Helping Low Income Pregnant Women Quit Smoking: Improving the First Breath Program

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ABSTRACT

Background: Maternal smoking during pregnancy can have dire consequences for both baby and mother. In 2000, the Wisconsin Women's Health Foundation developed the First Breath program to address this challenge, particularly among low-income women. While this prenatal smoking cessation program was successful, 2 factors necessitated changes in the program: changes in the health care reimbursement environnment and a high postpartum relapse rate.

Methods: The First Breath program was revised using the concepts of implementation science and included focus groups of First Breath clients, a randomized control trial to test new postpartum services, and an implementation project to test the new method of delivering First Breath.

Results: A year after implementing the new First Breath program, results are encouraging. First Breath expanded its reach by 34% over 2017. Eighty-eight new First Breath sites (to a total of 235 sites) have been added, resulting in increased diversity. While there was significant relapse within the new program from prenatal abstinence to 1-month postpartum abstinence (from 13.6% to 7.3% abstinence, biochemically verified, intent-to-treat) there was not additional relapse through 6 months postpartum.

Conclusion: Sustaining a valuable community-based tobacco dependence intervention program serving a vulnerable population requires continuous improvement built on measured outcomes and response to changes in the health care delivery system. First Breath may serve as a model program to aid underserved pregnant women who smoke.

BACKGROUND

Maternal smoking during pregnancy can have dire consequences for both the baby and the mother,[1-8] and smoking during pregnancy is more common in disadvantaged populations.[7,9-11] This health risk is particularly prevalent in Wisconsin where rates of smoking during pregnancy remain higher than national averages. In 2016, 11.3% of pregnant women in Wisconsin reported smoking sometime during their pregnancy,[12] 57% higher than the national rate of 7.2%.[9]

In 2000, the Wisconsin Women's Health Foundation (the Foundation) developed the First Breath program to address the challenge of prenatal smoking in Wisconsin, especially among disadvantaged women. The Foundation recruited programs providing health care services to low-income pregnant women—typically county health departments—to serve as First Breath sites. The Foundation trained staff from participating clinical sites to provide brief, evidence-based cessation counseling.[13] First Breath sites also collected limited program data and provided modest nonmonetary incentives to enrolled women. The Foundation was responsible for recruiting new First Breath sites, providing the initial training to site staff, and delivering ongoing training, support, program materials, quality assurance activities, and tracking of women enrolled in the program.

The First Breath program was successful. Between 2002 and 2017, over 16,000 women were enrolled in the First Breath program. By 2017, there were 157 active First Breath sites, including at least 1 site in 62 of the 72 Wisconsin counties. Thirty-five percent of the 2017 First Breath participants who completed the postpartum survey self-reported not smoking in the third trimester. An additional 44% reported a reduction in the number of cigarettes smoked per day.

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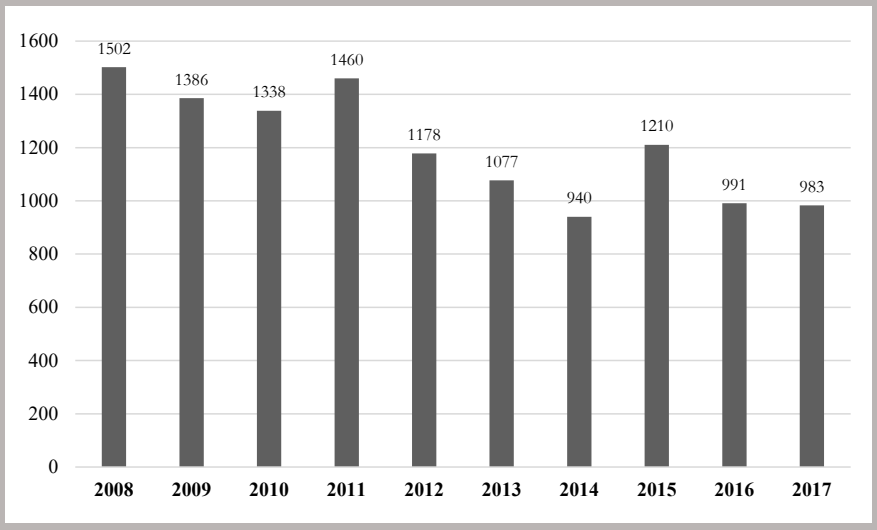
While successful, 2 factors compelled changes in the initial First Breath program: one related to a change in the external environment in which First Breath takes place and one related to outcomes. First, changes in the external environment contributed to a marked decrease in the number of women reached over time, from 1,460 in 2011 to 983 in 2017 (Figure). Many of the public health agencies that were long-term First Breath sites experienced significant reductions in funding and reimbursements, reducing their ability to provide prenatal services (including First Breath services) to the women in their communities. These changes suggested the need to change how the First Breath program was delivered. Second, even among First Breath participants, there was a high rate of relapse to smoking in the postpartum period, consistent with the literature that has documented a relapse rate of 50% to 80%[14,15] after delivery, with low-income women particularly likely to relapse.[16] And, the number of women resuming smoking increases as a function of time since delivery, with the relapse rate at 6 months postpartum exceeding that at 3 months postpartum.[17-19] The high relapse rate suggested the need to extend First Breath services into the postdelivery period for up to 6 months.

