Evaluation of a smoking cessation intervention for pregnant women in an urban prenatal clinic

Andrea C. Gielen, Richard Windsor\(^1\), Ruth R. Faden, Patricia O’Campo\(^2\), John Repke\(^3\) and Mary Davis

Abstract

A smoking cessation and relapse prevention intervention was tested in an urban, prenatal clinic serving predominantly low-income, African-American women. At their first prenatal visit, 391 smokers were randomly assigned to an experimental (E) group to receive usual clinic information plus a prenatal and postpartum intervention or to a control (C) group to receive only usual clinic information. The intervention consisted of individual skills instruction and counseling by a peer health counselor on the use of a self-help cessation guide and routine clinic reinforcement. Among the E group (\(n = 193\)) 6.2% were cotinine-confirmed quitters at third trimester and among the C group (\(n = 198\)) the quit rate was 5.6%. Quitters were light smokers at entry into prenatal care. Many had tried to quit smoking at least once prior to pregnancy.

Introduction

Smoking cessation and significant reduction during pregnancy can improve maternal and infant health (USDHHS, 1990; Healthy People 2000, 1992).

Health education methods provided during regular prenatal care have produced quit rates from 10 to 14\% in public and from 22 to 25\% in private prenatal care settings (Windsor et al., 1985, 1993; Windsor and Orleans, 1986; Ershoff, 1989; Mayer et al., 1990; Hjalmarson et al., 1991; Adams et al., 1992; O’Campo et al., 1992). The need, however, to develop and evaluate methods to achieve higher cessation and reduction rates and to prevent relapse persists (Windsor et al., 1993). Efficacious interventions are especially needed for educationally and economically disadvantaged African-American women who experience added risk if they smoke during pregnancy (Adams et al., 1992; O’Campo et al., 1992). Smoking cessation interventions, particularly in public health settings, must be neither labor intensive nor expensive to provide routinely (Windsor et al., 1988).

One intervention method for pregnant smokers proven efficacious (Windsor et al., 1985, 1993) and cost-effective (Windsor et al., 1988) in prenatal clinics has been reported. Windsor et al. (1985) in trial I (1982–85) used a tailored cessation guide and a 10 min counseling session provided by a professionally trained health educator in Birmingham, Alabama public health maternity clinics (\(N = 309\)). This study found a significantly higher biochemically confirmed cessation rate of 14\% among the experimental (E) group compared to a rate of 2\% among the control (C) group. These results were replicated in trial II (1986–91) with a larger sample of women (\(N = 814\)) from the same clinics (Windsor, 1993). Quit rates among African-American women were 18\% in the E group compared to 10\% in the C group and among White women, 10\% in the E group and 5\% in the C group.
The purpose of this study was to evaluate the efficacy of the Birmingham trial intervention methods in another urban setting—a large urban prenatal clinic in Baltimore, Maryland. The health education intervention, called the ‘Smoke-Free’ Moms Project, was expanded to include specific information on relapse prevention, a post-partum component and utilized a peer health counselor to deliver the intervention.

**Methods**

**Sample**

Study participants were recruited from the obstetrical care outpatient clinic at the Johns Hopkins Hospital. Most women were on medical assistance and approximately 85% were African-American. At the first prenatal visit, each woman completed a screening form, which obtained information on smoking history and selected demographic characteristics. The peer health counselor, identified as the ‘Smoke-Free’ Moms Counselor, described the study and obtained informed consent.

**Study design.**

Any woman who indicated that she had ‘smoked a cigarette—even one puff—in the past 7 days’ was classified as an eligible smoker. Smokers were not eligible if they were 28 weeks or more pregnant, if they were neither African-American nor White, if they were changing to another prenatal clinic or if they could not complete the baseline interview at the first prenatal visit.

Smokers were randomly assigned at their first visit to receive either the prenatal and post-partum smoking cessation/relapse prevention intervention in addition to routine clinic advice (E group) or only routine clinic advice about smoking cessation/relapse prevention (C group).

Smoking status was documented by self report and a saliva cotinine test. All women were interviewed: (1) at their first prenatal visit, (2) at over 28 weeks gestation, (3) in the hospital after delivery, and (4) by telephone at 3 months and (5) by telephone at 6 months post-partum. Saliva samples were collected during each interview and from any woman who reported not smoking at the 3 and 6 month post-partum interview. Samples were collected, stored and shipped for analysis according to the protocol described in the literature and recommended by the American Health Foundation (Haley et al., 1983; Etzel, 1990)

**Intervention and control methods**

Both E and C group women received the usual clinic and inpatient smoking cessation education: a brief discussion from a nurse about the risks of smoking, a recommendation to quit and pamphlets from area voluntary agencies.

