

Rapid assessment of the implementation of a smoking cessation intervention in public health clinics that serve low-income pregnant women—Ohio, 2013

Submitted by: Celia Quinn, Oluwatosin Ogunmoyero, Israel Agaku, and Sierra Mullen

To: Mary DiOrio, Ohio Department of Health; Elizabeth Conrey, Ohio Department of Health; Epidemic Intelligence Service Office, Centers for Disease Control and Prevention

Date: June 4, 2014

Background

1. Burden of perinatal smoking and associated morbidity and mortality in Ohio

Perinatal smoking is an important modifiable risk factor for pregnancy complications, prematurity, low birth weight, and infant mortality. Pregnancy complications associated with smoking include placenta previa, placental abruption, premature rupture of membranes, intrauterine growth restriction, and preterm delivery (Centers for Disease Control and Prevention, 2004). Exposure to smoking in utero also increases the risk of death during the first year of life. In the US, an estimated 5–7% of preterm-related deaths and 23–34% of Sudden Infant Death Syndrome (SIDS) deaths are attributable to prenatal smoking (Dietz, England, Shapiro-Mendoza, Tong, Farr, & Callaghan, 2010). Maternal smoking increases the risk of a neonatal intensive care unit admission by almost 20% (Adams, Miller, Ernst, Nishimura, Melvin, & Merritt, 2002).

Ohio has one of the worst infant mortality rates in the US, with overall infant mortality of 7.9 deaths per 1,000 live births (2011, Ohio Vital Statistics), compared with the US infant mortality rate of 6.1 deaths per 1,000 live births (Hoyert & Xu, 2012). Leading causes of infant deaths in Ohio include preterm birth, SIDS, birth defects, and injuries (Ohio Department of Health and Ohio Children's Trust Fund, 2013). Perinatal smoking is associated with many of the causes of infant death that contribute to Ohio's high infant mortality rate.

Perinatal smoking is an important public health problem in Ohio. Almost one in three women who had a live birth in Ohio in 2010 smoked in the three months before becoming pregnant, and 16.5% of all women who had a live birth were still smoking during the last trimester of pregnancy (Tong, et al., 2013). Lower income women are at much higher risk for continuing to smoke throughout pregnancy. In Ohio, women whose pregnancies were covered by Medicaid were more than 5 times as likely to report smoking during the last 3 months of pregnancy compared with women not covered by Medicaid during pregnancy (32.2% vs. 5.8%). Similarly, women participating in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) were almost three times as likely to smoke during the

last trimester of pregnancy, in comparison to women not participating in WIC (29.2% vs. 10.1%)(Ohio PRAMS, 2009–2010).

2. Ohio Department of Health efforts aimed at reducing perinatal smoking

To address perinatal smoking among low-income women in Ohio, the Ohio Department of Health (ODH) established the Ohio Partnership for Smoke-Free Families (OPSFF) in 2006. OPSFF has trained WIC programs and Child and Family Health Services (CFHS) direct perinatal care clinics to implement an evidence-based smoking cessation intervention known as “The 5A’s.” The 5A’s is a brief five-step tobacco cessation counseling intervention delivered by health professionals that includes five components: Ask, Advise, Assess, Assist, and Arrange. This intervention has been shown to be effective in diverse clinical settings and its use is recommended by the US Public Health Service in a Clinical Practice Guideline updated in 2008 (Fiore, Jaen, Baker, & et al, 2008). The American College of Obstetricians and Gynecologists also recommends the use of the 5A’s intervention to promote smoking cessation during pregnancy (American College of Obstetrics and Gynecologists, 2010). The 5A’s intervention has been adapted to various clinical settings, including WIC and other public health clinic settings. WIC clinics can face challenges related to implementing the 5A’s because these clinics do not provide clinical prenatal care and women participating in the program may not have multiple visits during pregnancy. However, the broad reach of public health programs, such as WIC, provides an important opportunity for promoting smoking cessation in a vulnerable population (Yunzal-Butler, Joyce, & Racine, 2010) (Davis, Lazariu, & Sekhobo, 2010).

Since 2006 in Ohio, WIC clinics serving 22 of 88 counties received training in the use of the 5A’s for smoking cessation. However, nearly half of trained WIC counties did not sustain implementation. Previous work assessing the use of the program, including audits and chart review by program managers, suggest that there is variability in the degree of fidelity with which programs are implementing this evidence-based intervention. The reasons for non-adherence and for discontinuation of the program in certain WIC clinics are unknown. Additionally, implementation among CFHS clinics, begun in 2012, has not been comprehensively assessed.

Ohio Department of Health has conducted several previous analyses to assess the implementation of the 5A’s in WIC sites in the state. These included an assessment of the pilot program for OPSFF in 2007 (Ohio Partners for Smoke-Free Families, 2007); a chart review of 5A’s documentation in 2010, after renewed funding allowed increased staff time to work on the OPSFF project; and a subsequent chart review in 2012. The 2010 chart review revealed that although use of the OPSFF reporting form was consistent in clinics still participating in the program, completion of all 5 steps of the intervention was highly variable. Preliminary analysis of data from the 2012 chart review, conducted by ODH, revealed similar findings. During these assessments, only participating clinics were included, and information about clinics no longer participating in the program was not collected in a systematic manner. WIC and CFHS clinics have the potential to reach nearly half of pregnant women in Ohio, but without adherence to all of the 5A components, this vulnerable population may remain at risk for continued perinatal smoking, poor pregnancy outcomes, and infant mortality.

3. Expansion of perinatal smoking cessation programs and need for rapid epidemiologic assistance

In July 2013, ODH was allocated funding from the state's general fund to address infant mortality, including \$1 million for immediate use to reduce perinatal smoking. With this state mandate and new time-limited resources, ODH aims to expand the quality and reach of the 5A's intervention for high-risk women served by publicly funded health programs. These smoking cessation funds will be used to provide assistance to WIC and CFHS sites actively providing the intervention to ensure that women receive the evidence-based 5A's with full fidelity. Funds will also be used to train 33 additional county WIC programs beginning in 2014, with complete expansion across Ohio by the end of the 2015. Additionally, ODH plans to incorporate the 5A's intervention into other state-funded programs (e.g., home visiting) that provide services to pregnant and post-partum women.

To facilitate the efficient use of these limited funds, a rapid assessment of the effectiveness of smoking cessation programs currently in use in state-funded public health clinic settings was needed. A systematic evaluation of facilitators and barriers to full-fidelity implementation of the 5A's program was conducted in order to provide recommendations to Ohio Department of Health prior to the scaling-up of perinatal smoking cessation programs statewide.

4. Epi-Aid response

On September 3, 2013, the Ohio Department of Health (ODH) requested CDC assistance to conduct a rapid evaluation of smoking cessation programs used in publicly funded clinics in the state. On September 9, 2013, EIS officers Israel Agaku (Office on Smoking and Health) and Oluwatosin Ogunmoyero (Division of Reproductive Health) departed for Ohio to participate in the investigation, joining EIS officer Celia Quinn (ODH) and CDC/CSTE Applied Epidemiology Fellow Sierra Mullen (ODH) in the field. Additional subject matter experts from the Office on Smoking and Health and the Division of Reproductive Health participated from Atlanta.

The objectives of the Epi-Aid were to:

1. Assess the degree of 5A's implementation (full, partial, or no) among trained WIC and CFHS clinics.
2. Estimate the impact of exposure to a clinic using the 5A's intervention on smoking cessation among pregnant women participating in WIC, using Pregnancy Nutrition Surveillance System data.
3. Identify facilitators and barriers associated with full, partial, or no clinic adherence to 5A's implementation protocols using qualitative methods.
4. Provide recommendations for rapid implementation of full 5A's intervention in WIC and CFHS clinics.

This report summarizes the methods, results, and conclusions of the investigation and outlines recommendations shared with ODH at the conclusion of the field investigation.

Methods and Results

Population under study

This assessment focused on two public-health funded clinic settings in Ohio: WIC program clinics and CFHS direct perinatal care clinics. Both programs serve low-income Ohio women. Perinatal smoking rates are twice as high among low-income women, and nearly 33% of women who participated in the WIC program reported smoking during the last trimester. Expansion of the 5A's intervention into all WIC and CFHS clinics has the potential to reach half of all pregnant women in Ohio.

