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Smoking cessation in pregnancy: do effective programmes exist?

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SUMMARY

Smoking has been described as the most important cause of poor pregnancy outcome in Western countries. None the less, evidence indicates that health care providers do not routinely provide smoking cessation interventions to pregnant women. The US Surgeon General has recommended that programmes to reduce smoking during pregnancy should be expanded in the public and private sectors. A review of the literature located 20 controlled evaluations of smoking cessation interventions in pregnancy. The studies were rated using the methodological criteria outlined by Windsor and Orleans (1986). Twelve of the studies were judged methodologically inadequate and excluded from the review. The remaining studies were found to support the efficacy of cognitive behavioural smoking cessation programmes in pregnancy. There was insufficient evidence to determine whether advice, feedback or nurse home-visitation programmes increased smoking cessation rates in pregnancy under ideal conditions. None of the methodologically adequate cognitive behavioural studies fulfilled the criteria necessary for a smoking cessation programme to be incorporated into routine antenatal care. Importantly, in only two studies were the smoking cessation interventions delivered by usual care doctors or midwives. The findings indicate that it is unsurprising that health care providers do not routinely deliver smoking cessation programmes to pregnant smokers. Future research and programme needs are discussed.

Key words: smoking prevention and control; pregnancy; prenatal care

The US Surgeon General (1990) has recommended that programmes to reduce smoking during pregnancy should be expanded in the public and private sectors. Smoking has been described as probably the most important cause of poor pregnancy outcome among women in Western countries (Cnattingius *et al.*, 1988; Foy, 1988; US Surgeon General, 1990). There are major health benefits associated with smoking cessation in pregnancy.

First, the link between maternal cigarette smoking and reduced birthweight has been well established in over 100 publications, based on studies of more than 500 000 births (Lumley, 1987). There is a clear dose–response relationship between the number of cigarettes smoked during pregnancy and lower birthweight (US Surgeon General, 1980). The US Center for Health Promotion and Education judged the evidence that smoking causes low birthweight sufficiently strong to recommend use of the term fetal tobacco syndrome (Nieburg *et al.*, 1985). It has been estimated that the elimination of smoking during pregnancy could prevent about 20% of low birthweight births in the United States (US Surgeon General, 1990). Women who stop smoking in the first 3–4 months of pregnancy have infants of the same birthweight as those born to women who have never smoked (US Surgeon General, 1990).

Second, there is also considerable evidence that smoking increases the risk of spontaneous abortion, pre-term birth, perinatal mortality, neonatal mortality and postneonatal mortality (Meyer *et al.*, 1976; Meyer and Tonascia, 1977; Cnattingius *et al.*, 1988; Malloy *et al.*, 1988; Brooke *et al.*, 1989). The aetiologic fraction of Sudden Infant Death Syndrome caused by

tobacco has been estimated at 0.22 (Holman *et al.*, 1988). Studies have shown a 25–50% higher rate of fetal and infant deaths among women who smoke during pregnancy compared with those who do not (US Surgeon General, 1990).

Third, where women continue to abstain from smoking after pregnancy, they also reduce their children's exposure to passive smoking. There is strong evidence that children exposed in the home to environmental tobacco smoke are more likely to develop otitis media and asthma and have higher rates of hospitalization (50–100%) for severe respiratory illness (Spitzer *et al.*, 1990).

Fourth, apart from the pregnancy-related risks, smoking is a major cause of other illnesses in women (US Surgeon General, 1980). Lung cancer deaths are now projected to have surpassed breast cancer deaths as the leading cause of female cancer mortality in the US and among younger women, smoking now accounts for an estimated 41 per cent of coronary heart disease deaths and an estimated 55 per cent of lethal strokes. Although the postpartum relapse rate is high, recent data demonstrate that approximately 35% of women who stopped smoking during pregnancy remained abstinent 6 months after birth (McBride and Pirie, 1990; Mullen *et al.*, 1990).

Moreover, the special nature of pregnancy offers a good opportunity to encourage women to stop smoking (Stoto *et al.*, 1988). Most pregnant women are highly motivated to provide optimal conditions for fetal growth and development (Alexander, 1987). The average smoking cessation rate of women during pregnancy is only matched by patients with pulmonary or cardiac diseases and subjects in intensive risk factor intervention trials (Schwartz, 1987). Lifestyle change is also facilitated by the regular contact with health care providers which occurs in the antenatal period.

Prevalence of smoking in pregnancy

Despite the benefits of smoking cessation during pregnancy, the prevalence of smoking in pregnancy remains at an unacceptably high level (US Surgeon General, 1990). Sexton (1986) reported that approximately 30 per cent of pregnant women in the UK, North America and Australia were current cigarette smokers. In the US, the prevalence of smoking during pregnancy declined markedly for married mothers aged 20 and over during the period 1967 to 1980, but remained essentially constant among married teenagers (Kleinman and Kopstein, 1987). There is also a marked socio-economic gradient with women of lower education attainment being more likely to smoke during pregnancy (Stewart and Dunkley, 1985; Johnson *et al.*, 1987; Madeley *et al.*, 1989; Lodewijckx and DeGroof, 1990).

Most smokers are still smoking at the end of their first trimester. Studies prior to the mid-1980s suggested that the proportion of smokers who quit by the time of their first antenatal visit was around 18% (Lumley, 1987). More recent data (Rubin *et al.*, 1986; Kleinman and Kopstein, 1987; Wakefield and Jones, 1991) indicate that this proportion is increasing and the Surgeon General (1990) has estimated that about 30% of US women who are cigarette smokers quit after recognition of pregnancy. Very few women who receive routine antenatal care quit smoking in the second or third trimester. The experience of control groups in randomized trials demonstrates the proportion is less than 6% (Lumley, 1987).