The intervention for the E group women consisted of four components:


2. A 15 min, one-to-one counseling session with the peer health counselor on how to use the Guide, which included showing the woman how the book was organized to be used daily and discussing the woman’s thought and concerns about quitting.

3. Educational materials for cessation support persons, which were included in the Guide.

4. Clinic reinforcement and support which included verbal support from RNs and MDs, a written prescription to stop smoking which the MD gave to the woman, and two letters of encouragement (one from the physician and one from the counselor), which were mailed 1–2 weeks after the first visit.

Women in the E group received Components (1)–(3) at their first prenatal visit and Component (4) at each prenatal visit. The prenatal Guide was developed based on a thorough needs assessment with pregnant women, which specifically incorporated constructs from a PRECEDE/PROCEED diagnosis and Social Learning Theory (Windsor and Smith, 1991; O’Campo et al., 1995). Prior to using the Guide in Baltimore, we tested its appeal with our population through several focus groups. We made minor modifications in the original text. We also added a new section on relapse prevention,
which followed the same self-help approach and theoretical orientation as in the original Guide. At delivery, the counselor provided E group women with educational materials and brief counseling on the use of a new guide targeted to either cessation or relapse prevention, depending on the woman's smoking status. The two post-partum Guides were identical in orientation and format as the prenatal Guide. Mothers who had not quit during pregnancy received a post-partum Guide that included both cessation and relapse prevention content. Mothers who had quit during pregnancy received a post-partum Guide that included only the relapse prevention content. Content changes from the prenatal Guide to the post-partum Guide included replacing references to pregnancy with references to motherhood and information on the hazards of second hand smoke for newborns.

The 'Smoke-Free' Moms Counselor was a woman recruited from the neighboring East Baltimore community who received training on how to present the Guide and to provide smoking cessation advice. Training for the counselor included two sessions with the principal investigators, who explained the rationale and content of the Guides and how it was to be provided to the women in the study. Soon after the study started, the principal investigators also observed the counselor in the clinic setting on several occasions to provide feedback on her implementation of the study protocol.

Impact variables

Three behavioral impact variables were measured: (1) smoking cessation, (2) significant reduction and (3) smoking patterns.

(1) Smoking cessation. Self-report and biochemical confirmation were used at the third trimester interview to determine smoking status. Cotinine confirmed cessation was defined as a self-report of having quit—did not have 'even one puff' in the past 7 days—and a saliva cotinine value of less than 30 ng (Haley et al., 1983; Etzel, 1990; Idle, 1990; O'Campo et al., 1993). Women who reported having smoked 'even one puff' in the last 7 days were counted as smokers.

(2) Significant reduction in cigarette consumption. Although less than the ideal outcome, significant reduction in the number of cigarettes smoked has been shown to produce meaningful health gains for pregnant women and their newborns (USDHHS, 1990). Trial I (Windsor et al., 1985) data and trial II (Windsor et al., 1993) confirmed significant reduction rates of 18 and 17%, respectively, among experimental group patients. An epidemiologic study using the trial II data confirmed a strong association between reduction rates and infant birth weights. Patients had who significantly reduced their consumption had on average an adjusted mean birth weight 92 g heavier than patients who did not change their smoking behavior (Li et al., 1993). For the present analysis, smokers were considered to be significant reducers if at the third trimester interview their cotinine value was 50% or less than their baseline value (Li et al., 1993; Windsor et al., 1993).

(3) Smoking patterns. Because of the expected link between previous quit attempts and cessation, we documented self-reported pre-pregnancy quit attempts, which were defined as not having smoked 'even one puff' for at least a 24 h period followed by a resumption of smoking. Relapse and slip episodes refer to the resumption of smoking, even for a short period of time, among women who during the current pregnancy had been successful quitters. A slip was defined as a period following complete cessation during which the woman reported smoking at least one puff up to smoking daily for less than 7 days. A relapse was defined as a period following complete cessation during which the woman reported smoking for 7 days or more. These events were assessed at each interview point for the interval between interviews.

