from multiple clinics over a 27-month period. When considered along with evidence from Trial I[12] and results of other intervention studies,[15,28] this study confirms that an additional 6% to 12% quit rate difference is achievable in public health clinics.

An evaluation study[15] of patients in the special supplemental food program for women, infants, and children (WIC) in Michigan, which adapted Trial I[12] and American Lung Association self-help cessation methods, reported quit rates of 11% with self-help (E_1 Group), 7% with risk information (E_2 Group), and 3% with no intervention (C Group). Another study in Washington, DC, undertaken among a predominately Black cohort of pregnant smokers who received the guide plus one-to-one counseling and other intervention

materials, reported a self-reported quit rate of "about one-third."[28] If this 33% quit rate is adjusted by applying our 32% E Group deception rate, a 22% quit rate is derived, which is similar to our 18% rate among Black E Group patients.

The C Group quit rate in Trial II (8%) was much higher than that in Trial I (2%),[12] the C Group quit rate in Trial II (3%), and the C Group quit rate in the WIC study (3%).[15] The WIC study risk information group (E_2), however, exhibited a 7% quit rate, which was comparable to the Trial II C Group rate of 8.5%. The WIC E_2 Group and Trial II C Group both received brief, one-to-one verbal and written risk information and strong encouragement to quit. These data suggest that, as implemented, the Trial II C Group may have become a "minimum intervention group." Strong advice to quit, readable risk information, and reinforcement from the health care practitioner *may* increase the "normal" public health quit rate of 2% to 4% to one of 6% to 8%.

No clear explanation was apparent for the large difference between C Group (8.5%) and C Group (3.0%). The difference may be attributable to (1) the presence, duration, and intensity of Trial II over a 27-month period; (2) the use of patient education reinforcement methods in Trial II but not in Trial I[12] or with the C Group in our formative evaluation; and/or (3) greater societal pressure to quit placed on pregnant women during the Trial II period (1987 to 1989) vs the Trial I period (1984). Additionally, a meta-evaluation of smoking cessation and pregnancy intervention studies conducted after 1985 reveals a trend of increases in C Group quit rates ranging from 5% to 8%.[29] No evidence is available to indicate communication between E and C Group patients.

The compliance rate, which was almost identical in both studies (65% in Trial I, 63% in Trial II) and the compliance rate of 67% reported by Coates and Maxwell[28] using the guide[19] plus one-to-one counseling,[28] was encouraging. Qualitative data from Trial I also confirmed good patient ratings of the guide.[12,23] Patients at this public health setting,[12,18,23,28] at HMOs,[14] and at WIC clinics[15,30] will use self-help methods. The qualitative and quantitative evidence from patients and health care practitioners is strong and consistent, supporting the efficacy of these methods. No adverse effects of the intervention were observed in the Trial I, Trial II, or other evaluation studies.

This study confirmed a large difference in quit rates between Black and White E and C Group patients. Although others have reported racial differences based on cotinine analyses, with serum cotinine levels of Black female adults aged 18 to 30 consistently *higher* than those of similarly aged White female adults,[31] no baseline difference in mean saliva cotinine levels by race was observed in Trial II or in the mean saliva thiocyanate levels in Trial I.[12] Additionally, our results, confirming a *higher* quit rate among Black smokers than among White smokers, were the opposite of those in other evaluation reports. White smokers are often *more* successful in quitting than Black smokers.[32] *Although no explanation was apparent for the observed quit rate differences by race, the substantially larger quit rate documented among Black pregnant smokers represents one of the most important findings of this study.* Smoking, both active and passive, is a primary cause of low birthweight, and the Black low-birthweight rate (13.2%) is twice that of White infants (6.6%).

Our results, as well as other efficacy[11,14–16,28,30] and cost-effectiveness analyses,[17,33–37] have also documented the potential impact of dissemination of "tested" health education methods[12,14–16,18] to the 1990 US Public Health Cohort of approximately 1 million pregnant women, 350 000 smokers, and 120 000 low-birthweight infants.[18] Low birthweight might have been prevented for approximately 1920 infants (120 000 × .20 × .08).[36,37] Assuming a cost per public health patient of $6.75, the total cost of intervention for the 1990 cohort would have been approximately $2.4 million ($6.75 × 350 000 pregnant smokers). Thus, a net economic benefit of approximately $20 to $56 million might have been produced by dissemination. Annual dissemination to the US maternity cohort of more than 1 million pregnant smokers (4.0+ million × 0.25 smokers)[18] may also help achieve approximately 31% to 78% of the *Healthy People 2000* Objectives for pregnant smokers.[6,37]

These estimates of impact, however, reflect only a small part of the economic, health, and emotional benefit to women, infants, and families. A national effort is needed in the 1990s to change the health education process and content for pregnant smokers.[7–10,18,38] Continuing education programs must be expanded to improve the cessation counseling methods and skills of health care practitioners. *The Handbook to Plan, Implement, and Evaluate Smoking Cessation Programs for Pregnant Women*[18] will assist in these efforts, particularly in public health settings. As dissemination plans are prepared, evaluation research will also be needed to document the degree to which health education methods are adopted in public and private health maternity care settings and to measure their behavioral and clinical impact. □

Acknowledgments

The National Cancer Institute Grant R01C-A41648 funded this study.

A special thanks is extended to our project officer, Dr. Thomas Glynn (NCI), for his assistance. Gratitude is also extended to Dr. Carole Samuelson, health officer, Jefferson County Health Department, and to Dr. Mary Ann Pass and Ms. Deborah Bailey Spanos of the Jefferson County Health Department Maternity Clinic Staff for their enthusiastic support of this project. Kristin Adams, Jenny Bartz, Ying Chen, Linda Contreras, Mary Davis, Hilaire Desai, Marlee Draper, Laurie Eldridge, Lee-Jane Ho, Constance Jones, Kim Jones, Sherri Lang, Nancey Legg, Dr. Chang Li, Eleanor Long, Steveanna Mason, Jim McNamee, Diane Praytor, Kim Puckett, Karen Reynolds, and Ellen Wilson helped conduct this study.

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