Figure. First Breath Annual Enrollment[a]



[a] Excluding enrollment in a randomized control trial, 2012 – 2015.

This article describes how the First Breath program was redesigned to address these factors and reports on outcomes from the first year (2018) following the statewide implementation of the new First Breath program.

METHODS

Implementation science methods were used to guide First Breath changes. Implementation science assesses the processes that promote the adoption and integration of evidence-based practices, interventions, and policies into routine health care and public health settings.[20] It holds that an intervention is more likely to be effective over time if it is based on published literature and guidelines, and changes in response to ongoing evaluation. Likewise, an intervention is more likely to be sustained over time if it adapts to changes in the external context (real world setting in which interventions are delivered).[21] Finally, program evaluation should assess perceptions of people receiving the intervention.[21]

There were 3 distinct steps to redesigning the First Breath program: (1) a series of focus groups and participant informant interviews, (2) a randomized control trial, and (3) an implementation/feasibility evaluation of the new program.

Focus Groups and Participant Informant Interviews

Twelve focus groups of First Breath participants (N = 66) took place in 6 Wisconsin cities, and an additional 67 First Breath participants were interviewed individually to gather their perceptions of postpartum relapse. Themes from this qualitative study highlighted the importance of extending counseling into the postpartum period, including findings that women smoked as a way to manage stress (including the stress of a newborn), motivation to stay quit decreased postpartum, and there is a need for cessation help and guidance for others in the family who may not be supportive of continued abstinence. Also, these First Breath participants requested more comprehensive services from cessation specialists. The focus groups and participant informant interviews results were largely consistent with the literature regarding postpartum relapse. Specifically, relapse is often triggered by stress, lack of sleep, depression, and/or lack of social support.[22] Additionally, other smokers in the household, especially the baby's father and grandmother, negatively impact women's smoking quit attempts and increase the risk of postpartum relapse.[15,23-25] This literature and the results of participant input highlighted the need to extend First Breath service into the postpartum period.

Randomized Control Trial

The randomized control trial compared the original First Breath program that provided only prenatal counseling with an expanded First Breath program that also provided postdelivery counseling. For this study, women who enrolled at existing First Breath sites were contacted by Foundation staff and told about the opportunity to participate in a research project. Those who gave verbal consent were randomly assigned to either the original First Breath program (n = 94) or the expanded program (n = 91). Those assigned to the expanded program received additional postpartum in-home services by Foundation staff that included 1 additional prenatal home visit to acquaint the woman with the Foundation counselor and to set expectations for postdelivery counseling, as well as 3 postpartum in-home smoking cessation counseling visits and 3 post-

Table 1. Study Conditions and Treatment Components

Condition	Components
Original First Breath *(Prenatal only)*	• First Breath cessation counseling at least 2 prenatal visits and 1 postpartum visit delivered by First Breath site staff • Link to Wisconsin Tobacco Quit Line • Optional enrollment in text program to receive motivational messages • One 6-month postpartum in-home abstinence evaluation visit (Foundation staff) • Potential to earn $40 in gift cards
Expanded First Breath *(Prenatal and Postpartum in-home visits)*	All original First Breath Components PLUS: • 1 prenatal and 3 postpartum in-home counseling visits • 3 postpartum counseling phone calls • Potential to earn $140 in gift cards

Abbreviation: Foundation, Wisconsin Women's Health Foundation.