Ohio WIC program

The Ohio WIC program is the 8th largest WIC program in the United States and one of the largest programs in the Midwest (Ohio Department of Health). Eligibility for WIC benefits are based on four factors: categorical eligibility, residence, income and nutritional risk (United States Department of Agriculture). The program primarily serves low-income, nutritionally at-risk pregnant and postpartum women, breastfeeding women, non-breastfeeding postpartum women (up to 6 months after birth or end of pregnancy), infants, and children up to five years of age. WIC applicants must be residents of Ohio, determined to be at medical and nutritional risk by a health professional, and must have an income less than or equal to 185% of the Federal Poverty Level (FPL). The Ohio WIC program primarily provides services focused on nutrition: nutrition education; breastfeeding education and support; supplemental, nutritious foods; referral to prenatal and pediatric health care; and referral to other MCH and human service programs.

WIC is a 100% federal- funded, grant program and operates in all 88 counties in Ohio. Funds are administered by the state and allocated to local agencies ("grantees"). Currently, there are 74 WIC programs ("projects") statewide. Each program has at least one WIC site ("clinic"). Once enrolled, women can access services through a local clinic site. WIC clinics in Ohio can be located at county health departments, community centers, churches, and hospitals. In an average month during 2013, WIC provided services to 61,581 women; 68,232 infants, and 133,871 children (total: 263,684) (Ohio Department of Health). WIC participants may enroll in the program as soon as they have confirmation of a pregnancy, if they meet the other eligibility criteria described above. Ideally, WIC participants should enroll as early as possible (i.e. first trimester) during pregnancy. However, women may encounter barriers that prevent this from occurring, such as lack of knowledge about WIC or its services, perceived problems qualifying for enrollment, and lack of transportation to a WIC clinic (Geller, Harrington, & Huang, 2012). Also, some women may be unaware of their pregnancy which could delay early enrollment for services. In Ohio, women typically become eligible once pregnant and approximately 34% enrolled during the first trimester in 2011 (CDC Pregnancy Nutrition Surveillance System). In a previous study conducted among WIC participants in eight states who smoked prior to pregnancy and at prenatal WIC enrollment, women enrolled in the first trimester were more likely to quit smoking by the last three months of pregnancy and postpartum registration compared to women who enrolled in WIC in the third trimester (Yunzal-Butler, Joyce, & Racine, 2010).

In Ohio, WIC projects are organized at the county level, and WIC services are available in all 88 counties. Notably, some WIC projects span more than one county. A WIC project may run multiple clinics in the county or counties it serves, depending on the size and distribution of population in the county. Ohio's counties are geographically diverse, and can be categorized by county type: Metropolitan, Suburban, Rural, or Appalachian.

5A's Training at WIC Sites

Between January 2006 and June 2007, ODH piloted the 5A's in WIC clinics in four geographically diverse counties, one of each county type (Metropolitan, Suburban, Rural, or Appalachian). Since the initial pilot, ODH has provided 5A's training to 19 WIC programs serving 25% of Ohio counties (22 of 88 counties were provided training in the intervention); training and implementation of the intervention was offered to all programs, but participation was voluntary. An important element of the 5A's training was the use of the Five A's Intervention Record, or "FAIR Form", to document each client's exposure to the 5 Steps of the intervention (Appendix 1). Clinics were expected to maintain the FAIR form in each client chart, and chart reviews were performed by OPSFF staff as part of regular site visits to assess each clinic's utilization of the 5A's intervention. Despite receiving training on the implementation of the 5A's, many trained programs stopped documenting their use of the intervention with the FAIR form at some time after their training. Of the 19 programs trained between 2006 and 2012, 12 were still actively using the 5A's at the time of this assessment. However, review of FAIR forms during program site visits suggested that the intervention was being implemented with variable fidelity at the program level.

OPSFF offers 5A's training to WIC programs on a voluntary basis, and to date has not done active recruiting for new clinics. Most WIC clinics currently using the 5A's intervention in Ohio are located in Appalachian counties and have small clientele. (Table 1).

Table 1. Current WIC Program Participation in 5A's, by County Type and Size (N=12)

County Type	# of Programs	Size*	# of Programs
Metropolitan	1	Small	4
Suburban	2	Mid-Size	8
Rural	4	Large	0
Appalachian	5		

* Program size derived from number of assigned caseloads each year (Small: <1,000, Mid-Size: ≥ 1,000 - <4,000; Large: ≥ 4,000). Source: Ohio WIC Program

Child and Family Health Services Clinics

The Child and Family Health Services (CFHS) program is designed as an organized community effort to eliminate health disparities, to improve birth outcomes, and to improve the health status of women, infant, and children in Ohio through four main components, including Perinatal Health. Although the CFHS program funds many activities across the state, this assessment focuses only on the smoking cessation interventions provided in CFHS direct perinatal care clinics. CFHS direct perinatal care clinics provide education and clinical services to under- and uninsured women of racial and ethnic groups who are disproportionately affected by poor health outcomes in

geographic areas of highest need. Functioning as a “safety net” for access to prenatal and postpartum care, clinic services include: mental health and environmental health assessments; referrals to home visiting programs; gestational diabetes screening; folic acid education; multivitamin distribution; and assistance with Medicaid enrollment. Currently, CFHS funds direct perinatal care clinics in 13 Ohio counties. Unlike the WIC program, each county or city CFHS program runs only one clinic site.

5A’s Training at CFHS Sites

In 2012, ODH required all 14 perinatal clinics in Ohio to implement the evidence-based smoking cessation intervention, the 5A’s. One did not apply for funding for direct perinatal care services after 2012, and no longer runs a CFHS perinatal clinic. There were therefore 13 CFHS programs providing direct perinatal care services at the time of the assessment, and all were utilizing the 5A’s, as required by ODH (Table 2). Like WIC clinics, CFHS programs are also expected to document their use of the 5A’s program using the FAIR form. Data collected using the FAIR form are then electronically reported to ODH using an electronic data system developed for CFHS direct perinatal care clinic sites. Assessment of the adherence to all components of the 5A’s within these clinics was limited prior to this assessment, since the clinics had only recently begun utilizing the intervention.

Table 2. CFHS Clinic Participation in 5A’s, by County Type and Size (N=13)

County Type	# of Clinics	Size*	# of Clinics
Metropolitan	6	Small	8
Suburban	5	Mid-Size	2
Rural	1	Large	3
Appalachian	1		

* Program size categorized based on average number of direct care for 2012 and 2013 calendar year (Small: < 200; Mid-Size: 201 – 599; Large: ≥ 600). Source: Ohio CFHS IPHIS Reports

Degree of 5A’s Implementation: Ohio WIC Clinics

Methods

Data collection

Chart reviews were conducted prior to this investigation by ODH staff for the 12 WIC programs that were using the FAIR forms at the time of ODH program site visits in 2012. For WIC programs with multiple clinic sites, charts were reviewed at the main clinic site, rather than at the smaller or satellite clinics. At each participating clinic, patient charts were selected using a stratified random sampling method without replacement of up to 40 smoking and 40 non-smoking clients, based on documentation of client smoking status in the WIC electronic record system. Patients were selected from the Ohio WIC electronic records system. Eligible patients were pregnant women who had at least one appointment at a participating clinic from March–August 2012. ODH staff abstracted data from the FAIR forms using a form developed for the chart reviews and focused on the completion of each step of the 5A’s. ODH staff performed data entry and provided chart review data to the Epi-Aid team in Excel format.