Comprehensive approach to smoking prevention

The Surgeon General (1989) has stated that the integration of educational and behavioural programmes with policy initiatives represents a most important development in smoking prevention. Evaluation studies indicate that school prevention programmes can be effective in reducing the initiation of smoking among adolescents by 40–70% (Perry *et al.*, 1988; Parcel *et al.*, 1989). However, the finding of delayed onset rather than total prevention has received most support (Glynn, 1989). The potential for regulations that restrict smoking in public places to achieve significant reductions in smoking also appears to be promising (Wasserman, 1992). Data provide support for fiscal policy as another effective strategy, with excise tax increases being consistently associated with declines in cigarette consumption (Peterson *et al.*, 1992). Programmes designed to reduce the prevalence of pregnancy smoking should be viewed as part of a comprehensive approach to tobacco control. In this context there is clearly a pressing need to develop effective cessation programmes for women who smoke in pregnancy.

Mass-media campaigns represent a potential way to encourage smoking cessation in pregnancy. However, a recent review found there was little evidence to support the implementation of mass-media programmes designed to alter health-risk behaviours (Redman *et al.*, 1990).

Three studies have attempted to evaluate the effectiveness of mass-media campaigns in reducing the prevalence of smoking during pregnancy (Dalton *et al.*, 1981; Chapman *et al.*, 1982; Olsen *et al.*, 1989). Although methodological problems limit the generalizability of the findings of all three studies, no significant differences in smoking prevalence were detected between groups of pregnant women exposed to the campaigns and those not exposed.

Role of health care providers

Advice from health care providers may represent a more effective strategy for promoting cessation. Physicians are a credible source of health information with a plausible message to convey (Slama *et al.*, 1989). In pregnancy, usual care providers, especially physicians and midwives, are well placed to provide smoking cessation interventions because of their regular contact with pregnant women. Most pregnant smokers have their pregnancy confirmed by a physician and over 90 per cent have visited a physician by the end of the first trimester (Stewart and Dunkley, 1985). Nurses comprise the single largest health professional group and within a hospital setting they spend the most time with patients (Smith, 1979). Pregnant women cite health care providers as the most important source of information about health behaviour in pregnancy (Aaronson *et al.*, 1988). Moreover, results of randomized, controlled trials have demonstrated that physicians can have a significant impact on smoking cessation rates of non-pregnant patients (Russell *et al.*, 1979; Richmond *et al.*, 1986; Wilson *et al.*, 1990).

Despite their potential impact, the evidence indicates that health care providers do not routinely provide smoking cessation interventions to pregnant smokers. In a direct observation study, Dickinson *et al.*, (1989) found that family physicians only detected 48% of female smokers presenting for contraceptive or antenatal care. Many surveys have demonstrated that the majority of pregnant smokers do not remember receiving any intervention about smoking from their family physician, with advice recall rates of 10% (Ashford *et al.*, 1986), 19% (McKnight and Merrett, 1986), 20% (Dalton *et al.*, 1981), 33% (Lilley and Forster, 1986) and 48% (Buist and Yu, 1987; Madeley *et al.*, 1989). Survey data on the midwife as a source of information have, with one exception, documented similar findings of 13% (Strychar *et al.*, 1990), 19% (Ashford *et al.*, 1986), 26% (Madeley *et al.*, 1989), 28% (Buist and Yu, 1987) and 85% (McKnight and Merrett, 1986) of pregnant smokers recalling advice about smoking. In one study (Strychar *et al.*, 1990) where a high level (90%) of pregnant smokers reported discussing smoking with a physician(s), only 4% recalled receiving any advice on how to quit. Shipp *et al.* (1992) recently stated that formal antismoking programmes are not a part of most prenatal care, despite their potential cost-effectiveness.

Whether or not health care practitioners provide consistent prevention services depends on many personal and environmental characteristics (Belcher *et al.*, 1988). For example, practitioners must perceive preventive services to be part of their role and possess the confidence and skills necessary to interact effectively with patients; time and remuneration should be available for the service provision and there should be support from peers, superiors and professional bodies. However, there is obviously a *sine qua non* need for an effective programme to be available which is suitable for use by usual care providers. To be suitable for incorporation into usual care procedures a programme must exhibit two features, efficacy and effectiveness. Efficacy can be defined as the power of a programme, applied under optimum conditions to alter favourably the history of a risk factor for individuals who comply with the intervention (Windsor *et al.*, 1984). Effectiveness can be defined as the power of a programme under practice conditions. It is a statement about the normal potential of a programme to alter the behaviour of a target group. Effectiveness is determined by a number of factors including the efficacy of the programme, health care provider compliance, patient compliance, and acceptability of the programme to providers and patients. The efficacy of an intervention when applied in the context of a controlled trial may be very different when introduced into routine health services (Smith, 1987).

This review addresses the issue of whether effective programmes exist which can be routinely implemented by usual care providers by exploring four questions:

(i) Are there methodologically adequate studies of smoking cessation interventions in pregnancy?
(ii) Can pregnant smokers be encouraged to stop smoking under ideal conditions?
(iii) Can usual care providers encourage preg-

nant smokers to stop smoking under ideal conditions?

(iv) Are smoking cessation programmes in pregnancy available, appropriate and acceptable for use by usual care providers?