Table 2. First Breath Program Modifications

Original First Breath Program	New First Breath Program
Role of community sites: • Recruit and enroll clients • Provide prenatal smoking cessation counseling • Collect survey data at baseline, third trimester, and postdelivery	***Role of community sites:*** • Refer potential clients to Foundation
Role of Foundation staff: • Establish community First Breath sites • Initial and ongoing site staff training • Enrollment tracking • Receive and analyze data • Program evaluation	***Role of Foundation staff:*** • Establish community First Breath sites • Enroll referred clients • Provide prenatal smoking cessation counseling • Provide postdelivery, in-home smoking cessation counseling • Involve significant other at request of enrolled client • Collect survey data at baseline, third trimester, and postdelivery • Data analysis

Abbreviation: Foundation, Wisconsin Women's Health Foundation.

partum phone calls. Support to others in the household, such as cessation counseling and guidance about how to be supportive of the new mother, was included in these postpartum services, as were monetary incentives for accepting the postpartum services and for abstinence for the mother (Table 1). This study was approved by the University of Wisconsin's Institutional Review Board.

The primary outcome measure was biochemically confirmed smoking cessation (ie, breath carbon monoxide [CO] level of <6 ppm) of the women participants at about 6 months postpartum and self-report nonsmoking in the previous 7 days (point prevalence abstinence). (Six women who reported some smoking achieved a CO measure of less than 6 ppm. These women were counted as smokers in the analysis.) Among those who completed the follow-up (n=95 of 185), the bioconfirmed abstinence rate of nonsmoking was greater for women who received postpartum care than women in the control group (36.6% vs 12.3%, respectively $P<.01$). Calculated on an intent-to-treat basis, abstinence rate was 15.5% for women who received postpartum help vs 7.4% for women in the control group ($P=.07$). While this difference was not statistically significant, this small study provided insights into the absolute rates of quitting.

Implementation/Feasibility Evaluation

This project adapted the postnatal services tested in the randomized control trial into a new delivery method that addressed the inability of current First Breath sites (primarily county agencies) to continue to provide First Breath services.

In this new delivery method, rather than relying upon indigenous staff at prenatal clinic sites to provide First Breath counseling, Foundation staff provided the counseling. The role of prenatal clinic site staff was limited exclusively to referring interested pregnant women to the program. This change had an added benefit of allowing the program to expand to prenatal clinic sites that in the past were unable or unwilling to provide the First Breath counseling component. Moreover, it was believed that having Foundation staff provide all the counseling would improve outcomes, because this staff is highly specialized and fully dedicated to providing smoking cessation counseling consistently. (All Foundation staff providing counseling are Certified Tobacco Treatment Specialists.) Having Foundation staff provide counseling also addressed the high employee turnover challenges of the local public health prenatal clinical setting.

This feasibility project enrolled 201 women. Participants expressed satisfaction with services provided, and the self-report quit rate (not biochemically verified) for those who completed the redesigned program was 46%.

Based on the focus groups, randomized control trial, and implementation/feasibility evaluation results, the revised First Breath program was implemented statewide in January 2018. In this new statewide program, counseling continues postpartum via home visits and telephone. Quitting counseling and support are provided to family members and significant others if requested. Eligibility for the program remains unchanged and includes pregnant women who: (1) are current smokers who want to quit, or (2) have already quit and want help to remain quit. Prior First Breath counseling sites were converted to First Breath referral sites. All counseling and data collection are now completed by Foundation staff. Quality assurance checks are conducted quarterly (Table 2). The primary

outcome is biological confirmed abstinence 6 months postpartum. Secondary outcomes include patient satisfaction, achieving a smoke-free home, and reducing infant exposure to tobacco smoke.

RESULTS

Reach

In 2017, prior to the changes, providers at First Breath sites told 987 women about the program. In the first year of the new First Breath program, providers at First Breath sites referred 1,324 women, an increase of 34%. Of those women referred, 488 (37%) enrolled in the First Breath counseling program. The greatest reason for not enrolling was an inability by Foundation staff to reach the referred woman (67%), which underscores the difficulty of reaching this population. Among those who were reached, the primary reason for not enrolling was a disinterest in the program (85% of those reached), followed by not being ready to quit (5%).

First Breath continued to reach its target population—low-income women (see Table 3). Of those referred to the program, 81% were on Medicaid, 59% unemployed, and 24% did not graduate from high school. Table 3 compares those enrolled in 2018 to those enrolled in 2015 and illustrates that 2018 enrollees were slightly younger, less likely to be African American, less likely to be Hispanic/Latina, not as likely to complete high school, more likely to be unemployed, slightly more likely to be moderate to heavy smokers (11-30 cigarettes/day), less likely to have the first cigarette in the morning within 5 minutes, and more likely to be smoking at time of enrollment.

Eighty-eight new First Breath sites and 401 new providers were added in 2018. These included rural reproductive health/WIC clinics, tribal clinics, new social services agencies, obstetrical clinics, pediatric clinics, and a county jail. In 2018, there were First Breath sites in all 72 Wisconsin counties compared to 62 counties in 2017.

