

INTRODUCTION

Helping pregnant smokers quit: meeting the challenge in the next decade

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Throughout the past decade, smoking has remained the single most important modifiable cause of poor pregnancy outcome in the USA. It accounts for 20% of low birth weight deliveries, 8% of preterm births, and 5% of all perinatal deaths.¹ New studies have found that maternal smoking during pregnancy contributes to sudden infant death syndrome and may cause important changes in fetal brain and nervous system development.²⁻⁷ New economic estimates indicate that the direct medical costs of a complicated birth for a smoker are 66% higher than for non-smokers—reflecting the greater severity of complications and the more intensive care required.⁸ While quitting smoking early in pregnancy is most beneficial, important health benefits accrue from quitting at any time during the pregnancy.¹

Moreover, the health hazards and health care burden to women and their family members caused by smoking do not begin or end with pregnancy. Before pregnancy, smoking increases the risk of serious medical complications for women using oral contraceptives and can impair fertility.¹ After pregnancy, in addition to adversely affecting women's health, smoking exposes infants and young children to environmental tobacco smoke. This exposure is linked to SIDS, respiratory illnesses, middle ear infections, and decreased lung function.³⁻⁹ Currently, 27% of US children aged 6 years and under are exposed to tobacco smoke at home,¹⁰ with the annual direct medical costs of parental smoking estimated at \$4.6 billion and loss of life costs estimated at \$8.2 billion.¹¹

Recent national survey data indicate that the goal of reducing smoking among pregnant women from 25% in 1985 to 10% by the 2000 was not met.¹² While some reduction was achieved, about 20% of US women currently smoke during pregnancy, based on the 1994, 1995, and 1996 SAMSHA national surveys (table 1).¹³ Rates are highest among unmarried women and for women with less than a high school education, with the smoking rate for low income, Medicaid enrollees estimated at approximately 35%. This translates to one in five US births/pregnancies, or 800 000 births per year.¹⁴ However, these survey data are likely to underestimate the true prevalence of smoking during pregnancy.¹⁵⁻¹⁷ Growing public awareness of the adverse effects of smoking on pregnancy has led an increasing number of

pregnant smokers to conceal or under report their smoking behaviour.¹⁷⁻¹⁸

The goal adopted for the year 2010 is to reduce cigarette smoking among pregnant women to a prevalence of no more than 2%.¹² This is an especially ambitious goal given that rates of smoking among teenage girls have risen substantially over the past decade.¹⁵ The 1999 Monitoring the Future Survey found over a third of 12th grade girls (17-18 years of age) report smoking in the past 30 days.¹⁹ Without vigorous, widespread, and innovative efforts over the next decade, we are unlikely to achieve this new goal. Hence, as we enter a new decade and a new century, reducing national smoking rates in pregnancy remains a national public health priority.

Pregnancy as a special window of opportunity

Pregnancy and the period preceding and following it provide a unique teachable moment to help women stop smoking. Women are highly motivated to stop smoking during this time, when they are concerned not only about their own health, but about the health of their infants. They also are likely to experience higher levels of social and family support for quitting. Accordingly, approximately 25% of women smokers quit smoking either as they prepare to become pregnant or as soon as they learn that they are.²⁰⁻²¹ Likewise, pregnant

Table 1 Percentage reporting past month cigarette use in the US population of females aged 15-44 years by pregnancy status and demographic characteristics: annual averages based on 1994, 1995, and 1996 samples combined

Demographic characteristics	Past month cigarette use	
	Pregnant	Not pregnant
Total	20.6	31.9
Age		
15-24 years	27.2	31.1
26-44 years	15.9	32.3
Race/ethnicity		
White non-Hispanic	23.3	35.1
Black non-Hispanic	20.9	29.0
Hispanic	11.6	21.5
Marital status		
Married	15.7	27.2
Not married	32.5	36.8
Adult education		
Less than high school	44.0	49.1
High school graduate	21.8	37.8
Some college	13.3	30.6
College graduate	7.4	17.2

Source: Excerpted from Office of Applied Studies—National Household Survey on Drug Abuse, main findings, 1996. SAMHSA-DHSS, April 1998; pages 17, 165