Although previous reviews of smoking cessation interventions in pregnancy exist (Windsor and Orleans, 1986; Lumley, 1987; Schwartz, 1987; Lumley and Astbury, 1988; Wakefield and Wilson, 1988; Walsh *et al.*, 1990; Floyd *et al.*, 1991), their emphasis has largely been on the methodological rigour and efficacy of these interventions. To assess the adequacy of existing programmes for use by health care providers, evaluative studies of smoking cessation interventions in pregnancy were sought. Sources for the articles reviewed by the authors included previous reviews of the subject, Australasian Medical Index and MEDLINE searches and an ongoing survey of major general medical and epidemiologic journals. Database searches were carried out primarily using the key words and phrases 'smoking prevention and control', 'pregnancy' and 'prenatal care'. In total, 28 English language studies were identified. However, six descriptive studies were omitted because they did not include control or comparison groups (Danaher, 1978; Danaher *et al.*, 1978; Hughes *et al.*, 1982; Grumstrup-Hughes *et al.*, 1983; Kaetz *et al.*, 1983; Aaronson *et al.*, 1985). In addition, two randomized, controlled trials were omitted because only preliminary data for a sub-sample of participants were available (Secker-Walker *et al.*, 1986; Windsor *et al.*, 1990). Therefore, 20 studies remained which were judged appropriate for inclusion in this review. Many new studies had not been considered in previous reviews. The studies included are listed in Table 1.

Eleven studies have been conducted in the United States of America, seven in the United Kingdom, one in Sweden and one in Canada. Most (15) studies have recruited patients exclusively in public clinics; fourteen in antenatal/maternity clinics and one (Mayer *et al.*, 1990) in a WIC (Special Supplemental Food Program for Women, Infants and Children). One study (Sexton and Hebel, 1984) recruited from private obstetricians as well as public clinics. Another study (Messimer *et al.*, 1989) recruited exclusively in private physicians' offices. Three studies (Loeb *et al.*, 1983; Ershoff *et al.*, 1983; Ershoff *et al.*, 1989) were undertaken in Health Maintenance Organizations (HMOs).

A range of intervention methods have been employed. Ten studies used behavioural treatments which addressed both the cognitive–motivational and behavioural aspects of smoking. Seven studies relied largely on health information and advice. Feedback methods were the principal teatments employed in two trials; in one case ultrasound technology was used (Reading *et al.*, 1982), in the other carbon monoxide testing (Bauman *et al.*, 1983). A comprehensive programme of nurse home visitation was tested in one study which actively recruited high risk pregnant women. It should also be noted that in three of the 20 studies (Reading *et al.*, 1982; Ershoff *et al.*, 1983; Olds *et al.*, 1986), tobacco was not the exclusive focus of the programme. Alcohol, other drugs and dietary habits were also being targeted.

ARE THERE METHODOLOGICALLY ADEQUATE STUDIES OF SMOKING CESSATION INTERVENTIONS IN PREGNANCY?

Unless studies are methodologically adequate, their conclusions will be of questionable validity. The guidelines recommended by Windsor and Orleans (1986) were used to assess the methodological adequacy of the interventions tested. The guidelines were proposed within five research criteria areas: (i) Research design, (ii) Sample representativeness, sample size and power estimation, (iii) Specification of population characteristics, (iv) Measurement quality and (v) Appropriateness and replicability of treatment and control procedures. Each study has been allocated a methodological rating score for the five criteria and a total score has been computed out of a maximum possible 25. Ratings of the 20 studies are shown in Table 1.

Criterion 1: research design

Eighteen of the 20 studies used a randomized pretest–post control group. In four studies (Baric *et al.*, 1976; Reading *et al.*, 1982; Sexton and Hebel, 1984; Burling *et al.*, 1991), where randomized allocation occurred it was not stated what method of randomization was used. Six experimental studies used a block method to assign subjects (Bauman *et al.*, 1983; Langford *et al.*, 1983; Macarthur *et al.*, 1987; Messimer *et al.*, 1989; Shakespeare, 1990; Hjalmarson *et al.*, 1991). The two quasi-experimental studies used

non-equivalent control groups; Gillies *et al.* (1990) recruited exclusively in a similar clinic and Ershoff *et al.* (1983) also recruited patients in the same clinic at a different time. The equivalence or non-equivalence of study groups in terms of baseline cigarette consumption and demographic variables was assessed in 15 studies.

Criterion 2: sample representativeness, sample size and power estimation

This criterion requires that data be presented which confirm the extent to which the study sample is representative of the pregnant women eligible for the project. Minimal exclusionary criteria for eligibles should be used. Investigators should attempt to achieve recruitment rates of 80–100%. Non-participants and participants should be compared on baseline measures to determine what, if any, selection biases were operating. This requirement is especially important in studies with high refusal rates or substantially different refusal rates between study groups.

Nine studies used exclusionary criteria which cast doubt on the representativeness of the sample; four (Baric *et al.*, 1976; Reading *et al.*, 1982; Shakespeare, 1990; Hjalmarson *et al.*, 1991) restricted eligibility to patients attending before the 20th week of pregnancy, Donovan (1977) excluded women smoking fewer than five cigarettes per day, Sexton ahd Hebel (1984) excluded women smoking fewer than 10 cigarettes per day and/or more than 18 weeks pregnant, Langford *et al.* (1983) only recruited women in the seventh month of pregnancy, Olds *et al.* (1986) actively recruited primiparous women under 19 years of age, who were single mothers and of low socio-econmic status and Burling *et al.* (1991) excluded patients with medical complications or an 'extremely young age'.

In seven studies no consent rates were given (Baric *et al.*, 1976; Donovan, 1977; Langford *et al.*, 1983; Sexton and Hebel, 1984; MacArthur *et al.*, 1987; Ershoff *et al.*, 1989; Burling *et al.*, 1991). Price *et al.* (1991) presented combined data for eligibility and consent rates which showed that only 40% of smokers were recruited. Of the remaining studies, only four failed to achieve recruitment rates of 80% or greater of women meeting their eligibility criteria (Loeb *et al.*, 1983; Windsor *et al.*, 1985; Olds *et al.*, 1986; Gillies *et al.*, 1990).