Services Delivered

One improvement of the First Breath program redesign was the ability to better track services delivered, because treatment was provided by Foundation staff. Thirty-nine percent of possible home visits were completed. Home visits were about 45 minutes in length. There were an additional 1,443 intervention contacts (telephone contacts, text messages), an average of 3 per enrolled woman. Telephone contacts were about 15 minutes in length. In addition, 91 partners and other caregivers of enrolled women received quitting education and/or other help.

Relapse

One hundred seventy-seven women were enrolled long enough in the new program in 2018 to reach the 6-month postpartum follow-up visit, thus permitted a tracking of relapse over time. Of these 177 women, 24 were not smoking prenatal (self-reported not smoking and passed the CO test [<6 ppm]), starting at 28 weeks gestation. (An additional 9 passed the CO test but reported some

Table 3. First Breath Client Characteristics, 2015 and 2018

	2015		2018[a]	
	%	(n)	%	(n)
Age[b]				
13–17	0.6[c]	(7)	0.8	(10)
18–24	17.2	(203)	25.4	(320)
25–34	63.5	(751)	59.5	(749)
35–44	18.2	(215)	14.0	(177)
≥ 45	0.6	(7)	0.2	(3)
Ethnicity[b]				
Hispanic/Latina	7.0	(82)	3.0	(39)
Employed[b]				
No	51.5	(583)	59.3	(255)[d]
Enrolled in Medicaid				
Yes	79.5	(962)	81.3	(1076)
Smoking status 30 days prior to pregnancy[b]				
None	0.8	(9)	2.2	(27)
<1/day	2.5	(29)	2.2	(27)
1–5/day	19.1	(223)	16.3	(201)
6–10/day	29.8	(347)	28.9	(357)
11–20/day	35.7	(416)	37.2	(460)
21–30/day	7.8	(38)	10.4	(129)
>30/day	4.4	(51)	2.8	(35)
Age of smoking onset[b,e]				
<15	40.2	(473)	21.2	(91)[d]
15–19	51.0	(601)	64.2	(276)
20–24	7.1	(84)	12.1	(52)
≥25	1.7	(20)	2.6	(11)
Race[b]				
American Indian/Alaskan Native	3.8	(44)	3.9	(48)
Asian	0.4	(5)	0.9	(11)
Black or African American	25.0	(291)	22.2	(276)
Native Hawaiian/Pacific Islander	0.2	2)	<0.1	(1)
White	69.0	(802)	68.0	(848)
Multiracial	1.4	(16)	4.2	(53)
Other	0.3	(3)	0.7	(9)
Education[b]				
Less than high school	3.7	(43)	1.4	(6)[d]
Some high school	16.9	(198)	23.0	(100)
High school or GED	46.8	(548)	41.5	(180)
Some college/2-year	29.1	(341)	31.3	(136)
College	3.2	(37)	2.8	(12)
Postcollege education	0.2	(3)	0	(0)
Smoking status at time of enrollment[b]				
Smoking	78.6	(881)	87.5	(378)[d]
Time to first AM cigarette				
Within 5 min	40.2	(455)	30.2	(114)[d]
6–30 min	26.1	(296)	25.9	(98)
31–60 min	16.2	(184)	12.7	(48)
>60 min	17.4	(197)	31.2	(118)
Treatment goal				
Quit for good	86.7	(951)	86.4	(483)[d]
Quit for pregnancy/lactation	5.1	(56)	6.6	(37)
Reduce	6.8	(75)	7.0	(39)
Previous quit attempts				
0–4	86.3	(895)	86.0	(370)[d]
5–9	9.7	(101)	9.8	(42)
≥10	4.0	(41)	4.2	(18)

Abbreviation: GED, general education diploma.
[a] Unless otherwise noted, data was collected at time of referral.
[b] $P<.01$.
[c] Reported percentages are the percent of those that answered the question.
[d] Data collected at enrollment call.
[e] 2015: asked age smoking started; 2018: asked for age of regular smoking.

smoking, suggesting very light smoking.) Thirteen were abstinent at 1 month postpartum (an additional 6 passed the CO test but reported some smoking.) Thirteen were abstinent 6 months postpartum (an additional 6 passed the CO test but reported some smoking). Calculated based on those women who completed treatment at each point in time (58) (completer analysis), the abstinence rate was 41.4% (24/58) prenatal, 22.4% (13/58) 1 month postpartum, and 22.4% (13/58) 6 months postpartum. Calculated on an intent-to-treat basis in which all women with missing data are assumed to be smoking, the abstinence rates were 13.6% (24/177) prenatal, 7.3% (13/177) at 1 month postpartum, and 7.3% (13/177) at 6 months postpartum.