Analysis

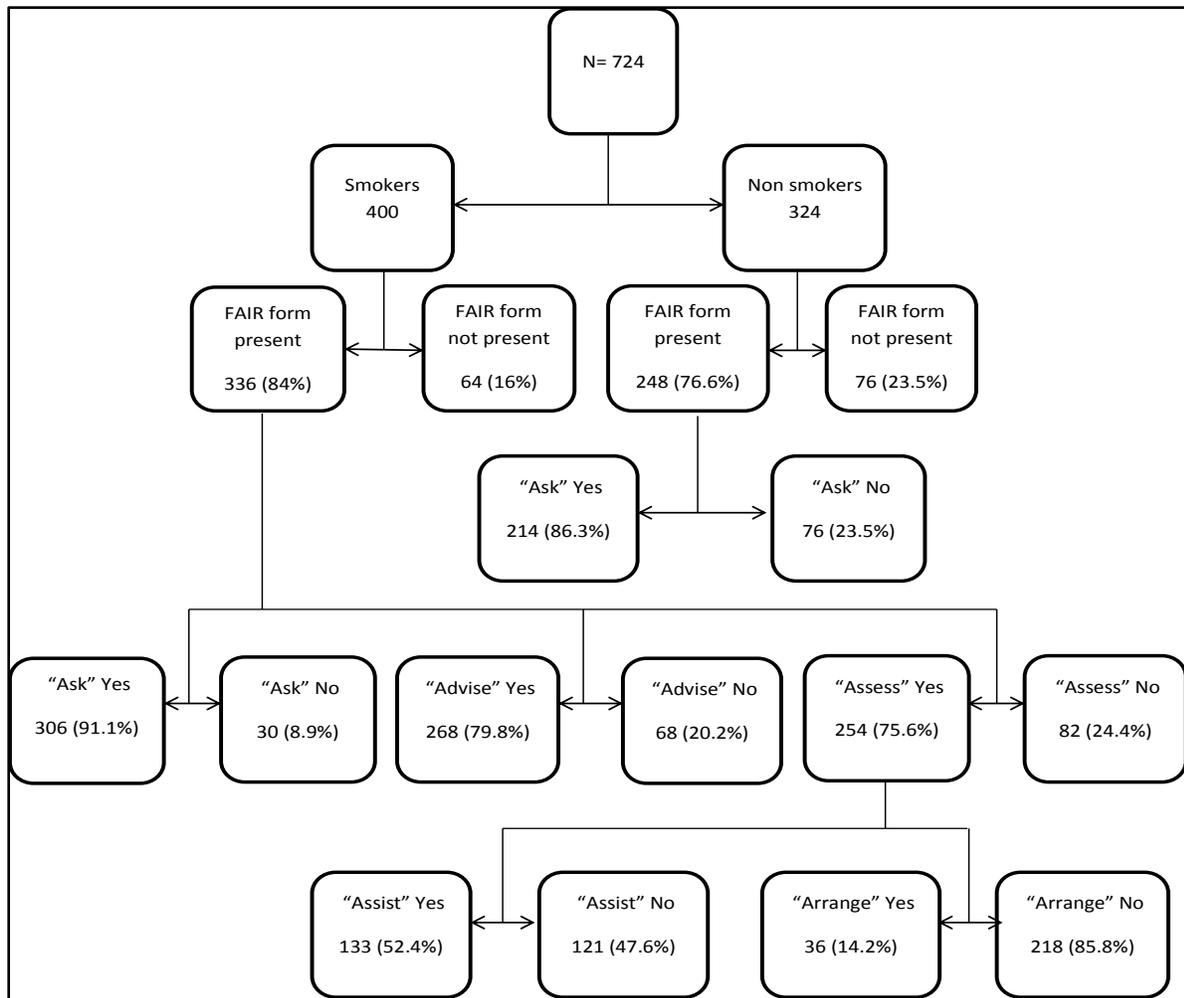
We used SAS 9.3 software for our analysis and we restricted our analysis to data from each client's first prenatal visit. The Epi-Aid team established a set of criteria to determine each site's degree of implementation of the 5A's. The criteria are as shown below:

- Full implementation – FAIR form present in >90% of reviewed charts, 'ask' documented in >90% of reviewed charts and 'advise' documented in >50% of reviewed charts.
- Partial implementation – Any other combination of documentation.
- No implementation – Never trained or trained but not currently using the FAIR forms

Results

A total of 724 charts were audited in 2012 (400 from smokers, 324 from non-smokers). FAIR forms were present in 584 (81%) of the charts; of these, 336 were charts of clients who reported smoking and 248 who reported not smoking at their initial visit. Among smokers who had a FAIR form present, 79.8% had 'advise' documented and 75.6% had 'assess' documented. Those qualified for 'assist' and 'arrange' had lower prevalence of these steps documented. Figure 1 below presents a schematic depicting each of these steps.

Figure 1: Prevalence of 5A's documentation among reviewed charts of pregnant clients in 12 Ohio WIC sites implementing the 5A's, 2012



Of 22 WIC programs ever trained to use the 5A's, 10 were no longer implementing the 5A's; of the 12 programs with any implementation, only three were fully implementing the 5A's in 2012. In most sites (10 out of 12), a FAIR form was present in at least 75% of charts reviewed. Six of the sites were documenting 'ask' for at least 75% of their clients. (Table 3).

Table 3: 5A's implementation status among reviewed charts of pregnant clients of 12 Ohio WIC sites implementing the 5A's, by site, 2012

WIC sites	Total ¹	FAIR form ² N (%)	Ask ³ %	Smokers N	Advise ⁴ %	Assess ⁴ %	Assessed N	Assist ⁵	Arrange ⁵	Status
A	63	58 (92.1)	72.4	32	59.4	53.1	17	23.5	0.0	Partial
B	70	53 (75.7)	86.8	33	72.7	81.8	27	40.7	0.0	Partial
C	55	55 (100.0)	100.0	27	96.3	81.5	22	90.9	68.2	Full
D	63	36 (57.1)	88.9	25	80.0	64.0	16	37.5	12.5	Partial
E	51	5 (9.8)	100.0	4	75.0	100.0	4	50.0	0.0	Partial
F	59	56 (94.9)	98.2	33	93.9	90.9	30	76.7	3.3	Full
G	51	50 (98.0)	98.0	24	33.3	33.3	8	25.0	0.0	Partial
H	51	41 (80.4)	100.0	19	73.7	63.2	12	25.0	0.0	Partial

I	70	65 (92.9)	55.4	39	84.6	79.5	31	51.6	6.5	Partial
J	64	52 (81.3)	98.1	32	87.5	87.5	28	46.4	35.7	Partial
K	65	65 (100.0)	96.9	38	84.2	81.6	31	45.2	9.7	Full
L	62	48 (77.4)	93.8	30	100.0	93.3	28	67.9	10.7	Partial

¹Total number of charts reviewed. ²The number of reviewed charts that had FAIR forms. ³Of reviewed charts that had FAIR form present in charts. ⁴Of reviewed charts of smokers that had FAIR form present in chart. ⁵Of reviewed charts of smokers who had been assessed for readiness to quit.

Summary

Twelve of the 22 trained WIC sites continued to implement the 5A's in 2012, though with varying degree of fidelity to all 5 steps. A higher proportion of clients who reported smoking at initial clinic visit had a FAIR form in file and had Ask documented compared to those who reported not smoking at initial visit. Documentation of 'Ask' was common; however, documentation of the subsequent steps of the 5A's was less frequent, decreasing to only 14% for 'Arrange'. Full implementation of the 5A's in each WIC site is very low; the majority of previously trained sites only partially implement the 5A's.

Degree of 5A's Implementation: CFHS Clinics

Methods

Data Collection

In Ohio CFHS clinics, staff providing clinical care use the FAIR form to document their use of the 5A's intervention with each client. The FAIR form is kept with the patient's chart, and data from the form is entered (usually by clerical staff at the clinic) into Ohio's Integrated Perinatal Health Information System (IPHIS). The IPHIS system is used by several different ODH programs, and does not contain a specific field for entering 5A's data from the FAIR form. In order to use the IPHIS system to track the implementation of the 5A's in CFHS clinics, program staff developed a data entry code system whereby clinics can enter data from the FAIR form into a general field in the IPHIS system. This field is called the "Local Use 2" field. Clinics were directed to enter a code describing the latest step of the 5A's completed at each visit for each client into the Local Use 2 field for the client visit (Appendix 6). Clinics can also document smoking status in IPHIS using a different field, under "Social Behavioral Risk Factors".

To assess the degree of implementation of the 5A's at CFHS clinics, since the expansion of the program into this setting in late 2011 and early 2012, we examined data collected in IPHIS between July 1, 2012 and June 30, 2013. This timeframe excludes the first 6 months of implementation, during which many clinics had difficulty adjusting to the new data entry codes.