Four studies made comparisons between the participants and non-participants on baseline measures (Windsor *et al.*, 1985; Olds *et al.*, 1986; Mayer *et al.*, 1990; Hjalmarson *et al.*, 1991). A further seven studies which failed to discuss the characteristics of non-participants either had consent rates of 99–100% (Ershoff *et al.*, 1983; Bauman *et al.*, 1983; Lilley and Forster, 1986; Messimer *et al.*, 1989), or inferred that all smokers were recruited (Langford *et al.*, 1983; MacArthur *et al.*, 1987; Ershoff *et al.*, 1989). However, three studies with low recruitment rates (43, 75 and 40%) also failed to document the characteristics of non-participants (Loeb *et al.*, 1983; Gillies *et al.*, 1990; Price *et al.*, 1991).

The related issues of sample size and statistical power estimation are also of paramount importance to cessation research. Windsor and Orleans (1986) estimated that the minimum sample size per study group for an evaluation of the effectiveness of a behavioural smoking cessation programme tailored to pregnancy was 100 and for an evaluation designed to assess the impact of weak 'risk information' interventions on quit rates was 500–1000.

Using the above guidelines, 11 studies evaluating impacts on smoking behaviour had inadequate sample sizes (Baric *et al.*, 1976; Donovan, 1977; Reading *et al.*, 1982; Ershoff *et al.*, 1983; Bauman *et al.*, 1983; Langford *et al.*, 1983; Lilley and Forster, 1986; Messimer *et al.*, 1989; Mayer *et al.*, 1990; Burling *et al.*, 1991; Price *et al.*, 1991). In one study (Olds *et al.*, 1986) with an adequate sample size, quit rates were not reported.

Most studies achieved high follow-up rates. One study (Donovan, 1977) did not document an attrition rate and a further six studies (Loeb *et al.*, 1983; Bauman *et al.*, 1983; Langford *et al.*, 1983; Ershoff *et al.*, 1989; Burling *et al.*, 1991; Price *et al.*, 1991) had attrition rates exceeding 20%. Two studies (Gillies *et al.*, 1990; Price *et al.*, 1991) had significantly different response rates in the experimental and control groups.

Criterion 3: specification of population characteristics

Windsor and Orleans (1986) have advocated that investigators characterize the important pre-intervention demographic, behavioural and health features of study subjects since such features have been found to influence the likelihood of cessation. A minimum of ten characteristics were recommended including demographic, behavioural and health variables. No study presented data on all the recommended characteristics. The average number of characteristics

Table 1: Methodological ratings and main methodological problems of smoking cessation intervention trials for pregnant women*

Investigators (year of publication) Country	Intervention strategy	No. 1 Design	No. 2 Sample	No. 3 Characteristics	No. 4 Measurement	No. 5 Interventions	Rating Score	Main methodological problems
1. Baric *et al.* (1976) Britain	Advice	4	3	2	1	0	10	Small sample size Treatment varied No biochemical validation
2. Donovan (1977) Britain	Advice	4	3	1	0	1	9	No attrition data No cessation data No biochemical data
3. Reading *et al.* (1982) Britain	Feedback	4	2	1	1	1	9	Small sample size No end-of pregnancy cessation data No biochemical validation
4. Loeb *et al.* (1983) U.S.A.	Cognitive-behavioural	4	3	2	0	1	10	Treatment varied Poor patient compliance 43% attrition
5. Ershoff *et al.* (1983) (USA)	Cognitive-behavioural	2	2	3	1	4	12	Small sample size Incomplete subject matching Included pre-intervention quitters No biochemical validation of controls
6. Langford *et al.* (1983) Canada	Advice	4	1	1	0	3	9	Small sample size Included pre-intervention quitters Recruited late pregnancy No biochemical validation
7. Bauman *et al.* (1983) U.S.A.	Feedback	5	2	4	1	3	15	Small sample size Short-term follow-up
8. Sexton and Hebel (1984) U.S.A.	Cognitive-behavioural	5	3	3	3	3	17	Included pre-intervention quitters Treatment varied
9. Windsor *et al.*, (1985) U.S.A.	Cognitive-behavioural	5	4	4	3	5	21	No post-partum cessation data

10.	Lilley and Forster (1986) Britain	Advice	5	4	2	0	1	12	Small sample size Short-term follow-up No biochemical validation
11.	Olds *et al.* (1986) U.S.A.	Nurse home visitation	5	2	4	2	1	14	Smoking treatment not described No cessation data Biochemical validation of unrepresentative sub-sample
12.	MacArthur *et al.* (1987) Britain	Advice	5	5	2	0	0	12	Poor provider compliance Biochemical validation abandoned
13.	Messimer *et al.* (1989) U.S.A.	Cognitive-behavioural	5	4	1	0	4	14	Small sample size No biochemical validation
14.	Ershoff *et al.* (1989) U.S.A.	Cognitive-behavioural	5	4	2	1	5	17	No end-of-pregnancy self-report cessation data
15.	Mayer *et al.* (1990) U.S.A.	Cognitive-behavioural	5	4	1	0	4	14	Small sample size Biochemical validation of unrepresentative sub-sample
16.	Shakespeare (1990) Britain	Advice	4	4	1	2	0	11	Poor provider compliance No cessation data
17.	Gillies *et al.* (1990) Britain	Cognitive-behavioural	4	3	1	0	0	8	Included pre-intervention quitters Group recruitment rates different Group attrition rates different Biochemical validation of unrepresentative sub-sample
18.	Burling *et al.* (1991) U.S.A.	Advice	5	2	1	2	2	12	Small sample size Limited subject baseline data 31% attrition
19.	Price *et al.* (1991) U.S.A.	Cognitive-behavioural	4	1	1	2	3	11	Small sample size Flawed randomisation 40% recruitment rate Group attrition rates different
20.	Hjalmarson *et al.*, (1991) Sweden	Cognitive-behavioural	5	3	1	3	4	16	Restrictive eligibility (<12 weeks gestation) Limited subject baseline data

