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RESEARCH PAPER

A group randomised trial of two methods for disseminating a smoking cessation programme to public antenatal clinics: effects on patient outcomes

E Campbell, R A Walsh, R Sanson-Fisher, S Burrows, E Stojanovski

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Objective: To assess the differential effectiveness of two methods of disseminating a smoking cessation programme to public hospital antenatal clinics.

Design: Group randomised trial.

Setting: 22 antenatal clinics in New South Wales, Australia.

Intervention: Clinics were allocated to a simple dissemination (SD) condition (11 clinics) which received a mail-out of programme resources or to an intensive dissemination (ID) condition (11 clinics) which included the mail-out plus feedback, training, and ongoing support with midwife facilitator.

Main outcome measures: Independent cross sectional surveys of women on a second or subsequent visit undertaken pre-dissemination and 18 months after dissemination. Outcomes were: (1) levels of smoking status assessment by clinic staff; (2) proportion of women identifying as having been smokers at their first visit who reported receiving cessation advice; (3) proportion of these women who had quit (self report and expired air carbon monoxide (CO)); and (4) smoking prevalence among all women (self report and CO).

Subjects: 5849 women pre-dissemination (2374 SD, 3475 ID) and weighted sample of 5145 women post-dissemination (2302 SD, 2843 ID).

Results: There were no significant differences between the groups on change on any outcome. Change in either group was minimal. In the post-dissemination survey, the cessation proportions were 6.4% (SD) and 10.5% (ID).

Conclusions: Relatively modest strategies for encouraging incorporation of smoking cessation activities into antenatal care were not effective in the long term. Alternative strategies should be implemented and evaluated. The findings reinforce the importance of a whole population approach to tobacco control.

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Meta-analyses have concluded that smoking cessation programmes involving advice and provision of written materials can be effective in helping pregnant women quit, at least until the end of pregnancy.^{1,2} While the majority of the interventions have been delivered by personnel who are not usual care providers, a number of trials have indicated that interventions delivered by usual care providers during routine antenatal care can produce positive effects.^{3–7} However, lower intensity interventions by clinic staff have not always produced significant increases in validated quit rates.^{8–11}

Encouraging antenatal care providers to adopt smoking cessation interventions has been identified as a priority in a number of countries including Australia and the USA.^{12,13} Evidence suggests that such interventions are not routinely used by health care providers.^{12,14,15} There has been much discussion about the failure of practitioners to adopt health promotion strategies such as smoking cessation interventions.¹⁶ Altering the clinical behaviour of health care providers has been viewed as a challenging task.¹⁷

Passive dissemination interventions such as journal publication or targeted mail-outs rarely lead to changes in clinical behaviours.^{18,19} In dissemination programmes generally, it has been recommended that multifaceted interventions be used with potential strategies including audit and feedback, professional education, and social influence approaches.¹⁸ Nonetheless, the dissemination intervention should be such that it can feasibly be applied on a broad national or regional level. There is limited evidence on the relative effectiveness of different dissemination strategies.^{17,18} Although there have been a number of trials where antenatal clinics or midwives have been the unit of randomisation, these studies were

designed to evaluate new interventions or training programmes rather than to assess different methods of disseminating an effective programme.^{8,20,21} Only one trial comparing different methods of encouraging providers to adopt effective smoking cessation programmes with pregnant women could be located.²² Data suggesting the dissemination programme was effective were based largely on brief phone interviews of two senior staff in each hospital.

Evidence demonstrating the positive effects of the smoking cessation programme, Fresh Start Program for You and Your Baby (FSP), to be used in this dissemination trial has been well documented in a single clinic study.^{3,23} Two dissemination approaches were contrasted in this subsequent multi-clinic trial: a simple dissemination (SD) condition involving a mail-out, and an intensive dissemination (ID) condition involving feedback, training, and ongoing support from a midwife facilitator. The mail-out approach was chosen as the control condition because this mimicked a method commonly used by peak organisations to disseminate new policies.¹⁹