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women have greater contact with the health care system. Many women who do not otherwise seek or receive primary care or preventive services can be reached during family planning and prenatal care visits, with follow up later in hospitals, paediatric offices, health clinics, day care programs and during home nursing visits.²²

Similarly, providers and health care systems have especially compelling reasons to intervene, given the dramatic and immediate health benefits of quitting for the pregnant woman and her baby, and the significant cost savings associated with averting pregnancy complications and low birth weight deliveries.⁸ Health care professionals can take advantage of women's unique quitting motivation by reinforcing knowledge that quitting smoking will reduce health risks to the fetus, and reviewing the important postpartum benefits for both the mother and child.^{3 4 9}

Moreover, as outlined in the paper by Melvin and colleagues,²³ the past 15 years of intervention research has established that brief (5–15 minutes) medical quitting advice and counselling combined with pregnancy tailored self help material provided in the course of routine prenatal care produces quit rates that are significantly higher than those achieved with usual care (that is, 14–16% *v* 5–6%, including among the most underserved, low income women.^{17 20 21 24} Given the substantial savings associated with averting low birth weight deliveries, these “best practice” interventions have also proven highly cost effective. It is estimated that for every \$1 invested in these interventions, about \$6 are saved, with the result that the current “best practice” for brief cessation counselling in pregnancy is likely, for smokers, to be more cost-effective than all the rest of prenatal care.^{21 25–28}

A two part challenge

To achieve the ambitious national goal set for the year 2010, two challenges must be addressed. First, vigorous efforts are needed to make the current “best practice” intervention the standard for prenatal care with all pregnant smokers. Second, new research must be done to develop more powerful interventions, as well as to address the problems of high rates of smoking non-disclosure among pregnant smokers, and high rates of postpartum relapse among pregnant smokers who do succeed in quitting.

Unfortunately, most prenatal care providers fail to implement even the most basic “best practice” interventions. National survey data compiled for Healthy People 2000 indicate that only 49% of obstetricians and gynaecologists routinely advise cessation and provide assistance and follow up for all their tobacco using patients (pregnant and non-pregnant), and only 28% go on to discuss cessation strategies.¹⁰ These statistics fall way short of the year 2000 and year 2010 best practice intervention goal of 75% of all providers.^{10 12} Only 45% of managed care plans surveyed in 1997–98 reported offering a smok-

ing cessation strategy targeting pregnant women specifically.²⁹ Of these 147 plans which did offer a pregnancy specific strategy, only 40% followed the Agency for Health Care Policy and Research (AHCPR) clinical guidelines for smoking cessation in designing their program.³⁰ Furthermore, in 1999, only 24 states (two more than in 1998) reported coverage for any nicotine addiction treatment services under Medicaid (which provides health insurance coverage for 60–70% of all pregnant smokers) and only 10 states covered the non-medication counselling interventions appropriate for most pregnant smokers.^{31 32} These data underscore the critical need to understand and address provider, systems, and policy barriers to routine intervention in prenatal care.

Second, the quit rates of even the most effective “best practice” interventions for pregnant smokers seldom reach or exceed 20%, with lower rates among the most addicted smokers.^{20 21 24} Over two thirds of women who do quit smoking during pregnancy return to cigarettes within six months following delivery.³³ Some of the factors contributing to these statistics—such as the multiple stresses and lifestyle changes (for example, diet, exercise, alcohol intake) associated with pregnancy and breast feeding, and normal postpartum depression—can make it harder to quit during pregnancy and to stay quit afterwards. In addition, pharmacotherapies which have proven effective in increasing the quit rates associated with behavioural and counselling interventions, namely nicotine replacement therapies and bupropion,^{34–36} are not recommended for general use with pregnant smokers given the uncertain balance of risks and benefits to the fetus and the pregnancy.^{34 36 37} This raises the need for creative research to develop more powerful behavioural and counselling treatments to motivate and assist pregnant smokers to quit, and help sustain their abstinence after delivery.