* Includes only trials with control or comparison groups.

documented was about half (5.4 per study). Eight studies reported on at least three demographic variables plus daily smoking rate and gestational age at randomization (Donovan, 1977; Bauman *et al.*, 1983; Sexton and Hebel, 1984; Windsor *et al.*, 1985; Olds *et al.*, 1986; MacArthur *et al.*, 1987; Ershoff *et al.*, 1989; Mayer *et al.*, 1990). Only four studies provided a baseline biochemical index of smoke exposure for all subjects (Sexton and Hebel, 1984; Windsor *et al.*, 1985; Burling *et al.*, 1991; Price *et al.*, 1991).

Criterion 4: measurement quality

This criterion is concerned with the need for reliable and valid measurements of outcomes. Self-report of changes in cigarette consumption is too unreliable to be used as a primary outcome measure in smoking intervention trials (Richmond and Heather, 1990). Data suggest there may be a significant deception rate amongst pregnant women who report non-smoking (Hughes *et al.*, 1983; Ershoff *et al.*, 1989; Windsor *et al.*, 1989). Further, reduced smoking may not improve pregnancy outcomes (Ho-Yen *et al.*, 1982; US Surgeon General, 1990). The major outcome measure for intervention studies with pregnant smokers is end of pregnancy smoking status with self-report being biochemically validated for all smokers who claim to have quit. A minimum of four biochemical tests collected at the same time as self-reports of smoking status over the previous seven days are proposed. Windsor and Orleans (1986) also recommend that all smokers lost to follow-up at each observation should be assumed to be still smoking (failures) rather than excluded from the analysis of cessation rates.

Although Windsor and Orleans (1986) report that thiocyanate (SCN) levels in blood, saliva and urine are acceptable validation measures, more recent evidence suggests that SCN provided the poorest discrimination of available tests (Jarvis *et al.*, 1987; Stookey *et al.*, 1987). Carbon monoxide measured as blood carboxyhaemoglobin or in expired air had sensitivity and specificity of about 90%. Cotinine, whether measured in plasma, saliva or urine, is the best indicator of smoking, and the cost of measurement has declined in recent years, making it the measure of choice in smoking cessation research (Jarvis *et al.*, 1987; US Surgeon General, 1990).

No studies collected either self-report data or biochemical measures at the four points recommended by Windsor and Orleans (1986). Seven studies (Baric *et al.*, 1976; Donovan, 1977; Reading *et al.*, 1982; Langford *et al.*, 1983; Lilley and Forster, 1986; Macarthur *et al.*, 1987; Messimer *et al.*, 1989) reported no biochemical testing, including Macarthur *et al.* (1987) where tests were abandoned. Of the 13 studies reporting biochemical measures, six had serious methodological limitations; Loeb *et al.*, (1983) only tested a 6% random sample, Ershoff *et al.* (1983) only tested patients in the experimental group, Olds *et al.* (1986) tested a non-representative 33% subsample of the whole sample (smokers and non-smokers), Gillies *et al.* (1990) only reported tests on volunteers in the experimental group, Shakespeare (1990) only corroborated the self-report of those attending a 34-week visit and Mayer *et al.* (1991) sampled the last third of participants. Five studies (Ershoff *et al.*, 1983; Sexton and Hebel, 1984; Olds *et al.*, 1986; Mayer *et al.*, 1990; Shakespeare, 1990) did not state what cut-off values were used to classify subjects and did not document the percentage of biochemical tests which were inconsistent with self-reports of smoking status. Three studies reported cut-off points but failed to document the deception rate (Bauman *et al.*, 1983; Burling *et al.*, 1991; Hjalmarson *et al.*, 1991).

Only five studies (Loeb *et al.*, 1983; Windsor *et al.*, 1985; Ershoff *et al.*, 1989; Mayer *et al.*, 1990; Hjalmarson *et al.*, 1991) counted smokers lost to follow-up as programme failures. Three studies used cigarette intake as the principal outcome and failed to report post-intervention cessation rates (Donovan, 1977; Olds *et al.*, 1986; Shakespeare, 1990). Two studies (Langford *et al.*, 1983; Sexton and Hebel, 1984) included pre-intervention quitters in their calculations of group quit rates. Inappropriately short time intervals (6 weeks or less) between initial recruitment and treatment and final follow-up were a feature of three studies (Reading *et al.*, 1982; Bauman *et al.*, 1983; Lilley and Forster, 1986). Results in such studies may be biased by short-term treatment effects. Cessation rates based on biochemically validated self-reports of non smoking at 34 weeks or later were only documented in five studies (Windsor *et al.*, 1985; Ershoff *et al.*, 1989; Burling *et al.*, 1991; Price *et al.*, 1991; Hjalmarson *et al.*, 1991). Three of these studies (Windsor *et al.*, 1985; Ershoff *et al.*, 1989; Hjalmarson *et al.*, 1991) included a sustained abstinence criterion of cessation.

Criterion 5: appropriateness and replicability of intervention and control procedures

In the interests of replication, intervention and control procedures should be adequately described, standardized and monitored in terms of patient and provider compliance. Where the control group receives usual care this must be defined in terms of content and duration.