Analysis

Data extracted from the IPHIS system was analyzed using Excel and SAS9.3. Summary counts of number of clients, number of visits during the study period, and frequency of missing data were generated. To evaluate the validity of smoking data contained in the Local Use 2 field, we compared smoking documented in Local Use 2 with smoking documented as a Social Behavioral Risk Factor. To measure the number of smokers documented using Local Use 2, we assumed that any client who received any data entry code for steps 2-5 of the 5A's was a current smoker, and added these to the number identified using the code 1C (current smoker) from the "Ask" step. Although we could not assess with certainty the

T	114	863	18	28	26	-2	223	11	0	5%
U	123	312	11	31	26	-5	80	0	0	0%
V	129	704	<1	17	18	+1	129	2	2	3%
W	295	1711	40	19	19	0	327	28	1	9%
X	111	336	36	15	38	+23	126	53	0	42%

* = Too few visits to present data; LU2 = Local Use 2 field

Because the program was still relatively new in 2012, we compared the % of Local Use 2 fields left blank during the last 6 months of the study period (Jan 2, 2013 to June 30, 2013), with the study period as a whole. Some clinics had improved their data quality (as measured by number of missing Local Use 2 field data codes) during the second half of the study period.

Table 5. Comparison of percent of Local Use 2 (LU2) fields left blank, entire study period vs. last 6 months, Ohio CFHS clinics, 2012-2013

County	% LU2 left blank July 1, 2012 to June 30, 21013	% LU2 left blank Jan 2, 2013 to June 30, 2013
M	61	17
N	22	23
O	25	27
P	31	24
Q	75	49
J	3	2
R	32	8
S	Too Small	Too Small
T	18	10
U	11	10
V	<1	<1
W	40	12
X	36	32

Summary

Extensive cleaning of the data entry codes in the Local Use 2 field was required to assess any 5A's implementation for the CFHS clinics. Overall, there was substantial missing data from the Local Use 2 field; more than half of clinics had the Local Use 2 field left blank for 25% or more of visits. Some clinics did have improved reporting using the Local Use 2 field during the last half of the study period.

Most clinics had good agreement between the smoking status of clients documented in the Social Behavioral Risk Factors section of the IPHIS record and the Local Use 2 field. Documentation of referrals to smoking cessation counseling or the Ohio Tobacco Quit Line was poor; only one clinic documented a

referral for services at more than 50% of the visits where a client was identified as a smoker using the Local Use 2 field.

Impact of Exposure to WIC Clinic Implementing the 5A's

Methods

Data Source

To assess the impact of exposure to a WIC clinic implementing the 5A's intervention on a woman's odds of quitting smoking during pregnancy, we used data from the Centers for Disease Control and Prevention's Pregnancy Nutrition Surveillance System (PNSS). PNSS is a voluntary program-based surveillance system created to monitor the prevalence of nutritional and behavioral risk factors related to mortality and low birth weight among infants of low-income pregnant women. PNSS data are collected on pregnant women during the initial prenatal and postpartum visit to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). This study focuses on women receiving WIC services in Ohio. PNSS was discontinued in 2012, so we used PNSS data collected from the period one year prior to the initial pilot of the 5A's program (2005) through the last available data year (2011). The study was determined to be exempt from review by the Centers for Disease Control and Prevention's institutional review board.

From 2005-2011, 327,840 women met our inclusion criteria (having a first prenatal visit in the first or second trimester of pregnancy). Of these, 81,313 reported that they were currently smoking at the time of the first WIC visit and thus eligible to be in our study population. We excluded 9,786 women who were missing data on smoking during the last 3 months of pregnancy (ie., lost to follow up because women did not return for a postpartum visit). We additionally excluded 1 woman who was missing covariate data. Thus, our analytic sample included 71,526 women who reported smoking at their initial prenatal visit: 88% of our eligible population.

Definitions

We categorized mother's smoking status during pregnancy based on the woman's report of smoking at the initial prenatal visit and during the last 3 months of pregnancy assessed at the postpartum visit. Women who reported smoking at initial prenatal visit were coded as smokers, and those who reported smoking at the prenatal visit but not during the last 3 months of pregnancy were coded as quitters. We further categorized smokers as heavy smokers if they reported at the initial visit smoking 10 or more cigarettes per day.

Using chart review data from ODH's site visits at WIC clinics providing the 5A's (described in detail above), clinics were categorized by documentation status based on their utilization of the FAIR forms. Clinics were categorized as "documenting", if they had been trained and were documenting the 5A's using the FAIR forms at the time of the site visit; "non-documenting", if they had been trained but were not documenting the 5A's using the FAIR forms at the time of the site visit; or "untrained" if they had never received 5A's training provided by ODH. Because clinics were trained in different years and could have changed documentation practices from year to year, each clinic's implementation status was determined for each study year.

Statistical Analysis

We estimated the odds ratio for smoking cessation among smokers based on exposure to the levels of training and documentation of the 5A's, using a conditional regression model, stratified on clinic. We controlled for the following covariates in our model: maternal age, race/ethnicity, education, trimester of WIC enrollment, heavy smoking and calendar year. Analyses were performed using SAS (SAS Institute Inc., Cary, North Carolina). We assessed statistical significance at $P < 0.05$.

Results

Women who were excluded from the analysis were more likely to: have a lower education; enroll in WIC in the first trimester; and be of a race/ethnicity other than white. (Table 6)

Overall, 24.8% of women reported smoking at WIC entry, 23.0% of whom quit by the last 3 months of pregnancy. Among smokers, 88.1%, 5.4%, and 6.5% attended never trained, documenting, and non-documenting clinics, respectively.

Compared to women attending the same clinic prior to the clinic being trained on the 5 A's, women who attended the clinic after the clinic received training had an 18-20% higher odds of quitting smoking by the 3rd trimester (Table 7). Upon stratifying according to clinic documentation status (and adjusting for age, race/ethnicity, education, trimester of WIC enrollment, heavy smoking and year), compared to women attending the same clinic prior to the clinic being trained on the 5 A's, women who attended the clinic after training and the clinic was documenting the 5 A's had an 18% higher odds of quitting smoking by the 3rd trimester (aOR 1.18, 95%CI 1.03, 1.36)); whereas women who women who attended the clinic after training but the clinic was not documenting the 5 A's a 14% higher odds of quitting (aOR 1.14, 95%CI 0.98, 1.32)).

Summary

Smoking cessation was highest among pregnant women who attended a WIC clinic that was implementing the 5A's and using the FAIR form to document their use of the intervention. By expanding training and ensuring the 5A's are documented, Ohio may expect the odds of women quitting smoking to increase by 18%. Documenting clinics may benefit from identifying the factors related to the varying degrees of fidelity with which clinics are documenting the steps using the required forms. Furthermore, a better understanding of why non-documenting clinics are not currently documenting as trained is required. The barriers associated with documentation can then be addressed, and clinics encouraged to document as trained. These will potentially improve the smoking cessation results obtained from participating WIC clinics in Ohio and improve the gains for maternal and child health.

Table 6: Differences between smokers eligible to quit excluded from and those included in the study

Characteristics	Study population n (%)	Excluded	N (%)	P value
Maternal age(years)		9,787		<0.001
<15	154 (0.2)		11 (0.1)	
15-17	3,666 (5.1)		488 (5.0)	
18-19	11,643 (16.3)		1,568 (16.0)	

20-29	45,646 (63.8)	6,105 (62.4)	
30-39	9,800 (13.7)	1,474 (15.1)	
40+	617 (0.9)	141 (1.4)	
Maternal race/ethnicity		9,753	<0.001
White	60,857 (85.1)	7,814 (80.1)	
Black	8,128 (11.4)	1,556 (16.0)	
Hispanic	1,340 (1.9)	215 (2.2)	
American Indian	253 (0.4)	38 (0.4)	
Hawaiian/Pacific Islander/Asian	252 (0.4)	40 (0.4)	
Multiple	696 (1.0)	90 (0.9)	
Maternal education(years)		9,787	<0.001
<12	24,544 (34.3)	3,907 (39.9)	
12	38,492 (53.8)	4,771 (48.8)	
13-30	8,490 (11.9)	1,107 (11.3)	
Trimester enrolled in WIC		9,787	<0.001
1 st	37,756 (52.8)	5,814 (59.4)	
2 nd	33,770 (47.2)	3,973 (40.6)	
Type of smoker		9,787	0.04
Light	40,977 (57.3)	5,477 (56.0)	
Heavy	30,400 (42.5)	4,292 (43.9)	
Missing	149 (0.2)	18 (0.2)	
Quit smoking in 3rd trimester		466	0.36
No	55,043 (77.0)	367 (78.8)	
Yes	16,483 (23.0)	99 (21.2)	
Type of clinic attended		9,787	<0.001
Never trained	63,005 (88.1)	8,758 (89.5)	
Documenting	3,849 (5.4)	504 (5.2)	
Non-documenting	4,672 (6.5)	525 (5.4)	