An earlier report of the dissemination trial involved a survey of all clinical staff in participating clinics before programme dissemination and repeated 18 months after dissemination.²⁴ The report demonstrated that the average number of intervention items (maximum 13) increased significantly in the post-dissemination survey from 4.5 to 7, but was not influenced by type of dissemination. The staff survey results, however, did indicate the quality of interventions offered in the clinics which were allocated to the ID

Abbreviations: FSP, Fresh Start Program for You and Your Baby; ID, intensive dissemination; SD, simple dissemination

condition was higher, with significantly more clinicians in these clinics reporting use of the programme flip chart and quit packs, as well as use of specific counselling items.²⁴ For example, 47% of ID clinicians indicated they had recently used the intervention “negotiate quit date” compared with 23% of SD clinicians. The findings of the above report were based entirely on provider self report.

This study notably extends the earlier results, based on the survey of clinicians, by examining three crucial patient outcomes: recall of smoking advice received, biochemically validated smoking cessation proportions, and overall levels of smoking prevalence. The aim of this report is to assess the differential effects on these patient outcomes of two methods of disseminating the effective Fresh Start Program (FSP) to antenatal clinics in Australian public hospitals: simple dissemination (SD) by mail, and more intensive dissemination (ID).

PARTICIPANTS AND METHODS

Design

The intervention was directed at the clinic with the intention of changing patient outcomes and thus it is a randomised cluster design. Public antenatal clinics were allocated at random to either the SD or ID condition. Outcome data were collected using two independent cross sectional surveys of women who had attended at least one clinic session in their current pregnancy. Surveys were undertaken before dissemination and 18 months after dissemination commenced. Random allocation of clinics was undertaken within strata based on clinic size and patient smoking rates as determined at the baseline survey to achieve balance between groups.

Clinics

Of the 25 public hospitals in New South Wales, Australia with an antenatal clinic and more than 500 births a year, 23 agreed to participate. Clinics were informed that the study was a multi-centre trial designed to evaluate different methods of encouraging clinical use of a proven effective smoking cessation programme. Approval of the relevant ethics committees was obtained. One clinic did not provide follow up data; this clinic in the SD condition was the only clinic to report it did not receive the initial mail-out. Trial analysis is based on 22 clinics, 11 per condition.

Women

During pre- and post-dissemination surveys an interviewer approached all women in the waiting room. Women were ineligible if they were under 16 years, too sick, if they did not comprehend English either unaided or with the help of an interpreter or family member, if they could not read, or if their attendance was a first visit. Eligible women were asked to provide both a sample of expired air and to complete an anonymous questionnaire. Data were collected for two weeks, except in the 11 largest clinics at post-dissemination (5 SD, 6 ID). The post-dissemination samples were weighted to allow for the one week data collection period in these clinics.

The programme being disseminated: FSP

The FSP was designed to provide systematic, individualised smoking cessation advice to smokers during pregnancy.³ The components of this cognitive behavioural programme have been fully described elsewhere.^{3 25}

Experimental conditions

Simple dissemination (SD)

Dissemination involved a single mail-out of the following components:

Written information on the programme benefits and resource availability—Nursing unit managers were sent a letter that

summarised the risks of smoking during pregnancy, the effectiveness of the FSP, and described its use. Additional copies of resources, including material in languages other than English, could be ordered at no charge over the 18 month intervention period.

Programme resources—Clinics were sent one staff training video, one patient video, and samples of flip charts, chart stickers and self help kits.

Intensive dissemination (ID)

The ID approach was designed to address previously identified individual and institutional barriers to antenatal smoking cessation care provision.²⁵ Development of the ID intervention was guided by Rogers’ model²⁶ and by frameworks proposed for preventive medicine.^{27–29}

Dissemination involved the following components:

Written information on programme benefits and feedback on baseline levels of smoking cessation activity—Nursing unit managers were sent a letter very similar to that sent to SD clinics. In addition, each ID clinic was also offered smoking related data derived from their clinic’s pre-dissemination survey.

Programme resources—In the initial mail-out, clinics were provided with the same programme materials sent to the SD clinics.