Social support for cessation

How often women received advice to quit smoking from a physician and from a nurse was asked in two separate questions on the third trimester
interview. Each was coded as ‘every visit, most visits, some visits, only once or not at all’. We also asked two questions about how helpful family and friends were in women’s efforts to quit. Responses were coded on a five-point scale from ‘not at all helpful’ to ‘very, very helpful’ and then dichotomized: (1) less than very helpful or (2) very helpful or better.

Process evaluation

At the third trimester interview, E group women were asked if they had received the intervention materials—letters from the physician and counselor and the stop smoking prescription form. Guide use was assessed by asking how many days they had read the Guide and whether they had used each of the Guide’s nine recommended steps to quitting. A summary measure of compliance was created by dichotomizing patients into: (1) women who reported completing five or more of the Guide’s recommended steps and (2) women who completed less than five steps.(4)

Results

Of 2319 women screened, 1585 women were not eligible because they were non-smokers and 72 women were ineligible for the following reasons: (1) ethnicity (not African-American or White), (2) more than 28 weeks pregnant when presenting for prenatal care, (3) eligible but not able to interview at initial visit and (4) changing to another OB clinic. Of the 660 eligible women, 510 agreed to participate (77%). There were no significant demographic differences (for education, age, parity, or month of entry into care) between patients who refused (N = 150) and participants. Forty-three of the eligible participants were eliminated from the study because they either reported having quit smoking prior to the first prenatal visit (n = 25) or they did not wish to quit but consented to provide saliva samples during their pregnancies (n = 18). Thus, 467 women were enrolled and randomly assigned to either the E (N = 232) or C (N = 235) group. A total of 76 women were eliminated from the study between enrollment and third trimester due to miscarriages, abortions or withdrawal from the OB clinic. The remaining 193 E group participants and 198 C group participants were contacted, either in the clinic or by telephone for the third trimester interview. Of these women, 125 E and 121 C participants at third trimester provided saliva samples adequate for cotinine analyses. For the analysis of quit rates, the 78 E and 77 C participants who did not provide saliva samples (due to missed clinic appointments and early births) were counted as smokers.

Table I presents the baseline characteristics of the study sample. No significant differences were found between the E and C groups in parity, education, maternal age, gestational age at enrollment, mean cotinine values or the proportion of women who had attempted to quit smoking prior to pregnancy. However, women in the C group reported smoking significantly fewer cigarettes per day at enrollment and had a higher (not statistically significant) percent of African-American women. Because of the large measurement error in self-reports of numbers of cigarettes smoked due to deception, response bias and poor recall, and the confirmed comparability of the mean cotinine values for the E and C group, the self-reported difference in mean number of cigarettes smoked per day was not deemed to be valid.

Behavioral impact

As seen in Table II, the cotinine-confirmed quit rate was 6.2% in the E group (12 of 193) and 5.6% in the C group (11 of 198) at the third trimester observation point. An additional seven women in the E group and 10 women in the C group reported cessation but their cotinine values were 30 ng or above cut-off for cotinine confirmation. These data confirm deception rates of 37% for the E group and 48% for the C group. Women who were cotinine-confirmed quitters at third trimester had lower cotinines at enrollment in both groups: E group quitters’ baseline cotinine averaged 57 versus 165 ng for smokers; C group quitters’ cotinine averaged 50 ng compared to 156 ng for smokers. The percent of smokers who significantly reduced their cotinine value by 50%
Evaluation of a smoking cessation intervention

Table I. Baseline characteristics of participants by group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>E group (N = 125)</th>
<th>C group (N = 121)</th>
<th>Tests and significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>African-American (%)</td>
<td>81</td>
<td>89</td>
<td>$\chi^2 = 2.88$</td>
</tr>
<tr>
<td>Less than high school education (%)</td>
<td>58</td>
<td>48</td>
<td>$\chi^2 = 2.3$</td>
</tr>
<tr>
<td>First pregnancy (%)</td>
<td>40</td>
<td>42</td>
<td>$\chi^2 = 0.12$</td>
</tr>
<tr>
<td>More the three prior quit attempts</td>
<td>32</td>
<td>28</td>
<td>$\chi^2 = 0.62$</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>23.3</td>
<td>24.1</td>
<td>$t = 1.5$</td>
</tr>
<tr>
<td>Mean gestational age at entry (months)</td>
<td>4.1</td>
<td>4.2</td>
<td>$t = 0.44$</td>
</tr>
<tr>
<td>Mean no. cigarettes/day</td>
<td>9.7</td>
<td>7.5</td>
<td>$t = 2.5$</td>
</tr>
<tr>
<td>Mean cotinine (ng)</td>
<td>155.6</td>
<td>146.0</td>
<td>$t = 0.74$</td>
</tr>
</tbody>
</table>