Table 7: Crude and adjusted odds of quitting smoking by implementation, 2005-2011

Exposure status	Crude Odds Ratios (95% CI)	Adjusted Odds ratios (95% CI)
Never trained	1.00	1.00
Documenting	1.20 (1.06, 1.37)*	1.18 (1.03, 1.36)*
Non documenting	1.18 (1.03, 1.36)*	1.14 (0.98, 1.32)

Implementation Status	Crude Odds Ratio (95% CI ¹)	Adjusted Odds Ratio (95% CI ¹)
Documenting	1.21 (1.07, 1.37)*	1.15 (1.02, 1.31)*
Non-documenting	1.16 (1.03, 1.32)*	1.09 (0.96, 1.25)

Never trained	1.00	1.00
---------------	------	------

¹CI: confidence Interval. *Significant at $P < 0.05$

Facilitators and Barriers to Implementation of the 5A's Intervention

Methods

A mixed methods approach was used to evaluate the facilitators and barriers to implementation of the 5A's program: (1) semi-structured interviews with key informants and (2) electronic survey administered to staff at all sites that ever received training in the 5A's. A qualitative approach utilizing semi-structured interviews was chosen in order to ensure that the beliefs, attitudes, and contexts for clinic decision makers were captured by our investigation. The semi-structured interview allows interviewers to ask similar open-ended questions of each participant, and provides flexibility to vary the sequence or format of questions in order to pursue certain topics. This method allows data collection to be flexible, in-depth, and conversational. Because clinic decision makers might not have extensive experience in providing the 5A's counseling to clients, we also collected quantitative data from clinic staff using a survey adapted from previously validated tools designed to assess the provision of smoking cessation counseling in clinical settings.

Semi-structured Interview Participants

Clinic sites eligible for this assessment were all CFHS direct perinatal care clinics (N = 13) and any WIC program ever trained in using the 5A's (N = 19). Key informants were identified with assistance from ODH Program Consultants for each program. In most cases, the key informant was the current clinic or program director for each site. In some cases, the key informant was a former clinic or program director for the site; and in some cases, the key informant was a different staff person at the site. Key informants were notified of the project by the Ohio Department of Health CFHS program manager, prior to being contacted by the study team. When contacted, participants were informed about the purpose of the study and invited to schedule an interview at their convenience during the study period.

Semi-structured Interview Methods

Key informant perceptions and attitudes toward the 5A's intervention were evaluated through qualitative analysis of semi-structured interviews. The team developed three interview guides: one for CFHS clinics; one for WIC clinics currently implementing the 5A's with documentation using the FAIR form; and one for WIC clinics previously trained, but not currently documenting use of the 5A's using the FAIR form. The guides were reviewed by ODH staff familiar with the WIC and CFHS programs, and by CDC researchers participating in the investigation. After the development of the semi-structured interview guides (Appendices 2-4), the 4 researchers who were conducting interviews were trained in semi-structured interviewing techniques by a researcher with experience in conducting qualitative interviews. The interviewers practiced conducting interviews using the guides with each other, and with ODH staff members familiar with WIC and CFHS clinics.

Interviews were conducted over the phone or in person during a 10 day period in September, 2013. Interviews continued until saturation— the point where no new themes were emerging from the interviews. An effort was made to ensure that data collection continued long enough to capture clinics in different county types, of different sizes, and with different current 5A's implementation status.

A two-person team comprised of an interviewer and a note taker conducted phone or face-to-face interviews. Four WIC sites (Sites A, G, J, and K) and two CFHS sites (County O and County U) were selected for site visits. Site visits provided the researchers with an opportunity to learn about the services provided at the clinics and understand the context in which the 5A's intervention is occurring, as well as to observe the processes used at each site to implement the intervention. Key informants from the selected site visit clinics were given an opportunity to complete the interview during the site visit or at another time over the phone. Locations selected for site visits represented different types of settings (small and large programs), varied degree of 5A's implementation (based on 2011 chart review data), and county type (rural, Appalachian, and urban).

Notes taken during the interview were expanded into detailed field notes for thematic analysis (Halcomb & Davidson, 2006). With permission of the participants, each interview was digitally audio recorded. Digitally recorded interviews were immediately reviewed independently by the interviewer and the note-taker to expand each researcher's field notes. Use of the digital recording ensured that field notes were accurate and descriptive, although verbatim transcripts of each interview were not used for analysis.

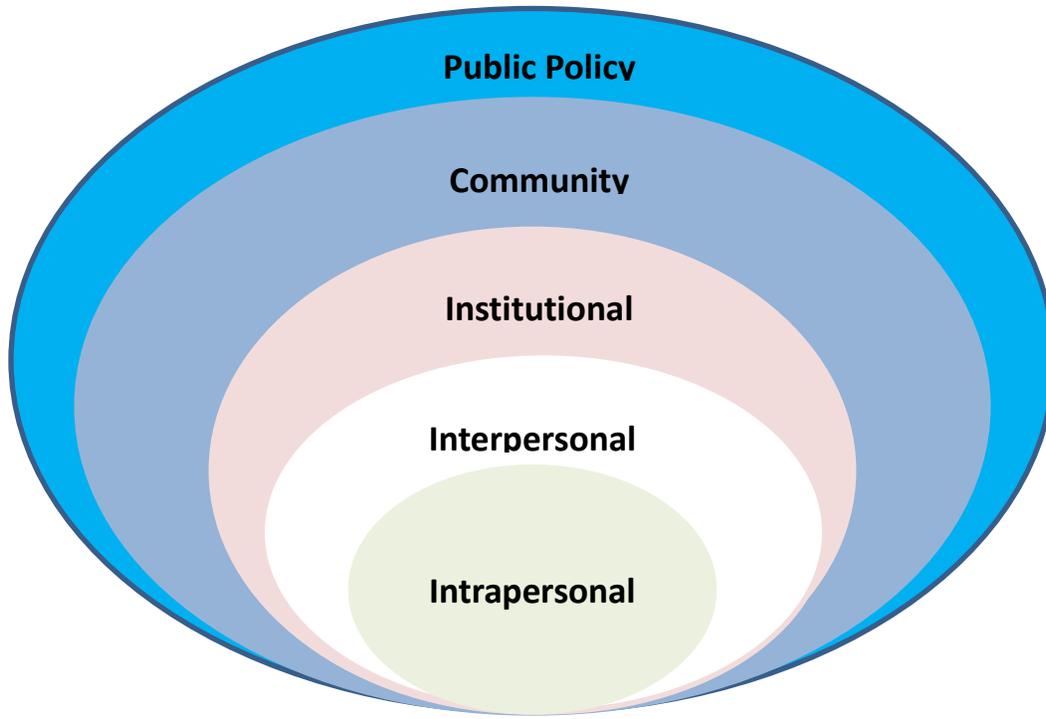
Qualitative Analysis Methods

Members of the 4-person interview team independently reviewed their expanded field notes and identified themes that emerged during the interviews. The team met to develop a list of common themes, and generated codes based on the themes. Each interviewer and note taker used codes to annotate the expanded field notes. Interviewer/note-taker teams met to reconcile any differences in coding. The 4-person team met daily to discuss new themes that were emerging and to assist with reconciling differences between coding performed independently by the interviewer/note-taker teams.

Once all of the expanded field notes were coded and differences in coding between team members were reconciled, the team reviewed the complete list of themes and developed a theoretical framework to interpret the identified themes in the context of the study objectives. Because the focus of this study was identifying facilitators and barriers to the implementation of the 5A's in the clinic setting, themes were categorized as either a facilitator or barrier. The facilitators and barriers were analyzed using a theoretical framework based on the social-ecological model (McLeroy, Bibeau, Steckler, & Glanz, 1988). The social-ecological model describes the interaction between the individual and his or her social environment at different levels of analysis, and its effect on human development or patterned behaviors (Figure 2). For this analysis, facilitators and barriers were examined at the intrapersonal, institutional, and community level. These findings were then used to

generate recommendations for the enhancement and expansion of the 5A's program in perinatal settings in Ohio.