Secondary Outcomes

Among those that completed the 6-month postpartum home visit, 70% reported no infant exposure to secondhand smoke, and 68% maintained a smoke-free home. Seventy percent were confident that they would be smoke-free in a year. Sixty-seven percent rated the First Breath program "excellent" and 22% rated it "good." One hundred percent said they would recommend First Breath to others. Among the First Breath elements, the gift cards were rated as the most valued, followed by the CO testing, and then the counseling provided at the home visit.

DISCUSSION

Despite successfully enrolling over 16,000 pregnant women who smoked over 15 years, changes in the health care reimbursement environment and high postpartum relapse prompted the Wisconsin Women's Health Foundation to adapt the First Breath program. As a result of these changes, reach in 2018 increased 34% over 2017. New First Breath referral sites and new providers within those sites have been added to the referral base. There are now First Breath sites in all 72 Wisconsin counties (prior = 62 of 72). The reduced requirements for being a First Breath site (referral only, no provision of smoking cessation counseling) is probably one contributor to both the increase in women being told about the First Breath program and the broader array of organizations serving pregnant women who became First Breath sites. The Foundation now collects information about the provision of service, which will greatly enhance its ability to understand and improve the program moving forward. Regarding relapse, abstinence rates fell about 50% (from 13.6% to 7.3%, intent to treat) from prenatal to 1 month postpartum, but there was no additional decline in abstinence through 6 months postpartum. Additional clinical intervention may be necessary to address this early relapse. This recommendation is consistent with a review of the literature, which found that the most effective interventions provided at least 3 intervention contacts within the first 4 postpartum months.[19]

The evolution of the First Breath program over time illustrates key concepts of implementation science.[20,21] Implementation is well served by strong and varied evaluation efforts. In addition to outcomes measured via program evaluation and rigorous evaluations, such as randomized controlled trials, qualitative information and anecdotal stories of success enrich the evaluation of programs.[26] Dedicated time for reflection to process information during implementation is also important.[21,27,28] The overall health care delivery system is changing rapidly. Such changes in the external context[21] often negatively affect otherwise sound community programs such as First Breath. Community agencies must be willing to monitor for such changes and be prepared to adjust protocols. For First Breath, reductions in the delivery of prenatal care services overall to economically disadvantaged women in Wisconsin was one such external threat. This change contributed to the decision to shift from services being delivered by prenatal site staff to services being delivered by dedicated counselors from the Foundation. Such external threats, if successfully addressed, can lead to positive changes. For example, it will now be easier for the Foundation to ensure fidelity to treatment protocols, because it collects relevant process data and counseling is provided by fewer, dedicated Foundation employees who are trained and fully dedicated to these tasks.

Programs benefit when representatives from the target populations participate in program development, implementation, and redesign. During the First Breath program redesign, interviews and focus groups assisted in updating educational materials, evaluating program processes, and refining outreach messaging. Developing a program that is "patient-centric" requires that such individuals have roles beyond just recipient of services and providers of data.[29-31] For example, one of the current First Breath counselors previously received services as a First Breath client.

Organizations providing community services should be prepared for unintended consequences and opportunities. The dedicated Foundation counselors make in-home observations. This has resulted in facilitating referrals for domestic violence, breastfeeding assistance, enrollment in Wisconsin Medicaid programs, and substance abuse/mental health treatment. While this has placed additional demands on staff (for example, staff now bring naloxone to their home visits), this opportunity afforded by the home visits has permitted the First Breath program to extend its assistance to this very vulnerable population far beyond smoking cessation services.

Challenges remain. For example, only 37% of women referred to the First Breath program ultimately enroll. The methods used to contact the women and the enrollment process, including the collection of contact information and burden on referred women, are being reviewed.

CONCLUSION

The First Breath program has evolved throughout its life span and has now been offered to over 18,000 Wisconsin pregnant women who smoked. It continues to help pregnant Wisconsin women, especially those living in poverty, thus benefitting their infants, themselves, and their families. As a result of this evolution, First Breath is well positioned to even more effectively meet its mission. This revised program, with its emphasis on services that continue

into the postpartum period, counseling provided by tobacco treatment specialists located regionally, and its reliance on a statewide network of community-based sites as sources of referrals, could be replicated in other states. Lessons learned for this program include the need to dedicate resources to key functions, such as collecting qualitative and quantitative data to guide program development, monitoring the external context, providing interventions early in the postpartum period, and developing a variety of meaningful roles for members of the target population.

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