To address this two part challenge, staff at the Robert Wood Johnson Foundation (RWJF) and in the Smoke-Free Families National Program Office have launched a number of initiatives to: (1) promote the wider integration of current “best practice” interventions into routine prenatal care; and (2) support innovative studies with promise to improve the efficacy of smoking related in tobacco interventions.³⁸ These initiatives are outlined below and in the many articles that make up this supplement.

Disseminating current “best practice” interventions

Our efforts to promote the wider integration of the current “best practice” intervention into routine prenatal care have included activities to strengthen and publicise the science base for these treatment strategies, build demand for them, and expand the capacity of providers and health care systems to deliver them. They are described below with reference to a generic “market oriented” product development model which has been proposed to describe the types of effort required to integrate better any

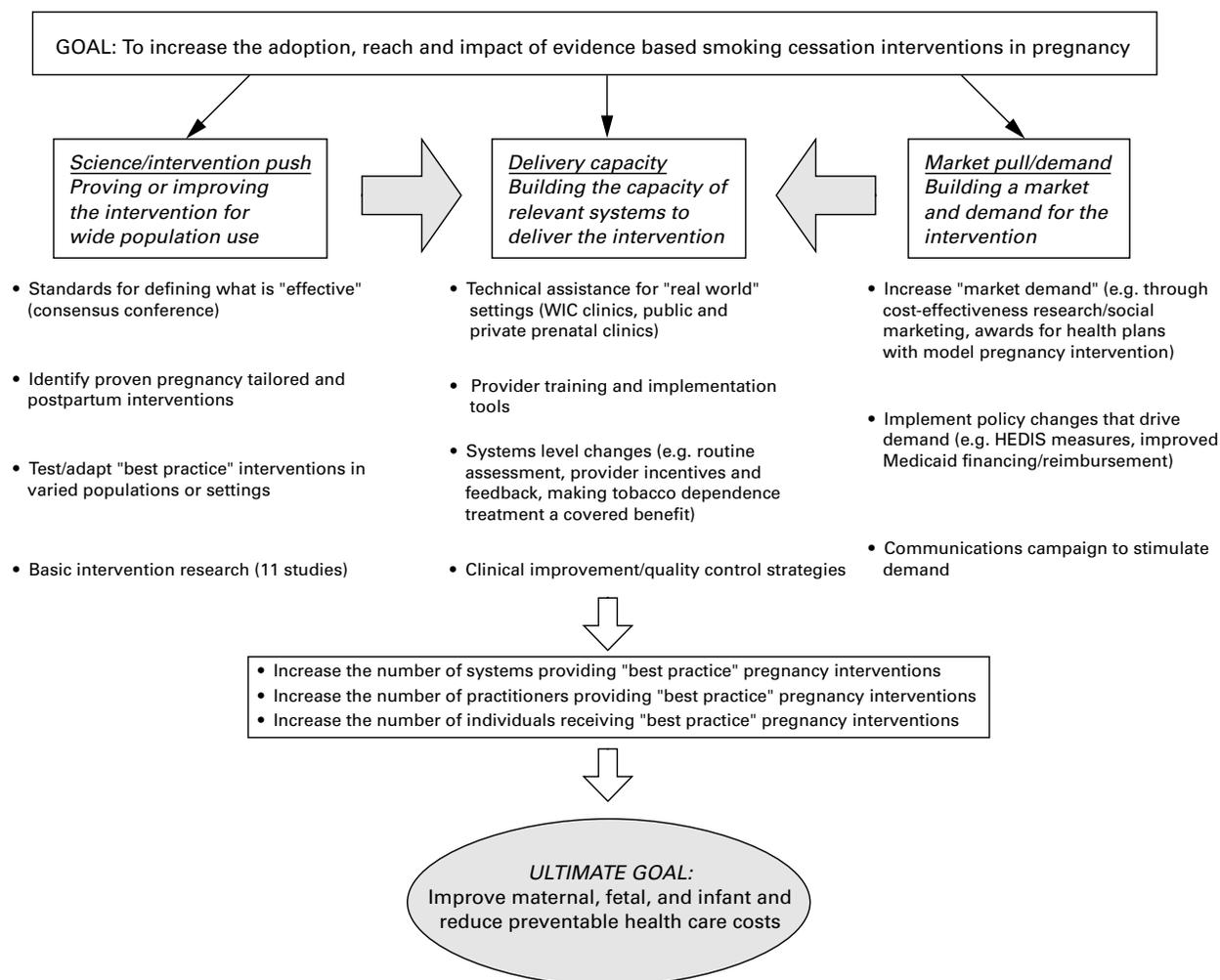


Figure 1 Model describing the types of effort required to improve integration of evidence based smoking cessation intervention into routine medical care for pregnant smokers.