Offer of visits to explain programme and provide training—One week after the mail-out, a midwife facilitator attempted to contact the nursing unit manager to offer to visit the clinic to discuss the programme and provide staff training sessions. The training involved showing the training video, discussing any difficulties staff believed they would have, and reiterating the advantages of using the FSP. Planned training strategies were practice orientated and focused on skill development.

Sample clinic smoking cessation policy—A sample policy on the detection and treatment of smoking was included in the mail-out.

Regular contacts to offer support and opportunities to order additional resources—Facilitators attempted to maintain phone contact with clinics at least once a month for as long as these contacts seemed useful over the 18 month intervention period. These contacts were intended to encourage clinics to implement policies, to adopt or continue to use programme elements, to discuss problems, and to order further resources at no cost.

Offer of computerised clinic feedback on smoking cessation activities—Clinics were offered the use of a waiting room attenders’ survey administered via touch screen computer to provide feedback on levels of smoking cessation activities.

Measures

The following outcome variables were assessed pre-dissemination and 18 months post-dissemination.

Patient recall of care outcomes

The primary outcomes relate to the uptake of a smoking cessation intervention: the proportion of women whose smoking status had been assessed by clinic staff; and the proportion of women reporting they had been smokers when they first visited the clinic who were provided with cessation advice.

Assessment of smoking status

Women were asked whether a clinic midwife had asked them if they smoked, on any visits in this pregnancy. The same question was asked about clinic doctors.

Provision of cessation advice

Women who reported to be current smokers or to have stopped since their first clinic visit were asked whether a midwife at the clinic had: talked with them about the risks of smoking in pregnancy and about methods that could be used

Table 1 Eligibility and consent data of women surveyed in the two clinic conditions pre- and post- the dissemination intervention

	Pre-dissemination		Post-dissemination	
	Simple dissemination	Intensive dissemination	Simple dissemination	Intensive dissemination
Attended (n)	3340	4624	2301	2617
Approached (n)	3209	4520	2125	2401
Ineligible				
Too sick (n)	15	22	20	27
No English (n)	96	106	165	198
Did not read (n)	2	0	3	9
<16 years (n)	3	12	2	3
Eligible				
Completed study measures (n)	2900	4211	1813	2001
Did not complete study measures (n)	193	169	128	163
Women completing study measures				
% of eligible	94	96	93	92
% of attendees	87	91	79	76
Survey samples				
Women on second or subsequent visit				
Sample size*	2374	3475	2302	2843
Sample size range per clinic*	55–422	48–848	40–454	52–630

*Weighted *n* at post-dissemination.

to stop smoking; and whether they had received the following smoking related services: advice to stop completely; discussion of a definite quit date; written information about smoking; and discussion of smoking at visits other than the first visit. They were asked the same questions about clinic doctors.

Patient smoking outcomes

The secondary outcomes were: the proportion of the women who had been smokers when they first visited the clinic who had now quit; and the proportion of all women who were current smokers.

Smoking among clinic attendees on second or subsequent visit

Smoking status was assessed via self report, corrected using expired air carbon monoxide (CO) data. Women were informed the breath sample, which was taken before questionnaire completion, would be used to examine their exposure to tobacco smoke, from their own and other people's smoking. Analysis of expired air CO levels was undertaken using Bedfont EC50 micro hand-held smokalyzers. A cutoff value of ≥ 9 ppm was used to indicate women were smokers.³⁰ In the questionnaire women were asked "Have you ever smoked tobacco?" with response options: No never; Yes, but I gave up in the last 12 months before I thought I was pregnant; Yes, but I gave up before my first clinic visit after I thought I was pregnant; Yes, but I gave up after my first clinic visit; and Yes, I am a smoker.

Quitting since first visiting the clinic

Women considered to be current smokers (based on self report or CO of 9+), plus those who reported they had given up after their first visit, were considered to have been smokers at their first clinic visit. Women who reported they had given up after their first visit, and who also had a CO of less than 9, were considered to have quit since their first clinic visit.

Descriptive variables

The questionnaire included information on age, marital status, education, Aboriginality, speaking a language other than English at home, weeks pregnant, number of children, and whether ongoing pregnancy care was being received outside the clinic. In total, data on 14 patient subject characteristics were collected.