Figure 2. Social-ecological Model



Semi-structured interview results

The team conducted interviews with key informants at a total of 21 clinics (9 CFHS, 12 WIC) located in various county types. Interviews with CFHS clinic sites were representative of county types served by CFHS direct perinatal care programs and included sites in metropolitan, suburban, and Appalachian counties. Interviews with WIC sites were representative of WIC programs participating in the 5A's program and included programs representing Appalachian, suburban, rural, and a small number of metropolitan counties. (Table 8). Most key informants were current program or project directors, but others were nurse managers, social workers, or former project directors.

Table 8. Characteristics of participating WIC and CFHS clinics.

	WIC (Interviewed/Eligible)	CFHS (Interviewed/Eligible)
Documenting	11/12	13/13
Non-Documenting	3/7	0/0
Appalachian	6/6	1/1

Rural, non-Appalachian	5/7	0/1
Suburban	2/4	2/5
Metropolitan	1/2	6/6
Total	14/19	9/13

We categorized themes as “facilitators” or “barriers” to the implementation of the 5A’s program at levels of analysis described in the social-ecological model: intrapersonal (client), institutional (clinic) and community. It is important to note that the themes relate to facilitators and barriers at each level are the *perceptions* of the key informants. All key informants were in administrative positions at the clinic level and may have varying connection to individual clients or communities that the programs serve. The participants did not provide insight into any facilitators or barriers that might be operating at other levels (interpersonal, public policy) levels of the social-ecological model. Similar themes were expressed by key informants for both WIC and CFHS clinics, so interview notes were not separated for analysis; results are presented together.

Themes and illustrative quotes from participants are grouped in Table 9. Interview participants spoke freely about the problem of perinatal smoking among their clients and the use of the 5A’s program within their clinic setting. These discussions generated rich information about facilitators and barriers at the intrapersonal, institutional, and community level. Some themes varied by context; for example, clinics located in counties where additional tobacco cessation support services were available identified those resources as a facilitator to their efforts to use the 5A’s, while clinics without additional smoking cessation resources perceived the lack of community resources as a barrier. Reflecting on the challenges of addressing perinatal smoking with clients, participants identified several barriers to using the 5A’s at the client level. Community level facilitators and barriers refer to themes or ideas that participants observed in their clinic’s community as a whole, including general attitudes toward perinatal smoking.

A perceived preference among clients (at the intrapersonal level) and perhaps even other institutional settings (at the community level) for a harm reduction approach was identified as a barrier to implementing the abstinence-focused 5A’s program. Participants noted that clients frequently reported already having “cut down” or tried a harm reduction approach prior to their visits: *“A lot of moms don’t really want to quit, they just want to slow down.”* Moreover, some participants noted that their clients reported that their physician or another health care provider had recommended a harm reduction approach rather than full abstinence from tobacco: *“Some of*

the physicians don't really press them to quit; they just encourage that they decrease the amount." Some participants also reported that they or their staff might try a harm reduction approach with a client who is not yet ready to commit to quitting smoking: *"Maybe we could suggest that she cut down a little bit."* It appears that harm reduction is a prevalent approach in the communities served by WIC and CFHS programs in the state, despite the fact that this approach is not recommended by experts in pregnancy and tobacco use.

Several concepts emerged during the interviews that suggested that staff need improved training in providing counseling. These included ideas related to the quality of the training (e.g. scope, audience, format, and implementation) as well as the quantity of training (e.g. frequency and duration). One of the frequently cited ideas related to the quality of training was that training should be "more hands on" and provide staff with the opportunity to "practice" the counseling skills. Although not cited by the majority of participants, several expressed concerns about the evidence for effectiveness of brief counseling interventions for smoking cessation. Some expressed a preference for abbreviated interventions such as the "2A's + R" model, suggesting that the rationale for the use of the 5A's model might need to be included in future training.

Table 9. Facilitators and Barriers to 5A's implementation by level

Intrapersonal (Client) Level		
Category	Theme	Quote
Facilitators	Risk awareness	<i>"I think that from all the information that has been put out in the community, that they realize that they need to quit."</i>
Barriers	Harm perception	<i>"[In some less educated parts of the population], they're gonna say that it's, you know, 'My mom did it, my sister did it, my grandma did it, it's ok- all our babies turned out healthy.'" "They really don't understand what this is doing to the baby, or they can easily rationalize, 'I really need that cigarette.'"</i>
	Lack of empowerment	<i>"It's hard for her to ask her parents not to smoke, in their own home." "Some of them maybe live with the baby's dad's parents... and they've been smoking for years and they can't ... make them quit because it's their home. And if they don't believe that it's harmful..."</i>
	Preference for harm reduction	<i>"A lot of moms don't really want to quit, they just want to slow down"</i>
	Stress	<i>"Going to that nicotine is their only escape"</i>
	Tobacco addiction	<i>"Just the fact that it's hard to quit smoking... It's hard to give up that hand-mouth thing." "That hit of the nicotine and whatever else is probably really helping them get through their day."</i>

	Lack of social support	<i>"Family members also smoke so they don't have that support."</i>
Institutional (Clinic) Level		
Category	Theme	Quote
Facilitators	Available community resources	<i>"We have a very good smoking cessation program here, and they have weekly meetings."</i>
	Material resources	<i>"We have education things that we hand out." "Having the materials to provide to the clients so it's not like 'Well, this is what we recommend, but you're on your own!'"</i>
	Integration of the 5A's into clinic routines	<i>"Since we do it all the time, I don't really think about it that much."</i>
	Innovation	<i>"If they have texting capabilities, we provide them with a sticker... that has the name of the program- it's similar to 'Text 4 Baby.'"</i>
	Perceived strengths of 5A's intervention	<i>"I think it helps us focus on what questions to ask, and the process." "Any time you have an initiative... it makes that awareness apparent."</i>
	Use or potential for technology	<i>"People learn in different ways... I don't know if it would be beneficial for those who when they start the program and they are smoking, to even have them watch a video, that's like a motivational-type video."</i>
Barriers	Time constraints	<i>"We're very limited on time."</i>
	Prioritization of topics during client visit	<i>"Just about the only challenge would be finding the time to get that put in. We address so many things, especially that first appointment- between breastfeeding, and nutrition, and registering to vote; going through the foods list, explaining the whole program- it can get to be quite... tedious."</i>
	Challenges with documenting use of intervention	<i>"[My staff] wish it could just be incorporated into the WIC paperwork, because sometimes they feel they are writing the same thing twice." "[It was] really confusing at first, like, what we were doing."</i>
	Lack of community resources	<i>"Why do all this counseling and then you have no one [for them] to follow up with? It's like a dead end." "Right now, all we have is the Quit Line and that doesn't work for everyone." "There's not a lot of community support... that was identified as one of the needs [as part of Community Health Assessment]" "We don't have any local quit groups either. We do use the Quit Line but we don't have any other local type of resources."</i>
	Concerns about	<i>"[Having] data would be the ultimate reason as to</i>

	effectiveness of intervention	<i>why staff would continue. If I could prove to them that we're actually making a difference, then they would feel more value for the program."</i>
	Inadequate training	<i>"Maybe have some sample plays... act out things." "I think we need more tools." "I don't know that they [staff] understand why exactly this is going on... like, 'why are we asking this every time?'" "That's where we're lacking, some extra education and background, and how we can make it work for our populations, too."</i>
	Lack of knowledge about Ohio Tobacco Quit Line	<i>"[re: Fax referrals] I've heard people say that they're so understaffed that it's hard to get a good response from them." "I've not called the Quit Line myself." "We don't have anywhere to refer people further other than the Quit Line."</i>
	Challenges with follow-up of individual clients	<i>"When they come back, if they don't need follow-up... and they just are picking up coupons, then the health professional does not see them. So we would not address it. At their next cert or re-cert, which is normally at the time the child is born, that's when it's addressed again."</i>
	Lack of self-efficacy	<i>"Having staff that are competent from asking to arranging is really what I think they need." "If there was any kind of real thing for when [clients] hand you that wall, like, 'nope, road block', if there were really strategies that we know really work that perhaps we're not using or that we could add to our toolbox, that would be wonderful."</i>

Community Level

Category	Theme	Quote
Facilitators	Risk awareness	<i>"I think that they [community members] know that it's wrong and that it's harmful... I think they look down on it [smoking during pregnancy]."</i>
Barriers	Social norms around smoking	<i>"Just cultural norms, you know, all their friends smoke." "They've been smoking for generations."</i>
	Lack of strong abstinence message	<i>"Some of the physicians don't really press them to quit; they just encourage that they decrease the amount" "Maybe we could suggest that she cut down a little bit"</i>

Survey methods

An electronic survey was also used to assess practices and attitudes related to the implementation of the 5A's intervention among clinic staff (Appendix 5). The survey was adapted from previously validated surveys. It was piloted to ODH staff before distribution to directors in both WIC and CFHS clinics. The directors were then asked to send the survey link to all staff members for completion. A follow-up e-mail was sent to project directors to remind them of the survey after 5 days. Results from this survey are presented using analytical functions within Survey Monkey, Excel, and SAS 9.3.