evidence based behavioural intervention into routine medical care^{39 40} (fig 1). According to this model, three related types of activity are required: (1) strengthening science, or intervention, "push" by proving or improving an intervention for wide population use; (2) boosting market demand or "pull" for proven interventions; and (3) building the capacity of relevant systems to deliver or implement them.

Increasing science or intervention "push" generally involves developing standards for defining what is effective, and developing and/or promulgating clinical practice guidelines, as well as research to test or adapt effective interventions in new settings or populations, or to improve on intervention efficacy. Viewed in this framework, the 1996 release of the AHCPR smoking cessation clinical practice guideline³⁴ represented a major "science push". To capitalise on this push, the RWJF, in collaboration with the AHCPR (now the Agency for Healthcare Research and Quality), awarded "guideline dissemination grants" to the American College of Obstetrics and Gynecology (ACOG), the American Medical Women's Association (AMWA), and the American Academy of Pediatrics (AAP). These grants supported their efforts to publicise the

guideline through their professional journals and meetings, and to develop and disseminate tailored versions of the guideline for women, including pregnant women and mothers and parents of young children. It also supported the American Cancer Society's (ACS) efforts to disseminate a "packaged" state-of-the-art intervention, and organised a consensus conference with other major funders (for example, ACS, Centers for Disease Control and Prevention (CDC), National Cancer Society, National Heart, Lung, and Blood Institute) to identify the essential elements of the current "best practice" intervention for smoking cessation in pregnancy, based on a comprehensive literature review and a review of early results of trials in progress. A subsequent conference, organised in collaboration with the National Institute of Child Health and Development, explored the risks and benefits of pharmacotherapy to revise current guidelines for nicotine replacement and other approved products for pregnant and lactating women.³⁷ The fruits of these efforts have been shared with the expert panel compiling the updated AHCPR guideline, and will be reflected in the revised year 2000 guideline.³⁶ To improve on current best practice and pave

the way to the next generation of more powerful interventions, the Smoke-Free Families National Program funded a series of innovative studies, which are described in the next section of this article and presented throughout this supplement.

We assumed that having a clearer picture of the costs of smoking in pregnancy, and of economic benefits of effective treatment, could motivate more health plans and health care policy makers to incorporate the evidence based treatments into the routine care they provide for pregnant smokers. Therefore, to help build demand or market “pull”, Melvin and colleagues⁴¹ were funded to estimate the full range of maternal and infant health care costs associated with maternal smoking during pregnancy, and economic analyses were conducted to lay the groundwork for estimating the cost benefits of Smoke-Free Families best practice and innovative treatment approaches. Our other efforts to increase demand have included: (a) ongoing qualitative social marketing research to find the most compelling ways to portray the benefits of current best practice interventions to health plans, insurers, providers, pregnant smokers, and their families; (b) efforts to inform health care policy makers of the health and cost benefits covering evidence based tobacco dependence treatment for all pregnant smokers enrolled in Medicaid; (c) efforts to broaden the current Health Plan Employer Data Information Set (HEDIS) measure of managed care provider intervention to quit smoking⁴²; and (d), in conjunction with the American Association of Health Plans (AAHP) and the RWJF’s Addressing Tobacco in Managed Care national program, the creation of an annual award to recognise health plans which have successfully implemented tobacco cessation strategies before, during, and after pregnancy. These efforts may lay the groundwork for a national communications campaign aimed at patients, providers, insurers, and health plans, potentially in collaboration with ACOG.