Analysis

In this study, the clinic was the unit of randomisation and patients were the unit of analysis. In line with expert recommendation, clustering effects were addressed in the analysis.³¹ For each of the primary and secondary outcome variables, an intraclass correlation coefficient was calculated as a measure of the correlation among patients within the clinics; a Breslow Day test for homogeneity of odds ratios was conducted to assess whether the odds of change over time in the SD condition were significantly different (at $p < 0.05$) from the odds of change in the ID condition. All analyses were conducted using the statistical software package SUDAAN,³² which uses a Taylor series linearisation variance estimation technique to adjust for the cluster design.

Comparability of descriptive characteristics of the pre-dissemination samples for the two conditions, of the post-dissemination samples for the two conditions, and of the pre-dissemination and post-dissemination samples within each condition, were assessed by noting whether there were any differences that were likely to be clinically meaningful (over 5% difference). The alternative of conducting χ^2 analyses on all variables was not undertaken, as due to the large sample size, it was highly likely that statistically significant differences would be obtained for clinically insignificant differences. The possible impact of the clinically significant differences on the outcomes of interest was explored as follows. First, χ^2 analyses were used to assess whether the characteristic was associated with each relevant outcome at pre-test or post-test. If these tests showed significant associations (at $p < 0.05$), Breslow Day tests were used to assess whether the odds of change over time were significantly different for women with different characteristics (for example, married/defacto versus not married/defacto). A significant difference in patterns of change would suggest that more sophisticated modelling of outcome change would be valuable.

The comparability and potential impact of descriptive variables was also assessed for the subsample of women who reported to have been smokers when they first visited the clinic. The approach was similar to that described for the overall sample, except that χ^2 analyses were used for all descriptive variables (given smaller samples) to assess whether the characteristic was associated with each outcome at pre-test or post-test. If these tests showed significant associations (at $p < 0.05$), Breslow Day tests were used to assess whether the odds of change over time were significantly different for women with different characteristics.

Table 2 Recall of clinical staff assessment of smoking status in the two conditions pre- and post-dissemination: percentages of all women surveyed

	Pre-dissemination		Post-dissemination		p Value for Breslow Day test
	Simple dissemination (n = 2374)	Intensive dissemination (n = 3475)	Simple dissemination (weighted n = 2302)	Intensive dissemination (weighted n = 2843)	
Percentage of women reporting midwife, doctor, or either had asked if they smoked					
Midwife	81.4	81.3	83.8	85.9	0.117
Doctor	79.2	80.2	80.0	81.4	0.783
Either	90.8	90.6	91.6	92.9	0.121

RESULTS

Eligibility, consent, and sample background details

Table 1 provides information on eligibility and consent rates of women, and sample sizes in the two conditions before and after the dissemination interventions. In relation to the characteristics of the women in the two conditions at the two time intervals, the differences on nearly all 14 characteristics were minimal (less than the defined 5% level). The proportion of women with more than high school education in the SD condition was higher at post-dissemination (22%) than in the pre-dissemination sample (17%). The ID condition, pre-dissemination, had a higher proportion of women who spoke a language other than English at home (45%) than the pre-dissemination SD condition (37%), and than the post-dissemination proportions in both the SD condition (35%) and the ID condition (33%).

A pre-dissemination survey showed that clinics in the two conditions did not differ on a wide range of antenatal care variables including number of clinic staff, length of appointment time, or staff perceptions of barriers to smoking cessation education.³³

Process measures of ID uptake

All ID clinics received specific feedback about the proportion of their patients who were smokers and the proportion of their patients who reported at pre-dissemination that they had received information about smoking cessation. Nine of the 11 ID clinics received at least one personal visit from the midwife facilitator, and three clinics had more than one visit.

Training sessions were, on average, of one hour's duration. Time constraints within clinics meant they often could not be repeated. Although training permitted information about the programme to be provided to clinicians and the training videotape modelled smoking cessation skills, the time period was usually inadequate to provide skill development as originally planned.

Telephone contact between clinics and the midwife facilitators occurred between 4–9 times per clinic, with the duration of calls between 12 and 95 minutes. Proactive calls by the midwife facilitator were discontinued after 12 months. Only one clinic took up the offer of the touch screen computer for feedback on smoking cessation care provision.