Seven studies included treatments that were standardized and described in sufficient detail to permit adequate replication (Ershoff *et al.*, 1983; Bauman *et al.*, 1983; Windsor *et al.*, 1985; Ershoff *et al.*, 1989; Messimer *et al.*, 1989; Mayer *et al.*, 1990; Hjalmarson, 1991). Several studies changed their treatments during the study or allowed it to vary substantially; for example, Sexton and Hebel (1984) noted that 'the intervention strategies were reviewed throughout the study and new ideas and approaches were incorporated' and in relation to the same study Nowicki *et al.* (1984) reported 'mailings were usually at the interventionist's discretion until the last year when a structured mailing system was developed'. In three studies, group sessions were abandoned during the study (Loeb *et al.*, 1983; Windsor *et al.*, 1985; Gillies *et al.*, 1990). In three other studies where part of the interventions were delivered to patients in groups, the sizes of the groups were not specified (Bauman *et al.*, 1983; Langford *et al.*, 1983; Sexton and Hebel, 1984). Only seven studies (Langford *et al.*, 1983; Sexton and Hebel, 1984; Windsor *et al.*, 1985; Lilley and Forster, 1986; Mayer *et al.*, 1990; Shakespeare, 1990; Price *et al.*, 1991) documented even the duration of the first treatment contact with subjects. In one other study, sufficient information was provided for an estimate to be made (Bauman *et al.*, 1983). Many studies contained vague descriptions of treatment components for example, Baric *et al.* (1976) noted the therapist discussed 'various ways' that could help women to stop smoking, Donovan (1977) stated that intensive individual advice was given at each visit, however, the outline provided by Donovan *et al.* (1975) of the technique is couched in broad terms such as 'once the patient has agreed to try, discuss how she may best give up'. Reading *et al.*, (1982) stated patients were given 'specific visual, verbal feedback as to fetal size, shape and movement' but no additional details were provided and in relation to Olds *et al.* (1986) very limited information was provided about the cessation counselling offered in programme descriptions (Olds, 1980; Olds, 1982).

The majority of studies have continued usual care procedures with the control subjects, but as Windsor and Orleans (1986) have noted, these are usually left to vary freely rather than made to conform to some minimal standard of medical practice. Only two studies estimated how long was devoted to smoking cessation counselling in control subjects (Windsor *et al.*, 1985; Ershoff *et al.*, 1989). Two studies reported patient recall of the interventions as a sole measure of compliance (MacArthur *et al.*, 1987; Shakespeare, 1990). Patient recall of smoking cessation counselling has been shown to underestimate the actual level of advice given (Folsom and Grimm, 1987). Messimer *et al.* (1989) used chart audits by a practice representative plus a terminal audit by every physician. The reliability of medical records and physician data as indicators of preventive medicine provision is questionable (Lewis, 1988). Direct observation methods would increase the reliability of compliance measures (Redman *et al.*, 1989).

In summary, most studies employed randomized designs. However, as noted in Table 1, methodological problems were common in the other four criteria areas. Recruitment rates were unacceptably low in a number of studies; most studies did not properly specify the characteristics of their subjects, incorporate high quality measurements of process and outcomes or adequately describe and standardise their treatment and control procedures. Overall, the methodologies of many studies of smoking cessation interventions in pregnancy remain fairly poor. The following discussion is based mainly on the findings of those studies which were judged to have exceeded the minimal acceptable score on the methodological rating. A cut-point score of 13 or more was chosen since it was considered that a study which scored less than half the maximum points was methodologically inadequate. Using this cut-point eight of the 20 studies were classified as methodologically adequate.

CAN PREGNANT SMOKERS BE ENCOURAGED TO STOP SMOKING UNDER IDEAL CONDITIONS?

Unless smoking cessation can be demonstrated to occur under ideal conditions, it is unlikely that successful programmes will be incorporated within the demands of routine antenatal care. Trials were categorized, as already described,

according to the main strategy employed in the intervention.

Feedback trials

Only one trial (Bauman *et al.*, 1983) using feedback techniques exceeded the methodological rating cut-off score. The quit rate in the experimental group (7 per cent) was not significantly different to that in the contol group (13 per cent). Wakefield and Jones (1991) have recently suggested that feedback during routine ultrasound may encourage smoking cessation. Two studies were cited to support this suggestion. One trial (Reading *et al.*, 1982) failed to reach the methodological cut-point established in this review and the second trial (Waldenstrom *et al.*, 1988) reported no data on cessation rates. In summary there is insufficient evidence to conclude whether feedback methods can significantly reduce smoking in pregnant women.

Nurse home visitation trial

Although a few trials included home visits in their protocol in only one trial was this the main strategy tested. The trial (Olds *et al.*, 1986) which sought to evaluate a comprehensive programme of nurse home visitation exceeded the minimum methodological cut-off score. Unfortunately quit rate data were not reported, only data demonstrating a significant difference in the early to late pregnancy change in the daily cigarette intake of smokers in the experimental group compared with smokers in the control group. There is insufficient evidence to conclude whether nurse home visitation can significantly reduce smoking rates among pregnant women.

Advice trials

There were seven trials which tested the effects of giving verbal and/or written information about the risks of smoking in pregnancy together with general advice about methods of smoking cessation. None of the advice trials reached the methodological cut-point score. In all five trials (Baric *et al.*, 1987; Langford *et al.*, 1983; Lilley and Forster, 1986; MacArthur *et al.*, 1987; Burling *et al.*, 1991) which reported quit rates, a higher percentage of women stopped smoking in the experimental group compared with the control group. However, in only two studies (MacArthur *et al.*, 1987; Burling *et al.*, 1991) were quit rates presented for the end of pregnancy. In summary there is insufficient evidence to conclude whether the provision of verbal and written anti-smoking advice significantly increases rates of smoking cessation by pregnant women compared with no intervention or standard care procedures.