Neither “push” nor “pull” can work alone to drive the adoption of best practice interventions without efforts to build the health care system’s capacity to deliver them. Capacity building efforts began with support for an effort to catalogue the existing self help materials that met “best practice” standards in order to make it easier for providers and health plans to obtain them,⁴³ and also included (in collaboration with AHCPHR) support for training programs offered by the AAP, ACOG, ACS, and AMWA to train practising prenatal care providers to offer these interventions routinely. In addition, the AAHP and Addressing Tobacco In Managed Care National Technical Assistance Office provide tools and technical assistance to health plans seeking help to implement “best practice” interventions for their pregnant and postpartum smokers. The Addressing Tobacco In Managed Care research program also is funding a variety of grants to evaluate the impact of varied systems changes—such as making tobacco use a vital

sign, offering incentives or feedback to providers, and including tobacco dependence treatment as a covered benefit—on the adoption of evidence based smoking cessation strategies, including those for pregnant smokers.⁴⁴⁻⁴⁷ Future capacity building efforts will include a partnership with the CDC and Health Resources and Services Administration to support region-by-region quality improvement efforts to expand the capabilities of a range of prenatal health care systems to deliver best practice interventions routinely.

Our hope is that these combined efforts will help to create a policy and practice environment favourable to the widespread adoption of current “best practice” interventions for pregnant smokers. The RWJF and the Smoke-Free Families National Program will continue to seek opportunities to work with other funders, public and private, and a variety of stakeholders, including professional societies, to change the standard of care for pregnant smokers.

Developing more powerful interventions

To help pave the way for the next generation of more effective interventions for pregnant smokers, the RWJF and its Smoke-Free Families National Program have supported a range of innovative studies evaluating novel smoking cessation approaches which had not been previously tested.⁴⁸ Convinced that treatment “breakthroughs” would be most likely to result from funding for interventions that reflected some “thinking outside the box” or employed promising new technologies (for example, interactive video, computer tailored self help materials), 11 controlled two year pilot studies were funded. These studies involved pregnant smokers from a variety of populations who were seen in varied public and private treatment settings, from WIC (Women, Infants, and Children) and public health prenatal clinics, to private offices, group practices, and managed health care plans. The grantees included investigators from a number of different backgrounds and disciplines (medicine, nursing, behavioural psychology, epidemiology, public health, health education, neuropharmacology), with several projects led by interdisciplinary research teams.

Since prospecting for breakthrough treatments necessarily entails some risk, we did not expect that all the interventions would prove to be significant improvements on the current best practice. However, our hope was to identify a few “breakthrough” interventions that would be competitive for larger scale investigations supported by the National Institutes of Health (NIH), as well as to learn more about barriers to making brief interventions a part of routine prenatal and postpartum care no matter what the intervention result. This supplement presents the fruits of these studies. Several promising interventions were identified and three investigators have already been successful in gaining NIH support for follow on research. A great deal was learned about the practical challenges to be addressed in

conducting controlled research in real world practice settings, and in expanding existing prenatal care to include systematic tobacco intervention.

From the findings presented in this supplement, the RWJF and Smoke-Free Families National Program Office have gone on to craft a second generation effort—to explore further promising interventions suggested by the first as well as to address a number of knowledge gaps that are holding back the field. As a result, \$11.5 million has been committed to fund controlled and pilot studies to: (1) identify effective motivational interventions using patient incentives and/or biochemical feedback of smoking health harms combined with a core best practice interventions; (2) identify additional innovative treatments for achieving smoking cessation during and immediately after pregnancy; and (3) support exploratory research to learn more about the determinants of smoking non-disclosure, spontaneous quitting before and early in pregnancy, and postpartum maintenance and relapse.⁴⁹ In addition, \$5 million in funding has been committed to the creation of a National Dissemination Office to work in concert with the National Program Office and with other funders and stakeholder groups to promote the widespread adoption of current and future “best practice” interventions for pregnant smokers. Our commitment is to continue to work with other leading organisations and agencies to build on the lessons learned from the work presented in this supplement as well as to disseminate widely promising new practices as they develop. Our aim is to help assure that we collectively can meet the nation’s important 2010 health goals.

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