Table II. Third trimester smoking status by study group

<table>
<thead>
<tr>
<th>Group</th>
<th>Quitters n</th>
<th>%</th>
<th>Smokers n</th>
<th>%</th>
<th>Total n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>E group</td>
<td>12</td>
<td>6.2</td>
<td>181</td>
<td>93.8</td>
<td>193</td>
<td>100</td>
</tr>
<tr>
<td>C group</td>
<td>11</td>
<td>5.6</td>
<td>187</td>
<td>94.4</td>
<td>198</td>
<td>100</td>
</tr>
</tbody>
</table>

or above during pregnancy was 11% in both the E and C groups.

To explore reasons for this lack of impact, we compared third trimester outcomes for both E and C women by smoking characteristics at enrollment and by prenatal exposure to health care provider advice, family support and friends' support. The study groups did not differ on any of these variables. Because there were no E versus C group quit rate differences, we combined the sample for analyses of the extent to which these variables were associated with cessation.

Table III displays the number of pre-pregnancy 1-day quit attempts by women's smoking status at third trimester. Almost one-half of the smokers had not attempted to quit. Cotinine-confirmed quitters at third trimester were much more likely to report having made three or more previous quit attempts (48%) than smokers (28%).

Over 80% of the women reported that their health care provider had advised them to stop smoking on more than one occasion during prenatal care, although this was not associated with cessation. However, cotinine-confirmed quitters were significantly more likely than continued smokers to report having very helpful family and friends (Table IV).

Because we had so few women who were cotinine-confirmed quitters at the third trimester, slip and relapse patterns during pregnancy can be
Table IV. Frequency of support from family and friends among quitters and continued smokers at third trimester: E and C groups combined

<table>
<thead>
<tr>
<th>Support</th>
<th>Quitters*</th>
<th>Smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 23</td>
<td>N = 223</td>
</tr>
<tr>
<td>With very helpful family (%)</td>
<td>61</td>
<td>33</td>
</tr>
<tr>
<td>With very helpful friends (%)</td>
<td>43</td>
<td>21</td>
</tr>
</tbody>
</table>

*Cotinine-confirmed only.

described but not analyzed. Of the 23 cotinine-confirmed quitters at third trimester, two (9%) had at least one slip (i.e. one puff daily up to 7 days) during pregnancy. No quitters relapsed (i.e. resumed smoking for more than 7 days) prior to the third trimester interview.

**Process evaluation**

Almost all of the E group women reported receiving each of the printed materials to be used with the Guide—letters from the physician and counselor (82%) and the stop smoking prescription form (88%). Compliance with the Guide was good and consistent with previous reports (Windsor et al., 1985, 1993): 87% of the E group reported reading more than half of the guide; 43% reported reading all of it. We had too few quitters to statistically compare impact by different levels of Guide use. However, the steps in the Guide most often used by quitters were: (1) telling family and friends of the intention to quit (73%), (2) filling out a stop smoking contract (73%), (3) finding a ‘buddy’ to help with the quitting process (73%) and (4) putting up an ‘I quit’ sign (73%). These reports were also consistent with previous reports of guide usage (Windsor et al., 1985, 1993).

**Post-partum data**

Because we were only able to collect 6 month post-partum follow-up data on 107 (54 E group and 53 C group) of the study participants, these results must be interpreted with great caution. Of 54 available E group women, 46 smokers received the in-hospital smoking cessation intervention for new mothers (the eight quitters received the in-hospital relapse prevention intervention). Comparing the 46 E group smokers to the 48 C group smokers who received standard care during the hospital stay, we found that seven (15%) of the E group and two (4%) of the C group reported being non-smokers at 6 months post-partum.

Because we had so few women who quit smoking, we were unable to provide an adequate evaluation of the in-hospital relapse prevention intervention. However, we did analyze relapse among the 13 women who were non-smokers at the third trimester interview (E and C group combined) for whom we had post-partum data; 85% of these women had relapsed by 6 months post-partum.