Survey results

A total of 118 staff members completed the electronic survey. In all, 18 of 19 (95%) WIC programs and 10 of 13 (77%) of CFHS direct perinatal clinics were represented. The number of respondents per clinic ranged from 0 to 11 in WIC programs and 0 to 8 in CFHS programs (Table 10). Among respondents who provided demographic information, nearly all (99%) were female and most (72%) reported age 40 years or older. Among respondents who provided their smoking history, most (69%) reported never smoking or smoking less than 100 cigarettes during their lifetime (Table 11). Roughly equal numbers of respondents reported working as nutrition or dietetic staff (32%) and medical staff (33%). Administrative roles were also commonly reported (20%). Other respondents reported working as social workers (7%), breastfeeding promotion (6%), and interpreting (2%). Staff members who reported working at a WIC site were more likely to work in a dietetic role ($p < 0.01$) and less likely to work in a medical role ($p < 0.01$) compared to staff at CFHS clinics (Table 12).

Fewer than half of all respondents (48%) reported ever receiving training in smoking cessation. Of those who received training, 41 of 55 (75%) received training provided by ODH. All respondents were asked about what topics related to smoking cessation they would like to know more. Among 113 who responded, the most common topics indicated were "motivating patients who continue to smoke to quit", "skill-building for how to talk to pregnant patients about quitting smoking", and "the role of medications in treating tobacco addiction." (Table 13). The survey also assessed self-efficacy by asking respondents to rate their level of confidence in performing different skills of related to smoking cessation counseling. After excluding those who reported that they do not provide smoking cessation services, most respondents (74%) reported a high level of confidence in providing referrals to others or the Ohio Tobacco Quit Line for appropriate treatment. The lowest levels of confidence (33%) were reported in discussing treatment options with clients. Moderate self-efficacy was reported in the category of motivating clients to consider quitting, with 50% reporting some confidence and 36% reporting a high level of confidence (Table 14).

Respondents were also asked to rate their level of agreement (1- strongly disagree to 10-strongly agree) with several statements about the receptiveness of their pregnant and postpartum patients to the smoking cessation intervention and its overall effectiveness. Respondents agreed more strongly with the statement that pregnant patients were receptive to smoking cessation

interventions compared to the statement that postpartum women were more receptive to smoking cessation interventions (mean score: 6.4 vs. 4.8, $p < 0.0000001$). However, the mean score for the statement “brief counseling is effective in helping pregnant women quit smoking” was 5.2, indicating some ambivalence about the effectiveness of the 5A’s program (Table 15). Finally, respondents were asked if they have encountered any barriers to providing smoking cessation counseling. Nearly half (47%) reported experiencing barriers with the most cited being lack of patient interest (59%), insufficient amount of time to spend with clients (51%), and lack of community resources for referral (43%) (Table 16).

Table 10. Survey participation by WIC and CFHS sites invited to complete the survey.

WIC programs	Number of respondents	CFHS direct perinatal care clinics	Number of respondents
Adams-Brown	5	Butler County	0
Allen	5	Clermont County	1
Champaign	3	Columbus Public Health	7
Clark	4	Cuyahoga County	0
Erie-Huron	1	Greene County	8
Geauga	2	Lake County	2
Hancock-Hardin-Putnam	7	Lucas County	1
Highland	2	Madison County	1
Hocking	1	Miami County	3
Holmes	3	Richland County	6
Jackson	1	Stark County	3
Knox	2	Warren County	6
Lake	7	Wood County	0
Marion	3	Other	3
Medina	4		
Muskingum	10		
Preble	4		
Shelby	0		
Summit	11		
Missing	2		

Table 11. Smoking status of respondents.

Smoking Status	Frequency	Percent
I have never smoked or have smoked less than 100 cigarettes in my lifetime	76	69%
I used to smoke, but I stopped and I am not smoking now	27	25%
I currently smoke, and I have never tried to stop	1	1%

I currently smoke, and I have tried to stop at least once	6	5%
---	---	----

Table 12. Role in clinic by site type (WIC compared with CFHS).

Role in clinic	Total (%); N = 117	WIC (%); N = 76	CFHS (%); N = 41	p-value
Dietetic (RD, Dietetic tech, other nutrition)	38 (32%)	37 (32%)	1 (1%)	<0.000001
Medical (RN, Medical assistant, other medical)	39 (33%)	14 (12%)	25 (21%)	<0.00001
Social work	8 (7%)	1 (1%)	7 (6%)	0.005
Administrative (Administrator, office staff)	23 (20%)	17 (15%)	6 (5%)	0.32
Breastfeeding peer	7 (6%)	6 (5%)	1 (1%)	0.45
Other (interpreter)	2 (2%)	1 (1%)	1 (1%)	>0.99

Table 13. Topics related to smoking cessation that WIC and CFHS direct perinatal care clinic staff would like to know more about.

Answer Options (N = 113)	Percent	Response
Motivating patients who continue to smoke to quit	46.9%	53
Skill-building for how to talk to pregnant patients about quitting smoking (i.e., motivational interviewing techniques)	40.7%	46
The role of medications in treating tobacco addiction during pregnancy and the postpartum period	40.7%	46
How to ask clients about smoking so you get an honest response	36.3%	41
What to do if a client continues to smoke	36.3%	41
What self-help materials to give a smoker	34.5%	39
How to help the smoker get support from her home or workplace	33.6%	38
How to advise a client to stop smoking	32.7%	37
How to provide social support as part of cessation treatment for a woman who smokes	29.2%	33
The negative effects of smoking on a pregnant woman, the developing fetus, other children, and other household members	27.4%	31
Working with pregnant smokers under the age of 18	23.9%	27
Understanding other social and medical problems that sometimes occur in smokers (other drug and alcohol use, mental health issues, etc.)	19.5%	22
Understanding tobacco use as an addiction	17.7%	20
How to organize the clinic in terms of record keeping and client flow so that the smoking status of a client is assessed at follow-up visits	3.5%	4

Table 14. Confidence of WIC and CFHS direct perinatal care clinic staff in their ability to perform components of the 5A's intervention.

Please rate your confidence in doing the following to help your clients quit smoking	Low confidence	%	Some confidence	%	High confidence	%	total
Advise client to quit smoking	3	3%	31	33%	61	64%	95
Assess client willingness to quit	10	11%	36	38%	48	51%	94
Discuss treatment options with clients	31	33%	35	38%	27	29%	93
Motivate clients to consider quitting	13	14%	47	50%	34	36%	94
Refer to others or quit line for appropriate treatment	5	5%	19	21%	68	74%	92
Monitor client progress in attempting to quit	10	11%	36	40%	44	49%	90
Provide support to clients who have relapsed	22	24%	41	46%	27	30%	90

Table 15. Mean scores for agreement with statement, 1=strongly disagree; 10=strongly agree.

Rate your agreement with the following statements:	Mean	Median	N
Pregnant smokers are receptive to smoking cessation interventions	6.4	7	102
Postpartum smokers are receptive to smoking cessation interventions	4.8	5	102
Brief counseling is effective in helping pregnant women quit smoking	5.2	5	102
I do not counsel my patients to quit smoking because other providers outside of my clinic provide these resources	2.9	2	91
Learning how to counsel my patients to quit smoking is not a priority for me because I must focus on other health issues with my patients	3.4	2	94

Table 16. Barriers encountered when providing smoking cessation intervention at WIC and CFHS direct perinatal care clinics.