Cognitive behavioural trials

Ten trials evaluated the effects of cognitive behavioural programmes and eight of these programmes included self-help materials specially tailored to pregnancy. Six behavioural trials met the minimum methodological cut-off score. End-of-pregnancy quit rates were compared in the experimental and control groups of the six behavioural trials of acceptable methodololgical rigour. Table 2 represents the quit rate data. In trials where there were two experimental groups (Windsor *et al.*, 1985; Mayer *et al.*, 1990) the quit rate in the group which received the intervention tailored specifically for pregnant women was used in the calculation. In the case of the Sexton and Hebel (1984) trial the quit rate estimates recomputed by Windsor and Orleans (1986) were used to take into account that some women stopped smoking prior to the intervention. Since four studies had only reported point prevalence quit rates, it was decided to use the data from Ershoff *et al.*, (1989) which most closely approximated the point prevalence quit rate rather than the sustained abstinence rates which were also available in their report. There was a 12% difference in the mean end-of-pregnancy quit rate of the experimental groups (20%) compared with the control groups (8%) in the six trials. Only one study (Messimer *et al.*, 1989) did not find a statistically significant difference between experimental and control groups. The evidence supports the view that cognitive behavioural programmes tailored to pregnancy can produce clinically significant improvements in the smoking cessation rates of pregnant women compared with usual care procedures in both public and private settings under ideal conditions.

CAN USUAL CARE PROVIDERS ENCOURAGE PREGNANT SMOKERS TO STOP SMOKING UNDER IDEAL CONDITIONS?

Even though programmes with demonstrated efficacy exist, if they have not been delivered by usual care providers, they may not be appropriate for their use. Further, the efficacy of an intervention may differ when provided by trained counsel-

lors and usual care providers. Most (16) of the trials reviewed did not involve usual medical or nursing care providers in delivering the active treatments. In the six cognitive–behavioural interventions rated methodologically adequate, the programmes were delivered by research staff (Sexton and Hebel, 1984; Windsor *et al.*, 1985), a single health educator (Ershoff *et al.*, 1989; Mayer *et al.*, 1990), and usual care physicians (Messimer *et al.*, 1989; Hjalmarson *et al.*, 1991). Health educators are not usually available in British, Australian or Canadian antenatal settings. In the US most private physician offices do not employ a health educator. The two groups of health care providers with the greatest involvement in antenatal care provision are physicians and midwives. In the study (Messimer *et al.*, 1989), where the intervention was delivered by physicians in eleven U.S. private primary care practices, no significant difference was found between the end-of-pregnancy cessation rates of experimental and control groups. However, it should be noted that women in the control group received a relatively intensive intervention. The only methodologically adequate study involving physicians in a public setting as intervention providers was undertaken in 13 Swedish maternity clinics (Hjalmarson *et al.*, 1991). Although there was no significant difference between intervention groups in end-of-pregnancy point prevalence quit rates, there was a significant improvement in the sustained abstinence rate. The generalizability of these results to clinics in other countries is uncertain. For example, the inclusion criteria employed of fewer than 12 weeks gestation would render ineligible many pregnant women attending public clinics in English-speaking countries (Windsor and Orleans, 1986). In summary, the evidence that physicians and midwives can significantly improve smoking cessation rates of pregnant women is limited and of questionable generalisability.

ARE SMOKING CESSATION PROGRAMMES IN PREGNANCY AVAILABLE, APPROPRIATE AND ACCEPTABLE FOR USE BY USUAL CARE PROVIDERS?

Even if programmes delivered by usual care providers had been clearly shown to be efficacious in encouraging pregnant women to quit smoking, a smoking cessation programme should meet five other criteria to be suitable for routine application by usual care providers: (i) Programme materials must be readily available, (ii) Time commitment must be feasible for the provider, (iii) Training required to use the programme must be clearly described and of acceptable duration, (iv) Programme components must be acceptable to providers, (v) Programme components must be acceptable to patients. In order to examine their potential for incorporation into usual antenatal care procedures, the six methodologically adequate behavioural trials were assessed according to these five criteria areas. Results of this assessment are summarized in Table 2.

Criterion 1: programme availability

If health care providers are to implement a smoking cessation programme, it needs to be packaged and readily available. Only two reports (Windsor *et al.*, 1985; Messimer *et al.*, 1989) indicated that all the structured materials used in their intervention were available for use by other researchers and clinicians. Two other studies (Mayer *et al.*, 1990; Hjalmarson *et al.*, 1991), used self-help manuals which were adapted in unspecified ways from Windsor *et al.* (1985).

Criterion 2: provider time commitment

Unless the time commitment required to deliver a smoking cessation programme is small, health care providers are unlikely to use it on a routine basis. Two studies (Messimer *et al.*, 1989; Hjalmarson *et al.*, 1991) did not provide any data on the provider time commitment. In the case of the Sexton and Hebel trial (1984), the first interview alone took more than 45 minutes making it unsuitable for use under usual care conditions. The provider time commitment of the three behavioural interventions (Windsor *et al.*, 1985; Ershoff *et al.*, 1989; Mayer *et al.*, 1990) with estimates of their duration were 10, 7 and 20 minutes respectively, suggesting that they would be feasible in most antenatal settings.

Criterion 3: training

Training required to deliver a smoking cessation programme should be relatively short, simple and capable of integration into normal antenatal staff training procedures. However, no study provided information about the duration or content of training required by health care providers to deliver the intervention.