**Discussion**

The peer delivered intervention was not effective in this study. Almost 85% of the patients in both groups continued their pre-conception smoking pattern throughout pregnancy. Among the small number of women ($n = 13$) who did successfully quit smoking and were followed to 6 months post-partum, 85% relapsed.

Although over 80% of all of our participants remember being advised by their physician and nurse to quit smoking, few heeded this advice. Women who were able to quit prenatally more often reported that their family and friends were helpful. Women in the E group also seemed to respond favorably to the Guide’s suggestions to tell family and friends that they intended to quit and to get a buddy to help them quit. Women who quit prenatally more often reported that they filled out the contract to quit and put up the ‘I Quit’ sign in their home. Prenatal care providers in comparable settings can use this information to enhance their communication with pregnant women by offering concrete suggestions about how to quit. The observed relapse rate indicates additional effort is needed in the post-partum period.

A major limitation in this study was our loss to follow-up rate, a persistent problem faced by
evaluations conducted in this setting. Patients in public prenatal care often miss prenatal appointments, move frequently and live in several temporary residences. Access to a working telephone is also sporadic. Thus, follow-up rates over 50% are difficult to achieve without additional staff to conduct follow-ups or monetary incentives—resources not available in this study. The lost to follow-up rate produced small sample sizes which constrained us in our efforts to understand smoking cessation patterns, e.g. slips and relapses. We, as did Windsor et al. (1985, 1996), found little evidence of relapse during the prenatal period among women who had quit smoking prior to the third trimester. However, the problem of post-partum relapse was substantial.

Although we replicated methods confirmed by biochemical tests as efficacious in both Birmingham trials (Windsor et al., 1985, 1993) our results differ substantially. The Birmingham trials found a difference of 14% (E group) versus 2% (C group) in trial I (Windsor et al., 1985) and 14% (E group) versus 8% (C group) in trial II (Windsor et al., 1993). Coates and Maxell (1990) studied a predominately Black OB population in Washington, DC in 1990 who received the Guide (Windsor and Smith, 1991), counseling and similar educational materials, and found a self-reported quit rate of 33%. As discussed in Windsor et al. (1993) if this self-reported quit rate is attenuated to reflect inaccuracy, a quit rate of 20% or above is derived. This is comparable to the Black E group quit rate of 18% in trial II (Windsor et al., 1993). Mayer et al. (1990) using similar intervention methods with a WIC/medicaid patient cohort reported E group quit rates of 11% and C group quit rates of 3%.

Explanations for these inconsistent results are not clear. There may be underlying population differences between medicaid patients in maternity clinics in Birmingham and in Baltimore (selection factors). While there is much poverty in Alabama, the Baltimore site is in a particularly disadvantaged inner city area of a major metropolitan area. Many women served at the Baltimore clinics face multiple hardships in their daily lives and in their neighborhoods, including unemployment, poverty, drug use, violence and crime (Gielen et al., 1994; O’Campo et al., 1995). Thus, the salience and priority given to smoking cessation and support for quitting may be lower among the Baltimore cohort.

A second plausible reason for our findings was the use of a professional health educator in Birmingham and a ‘peer counselor’ in Baltimore. All evaluations that have replicated or used comparable methods to the Birmingham trial have used a professional counselor and all reported significant E versus C group quit rates. The consistency of the findings of the superiority of the methods with African-American pregnant smokers in the Birmingham trial II and Washington, DC studies suggests that who provides the counseling may be critical to its efficacy. Whether the counseling would be more effective if provided by a health professional or health educator in the Baltimore setting, however, cannot be answered by our data. Because the most efficacious type of counselor may vary from setting to setting, and by social and cultural environment, this question should be pursued in future evaluation research (Windsor et al., 1994).

Our data do not allow us to make definitive recommendations. However, we feel that interventions such as a self-help skills-based guide that relies on written materials may need to be supplemented when used with maternity populations such as ours. Some women may not be well positioned to make effective use of reading materials. Future interventions could consider increasing the interpersonal counseling component to help women through the self-help quitting steps and other methods to enhance social support. Such increased effort, however, has specific and probably substantial implications for personnel time and program costs. Finally, more research is needed to understand determinants of relapse and to develop effective relapse prevention interventions specifically for pregnant women and new mothers.

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