Patient recall of care outcomes

Table 2 provides information on the levels of smoking assessment before and after the dissemination intervention. Data on the provision of cessation advice to women who reported being smokers when they first visited the clinic is given in table 3. The odds of change over time were not significantly different between the conditions for any of the outcomes in tables 2 and 3.

Patient smoking outcomes

Table 4 provides information on the cessation proportions since the first clinic visit and on the smoking prevalence among all women. The odds of change over time were not significantly different between the conditions for quitting or overall smoking prevalence.

Only one clinic (ID condition) had a borderline significant increase in the quitting proportion from pre- to post-dissemination. For the whole sample, the demographic variables of post-high school education and speaking a language other than English at home were explored for associations with the outcomes that applied to the whole sample (assessment of smoking status, smoking rates), and impact on outcome change over time. For the subsample of women reporting to be smokers at their first clinic visit, the following variables were explored in relation to the remaining outcomes: age, marital status, speak language other than English at home, Aboriginal or Torres Strait Island Origin, first child, tertiary qualification, and weeks pregnant. While some associations with outcomes were found, the impact of

Table 3 Recall of clinic midwife or doctor provision of cessation advice in the two conditions, by women who reported they were smokers when they first visited the clinic, percentages at pre- and post-dissemination

	Pre-dissemination		Post-dissemination		p Value for Breslow Day test
	Simple dissemination (n = 622)	Intensive dissemination (n = 899)	Simple dissemination (weighted n = 503)	Intensive dissemination (weighted n = 686)	
Staff talked about risk of smoking in pregnancy	60.9	57.0	63.8	64.5	0.206
Staff discussed methods could use to quit	22.3	25.1	24.8	30.0	0.548
Advised to stop smoking completely	38.2	36.7	38.7	41.1	0.320
Discussed a definite quit date	1.9	2.3	4.3	5.8	0.851
Received written material about smoking	31.4	34.8	32.2	33.8	0.636
Discussed smoking at more than one visit*	14.6	14.6	12.4	14.4	0.520

*Only for women who had attended at least two visits before current visit. n = 519, 740, 425, and 595.

Table 4 Quitting since first clinic visit, and smoking prevalence in the two conditions among women on a second or later visit, pre- and post-dissemination: percentages and *n* sizes

	Pre-dissemination		Post-dissemination		p Value for Breslow Day test
	Simple dissemination	Intensive dissemination	Simple dissemination	Intensive dissemination	
Quitting since first visiting the clinic					
% quit (self report and CO <9)	7.3	8.8	6.4	10.5	0.198
<i>n</i> size	696	956	688*	781*	
Smoking prevalence					
% smokers (self report or CO 9+)	27.2	25.1	28.2	24.8	0.442
<i>n</i> size	2374	3475	2284*	2821*	

*weighted *n* at post-dissemination.

these variables on change over time was not significant for any outcome.

At follow up, possible intra-class correlation effect induced by intervention was explored and found to be non-significant. This indicated there had been no differential long term implementation of the intervention between clinics.

DISCUSSION

This study showed that neither mailing information and resource materials for an effective smoking cessation programme to public antenatal clinics, nor a more intensive intervention involving contact with a midwife facilitator, were effective in producing long term changes in clinic smoking cessation practices based on patient self report or in influencing validated smoking cessation proportions among patients.

The strengths of the study include the use of a biochemical measure, the substantial patient sample sizes, and the large number of clinics of varied sizes, which enhances the generalisability of the findings. The follow up time frame of 18 months was chosen as it was considered that clinics would require time to integrate a programme into routine care, and because the most desirable outcome is sustained implementation. Logbook data also confirm that the ID clinics did have substantially more contact with the researchers.