Table 2: Description of methodologically adequate cognitive behavioural smoking cessation interventions with criteria for incorporation into usual antenatal care and end-of-pregnancy cessation rates

Investigators (year) site	Intervention description	No. 1 Programme materials availability	No. 2 Provider time commitment
Sexton & Hebel (1984) Private obstetric practices and university hospital obstetric clinic	C = No contact E = Minimum one home counselling session (often more) + Phone contacts + Mailings + Lottery + Quit packet	No	C = NA E = Variable but first interview >45 minutes
Windsor *et al.* (1985) Public health maternity clinics	C = Routine advice E_1 = Counselling to teach use of 'Freedom from Smoking' manual + Risk booklet + routine advice E_2 = as above except 'A Pregnant Woman's Self-Help Guide to Quit Smoking' was substituted	Yes	C = 2–3 minutes E_1 = 10 minutes E_2 = 10 minutes
Messimer *et al.* (1989) Private obstetric and family physician practices	C = Counselling on three occasions E = Counselling every visit + flipchart + slide tape + American Lung Assoc. (ALA) packet + poster	Yes	C = not stated E = not stated
Ershoff *et al.* (1989) Health maintenance organization	C = Standard care + pamphlet + offer of smoking cessation course E = Standard care + self-help program consisting of overview and 8 booklets (7 mailed weekly)	No	C = 4 minutes E = 7 minutes
Mayer *et al.* (1990) WIC (Special Supplemental Food Program for Women, Infants and Children) Clinic	C = Usual care + printed information E_1 = Risk information + ALA flipchart and brochure E_2 = Counselling + ALA flipchart and brochure + self-help manual	Some—not self-help manual	C = not stated E_1 = 10 minutes E_2 = 20 minutes
Hjalmarson *et al.* (1991) Public Health maternity clinics	C = Midwife & doctor recommendation to stop + information sheet	No	C = not stated
	E = Midwife & doctor recommendation to stop + self-help manual	No	E = not stated

Usual care criteria			End-of-pregnancy cessation rates
No. 3 Training duration and content to deliver intervention	No. 4 Provider acceptability	No. 5 Patient acceptability	
Not stated	No data	No data—general comments	C = 3% E = 27% validated biochem
Not stated	No data	No data	C = 2% E_1 = 6% E_2 = 14% validated biochem
Not stated	No data Physicians delegated some intervention tasks	Few women who altered their smoking habit cited the program as the reason—C = 11%, E = 16%	C = 14% E = 28% self-report
Not stated	No data	Data demonstrated that most of experimental group read the booklets and found them acceptable	C = 17% E = 26% validated biochem
Not stated	No data	No data	C = 3% E_1 = 7% E_2 = 11% self-report
Not stated	No data	No data	C = 8.6% E = 12.6% validated biochem

Criterion 4: provider acceptability

Unless a smoking cessation programme can be demonstrated to be acceptable to health care providers, problems with compliance may occur. Compliance by usual care providers has been reported to be a major problem in antenatal smoking cessation interventions (MacArthur *et al.*, 1987; Shakespeare, 1990;). Hjalmarson *et al.* (1991) did not state how acceptable their intervention was to the obstetricians involved. Messimer *et al.* (1989) reported that study physicians complied with their protocols with 'only minor deviations'. However, it was also noted that 'Some physicians delegated some of the intervention tasks to nurses or physician assistants in their practices'.

Criterion 5: patient acceptability

For a smoking cessation intervention to be effective under practice conditions, it must be acceptable to pregnant smokers. Only one study provided objective data on the acceptability of the programme to patients other than the initial consent rate. Ershoff *et al.* (1989) demonstrated that most of the experimental group read the self-help booklets and found them acceptable. Messimer *et al.* (1989) provided indirect evidence of the intervention's acceptability to some of the women by reporting that only a small proportion of those who reduced their smoking or quit cited the programme as their reason. In relation to the Sexton and Hebel (1984) trial, Nowicki *et al.*, (1984) presented subjective information which is difficult to interpret: 'In general the women were receptive to follow up contact' and '. . . the women still reacted very positively to being given something concrete that would help in their efforts to quit'.

In summary, none of the methodologically adequate behavioural interventions have been shown to meet more than two of the five criteria necessary for their incorporation into usual care procedures.

CONCLUSIONS

Despite the major health costs attributable to smoking during pregnancy, still little is known about how health care providers might best go about helping pregnant women to stop smoking. There is an urgent need for further research and better smoking cessation programmes. Several issues were identified by the review. First, it was found that 12 (60%) of the studies failed to score at least half points on the methodological ratings. Although Windsor and Orleans (1986) noted a clear trend for improved methodological rigour over time, a number of studies published since their review achieved low ratings. The quality of much research in the area of smoking cessation interventions for pregnant women needs improvement. The methodological standards recommended by Windsor and Orleans (1986) should provide a guide to future researchers to ensure the validity of their studies.

Second, there was insufficient evidence to determine whether feedback, nurse home visitation or advice programmes significantly increase smoking cessation rates among pregnant women compared with no intervention or standard care. Cognitive–behavioural programmes appear to be efficacious. Five of the six methodologically adequate behavioural trials demonstrated a statistically significant improvement in smoking cessation rates in the women receiving the intervention tailored to pregnancy compared with women in the control group. In one of the five trials (Hjalmarson *et al.*, 1991), the difference in cessation rates was significant eight weeks after delivery and using a continuous abstinence criterion but not at 30–34 weeks gestation.

Third, few (four) studies involved interventions delivered by medical or nursing staff responsible for the usual antenatal care of the patients and only two of these were methodologically adequate behavioural trials. This finding highlights the importance of future research which focuses on cognitive–behavioural smoking cessation programmes delivered by usual care providers.

It is hardly surprising that evidence indicates health care providers do not routinely provide smoking cessation interventions to their pregnant patients. None of the methodologically adequate behavioural trials in this review demonstrated that they fulfilled more than two out of the five criteria for a smoking cessation intervention to be incorporated into routine antenatal care provision. Future research should concentrate on the development of efficacious interventions which document their appropriateness and acceptability to health care providers and pregnant smokers. Smoking cessation interventions in pregnancy should be one strategy in a comprehensive tobacco control programme.

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