The study does have some limitations. Data on the provision of smoking care by clinic staff rely on patient self report. Patient self report has sometimes been found to overestimate the proportion of patients given advice.³⁴ This is less likely when some weeks have elapsed between the advice and patient recall and, in fact, one such study found evidence of substantial under-reporting.³⁵ However, if overestimates occurred, they are likely to be less than those derived from clinic staff report.³⁶ The likelihood of bias due to differential over- or under-reporting by women in different groups also seems minimal as women would not have known their clinic was involved in a trial. For outcomes relating to smoking cessation, it was not possible to follow individual women over time to provide cessation data. Independent cross sectional surveys were undertaken before and after dissemination of women attending a second or subsequent clinic visit. The quitting measures are based on retrospective definitions of whether women were smokers when they first visited the clinics, and include women at all stages of pregnancy. While this may limit direct comparisons with quit rates reported in some previous trials, the inclusion of CO measurement incorporates some correction for potential deception into the measures of quitting.

The sample size and proportion of attenders participating was lower at follow up than baseline. Resource limitations are likely to have contributed to the higher rates at which women were missed, or excluded due to insufficient English. Despite this, differences in demographic and other descriptive variables were minimal, and did not impact on outcomes.

Even with some potential overestimation, the levels of assessment and advice provision improved little in either condition at post-dissemination, and remained less than optimal. While reported rates of smoking assessment, at around 90%, are encouraging, such assessment should be standard procedure for all patients. Discussion of the risks of smoking in pregnancy and advice to stop smoking completely should also be provided to all women who smoke. These behaviours were reported by only around 60% and 40% of women, respectively. Only about one in seven women reported that smoking was discussed on repeat visits, which is also important for reinforcing cessation messages.

These findings are broadly consistent with the results of pre- and post-dissemination staff surveys which suggest limited adoption and ongoing implementation of the intervention.²⁴ Although there is considerable agreement between the patient derived data presented here and the provider reports,²⁴ there are also important differences. Patient report does not support the staff survey finding²⁴ that there was an overall increase in the mean number of smoking interventions offered for the combined conditions from pre- to post-dissemination or that staff in the ID condition offered higher quality interventions than those in the SD. For example, the percentage of staff²⁴ both in the ID and the SD conditions who reported recent use of the intervention "negotiate quit date" was much higher at post-dissemination than the proportion of patients in the two conditions who recalled this intervention. Furthermore, the between condition difference on this intervention item at post-dissemination was significant based on staff report but not when based on patient recall.

Given the limited extent to which intervention elements appear to have been adopted by clinics in either group after 18 months, it is not surprising that there were no significant differences between the dissemination conditions in terms of change in cessation proportions or overall smoking prevalence. Validated quit rates were very low in both conditions at pre- and post-dissemination. However, it is worth noting that the quit rate difference of 4.1% at post-dissemination is not that dissimilar to the absolute difference of 6.4% of women continuing to smoke between intervention and control groups in the Cochrane meta-analysis.²

The findings emphasise the difficulties associated with reorienting health services to adopt preventive strategies such as smoking cessation programmes.^{12 33 37} The results of this trial should be used to plan future dissemination interventions that may be better equipped to deal with the barriers facing the clinical environment. This is likely to require more intensive efforts such as greater individual clinic tailoring, on-site specialist cessation assistance and social influence approaches designed to engage doctors and midwives, and to generate high level hospital backing. The computer feedback strategy offered to ID clinics proved unacceptable. A more traditional strategy such as record audits may be worth

What this paper adds

Efficacy trials have demonstrated that counselling interventions can encourage a small, but significant, additional proportion of pregnant smokers to quit. Antenatal care providers do not routinely provide potentially effective cessation interventions. Multifaceted dissemination programmes have been recommended as a way of encouraging doctors and midwives to adopt such interventions.

Patient report indicated that dissemination programmes failed to improve the smoking care offered by antenatal clinic staff, or the proportion of smokers who quit. Clinics randomised to receive more intensive dissemination had no better outcomes than those receiving a single mail-out. This raises doubts about the capacity of medium intensity dissemination programmes to contribute to a large decrease in the prevalence of smoking in pregnancy.

incorporating in future studies. Cost effectiveness and cost benefit data will be crucial in future evaluations of more resource intensive methods.³⁸ Finally, given the difficulties involved in replicating more widely even the modest cessation gains found in single clinic efficacy trials, this study highlights the importance of tobacco control measures which target the whole community.

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