Answer Options (N = 53)	Response Percent	Response Count
Lack of patient interest	58.5%	31
I don't have enough time to spend with patients	50.9%	27
Lack of community resources for referral	43.4%	23
I don't have enough experience counseling smokers	41.5%	22
Unable to prescribe medications to assist with smoking cessation	32.1%	17

Other client services have are a higher priority	30.2%	16
Lack of educational materials	24.5%	13
I don't have confidence in my intervention skills	18.9%	10
Reimbursement for smoking cessation counseling	11.3%	6
Other (please specify)	11.3%	6
No existing mandate/policy/requirement to provide smoking cessation services	7.5%	4
Lack of staff support	7.5%	4
I don't believe smoking interventions are effective	5.7%	3
I don't see very many smokers in my practice	3.8%	2
I don't spend much time on direct patient care	3.8%	2
I don't feel motivated to provide these services	1.9%	1

Conclusions

Assessment of implementation of the 5A's intervention

The results of the analyses conducted as part of the Epi-Aid indicate that the 5A's smoking cessation counseling intervention has been implemented with variable degrees of fidelity in WIC and CFHS clinics in Ohio. Chart reviews conducted periodically by the OPSFF program staff to gather data on the implementation of each of the 5 steps at WIC sites demonstrated that nearly half of trained sites were no longer documenting the use of the 5A's using the FAIR forms, and that only 25% of the sites actively using the 5A's were documenting that the intervention was being fully implemented at the time of the chart review. Data extracted from Ohio's IPHIS electronic data system similarly showed wide variation in the documentation of any component of the 5A's intervention; only one clinic documented that most visits where smoking was identified as a risk factor resulted in a referral for smoking cessation services.

The finding that most WIC sites are not documenting full implementation of the 5A's is particularly concerning, because our definition of "fully implementing" was fairly loose, only requiring that nearly all clients be asked about smoking status, and that more than half be advised to quit smoking. There are some limitations to our analysis of the fidelity of implementation of the 5A's in WIC sites. We relied on chart reviews conducted by ODH staff about 1 year prior to the Epi-Aid, and practices at the sites could have changed. As mentioned earlier, for WIC programs with multiple clinic sites, charts were reviewed at the main clinic site, rather than at the smaller or satellite clinics. Thus we made an assumption that the degree of implementation in smaller or satellite clinics was the same and reflected by that obtained for the main WIC clinic visited. It is possible that the degree of implementation of the 5A's in satellite or smaller clinics actually differed from that in the main WIC clinics. Furthermore, the criteria for determining degree of implementation (i.e. full or partial) were set arbitrarily by the research team and not by a standardized set of criteria. Thus, it is possible that clinics be categorized differently if stricter (or more generous) cut offs were set and used for the analysis.

Our assessment of the fidelity of the implementation of the 5A's intervention at CFHS clinics also had some important limitations. We conducted our analysis at the visit level; some women had multiple visits during the study period. This means that actual smoking rates cannot be inferred from the data presented here. Also, it is unclear from the analyses we were able to complete whether a woman who received the 5A's intervention at one visit would be more or less likely to receive additional counseling at subsequent visits. Thus, we cannot be sure what percent of smoking patients were referred for services, because there might be women who received a referral at each visit, and they would be counted multiple times. However, analyzing at the visit level can be helpful for program evaluation purposes, since the intention is that the 5A's intervention is provided to every patient at every visit. Further analyses of this data should be conducted at the individual client level.

We were unable to use the data contained in the IPHIS system to assess the percent of women who received each step of the intervention. The data entry code system was designed for clinics to report the last step provided to each client; since it is possible that providers could have performed steps out of order (for example, providing a referral or arranging follow up without first assessing a client's willingness to quit), the current system does not allow for a detailed examination of the implementation of each step, as was conducted using the chart review data for participating WIC clinics. Nevertheless, the low rate of referrals overall and the large amount of missing data in the Local Use 2 field are an indication that the program should be strengthened in the CFHS clinics as part of the overall program expansion. Especially in light of our qualitative findings, that the burden of documenting the use of the program was perceived as a barrier to implementing the program with fidelity, it is important to carefully consider how the data collected through this system can be useful to the participating clinic sites.

Assessment of the impact of the 5A's program in WIC clinic in Ohio.

This is the first study conducted in Ohio that attempts to measure the impact of use of the 5A's program on smoking cessation among women utilizing WIC services. Our analysis indicates that there has been a moderate positive effect on smoking cessation during pregnancy. However, our analysis does have some limitations. First, smoking status was self-reported with no biochemical confirmation. Studies have shown that self-reported smoking status is generally reliable, although might be less so among pregnant women due to social desirability bias. Second, approximately 10% of smokers were lost to follow up and so we had no information on whether they quit. The women who were lost to follow up did not differ from our sample by exposure status but were less likely to be white and more likely to be less educated. Finally, we were unable to fully assess the true fidelity of the implementation in each clinic and so used any documentation with the FAIR form as a proxy.

Assessment of facilitators and barriers to implementation of the 5A's intervention

Information gathered directly from WIC and CFHS direct perinatal care clinic staff through the use of an electronic survey largely supported the qualitative data gathered through semi-structured interviews. For example, one important theme in the qualitative analysis was that lack of self-efficacy among clinic staff in providing smoking cessation counseling was a barrier to the

implementation of the 5A's intervention. This finding was supported by the survey results showing low to moderate confidence among staff members, especially in tasks that required motivating a client to commit to quitting smoking. Building on the finding from chart review analysis that steps of the intervention least likely to occur at every visit are the Assist and Arrange steps, we found in the staff survey that providers feel least confident in their ability to complete steps that require more advanced counseling skills. This finding was echoed in the qualitative analysis by key informants who identified a lack of self-efficacy in providing counseling among their staff as a barrier to the successful implementation of the intervention.

Although barriers to implementation of the 5A's were identified on all three levels of the social-ecological model that we analyzed, clinic level factors will likely be more readily addressed through ODH initiatives to improve adherence and enhance implementation of the intervention. Semi-structured interviews with key informants at WIC and CFHS direct perinatal care clinics provided rich detail around the issues related to implementation of smoking cessation interventions at the clinic level. This detail led to a number of actionable conclusions that can be applied to the strengthening and expansion of such interventions in Ohio. See Box 1 for complete list of conclusions.

Box 1. Summary of Conclusions from Qualitative Data Assessment

1. Training in use of the 5A's was not adequate for providers to develop self-efficacy in providing smoking cessation counseling
2. Providers using the 5A's need more information about specific topics related to smoking cessation and counseling, including working with younger patients, dealing with resistant or difficult patients, understanding the role of pharmacologic therapies for smoking cessation during pregnancy, and how to address the use of alternative tobacco products (i.e., e-cigarettes)
3. Harm reduction is a pervasive strategy for dealing with smoking during pregnancy, though most participants recognized that harm reduction is not the ideal approach
4. Availability of community resources for referral is important to the success of implementing a 5A's program in the clinic setting
5. The perception that the documentation required for the 5A's program is complex or duplicative is a barrier, and led to discontinuation of the program in some settings
6. Some project directors are curious about whether using the 5A's program has an impact on their clients' smoking behaviors
7. There is wide variability in the degree to which clinics have integrated the 5A's counseling interventions into their existing practices
8. Many clinics are interested in abbreviated counseling approaches (i.e., 3As or 2As + R)

The qualitative approach used to identify facilitators and barriers to the implementation of the programs had some limitations that should be noted. First, the qualitative analysis relied on the perceptions and interpretations of individuals, in this case key informants. We chose to focus on project directors because of their detailed knowledge about the implementation of the smoking

cessation program, but their perceptions and interpretations of smoking cessation counseling might differ from those of clients or front-line clinical staff. Second, data collection in qualitative research is heavily dependent on the skills of the interviewers, which may have varied across the team; although the semi-structured interview approach provides flexibility to modify the interview questions as needed, this can result in inconsistencies across interviews. We conducted most of the interviews by phone, which may have made it more difficult to gauge social cues for respondents' accuracy. As is often the case in qualitative research, some key informants provided more insightful answers than others, and some were more willing than others to spend time with the interview teams discussing the intervention. Furthermore, participants knew that the interviewers were working on behalf of ODH, which provides funding for their programs; participants may have been affected by social desirability bias, providing answers that would portray their own programs in the most positive light. This possibility was mitigated by our use of interviewers who are not involved with the routine administration of the program, but was likely not entirely eliminated.

A final important limitation that applies to our evaluation of WIC programs specifically is that our assessment only included WIC sites that have previously volunteered to receive training and implement a 5A's smoking cessation program. This program has been provided by ODH on a voluntary basis since 2007. WIC programs that never received training because they never elected to participate were not included in our assessment. Although our data collection reached WIC sites representative of the group of programs that have participated in the 5A's (whether currently participating or no longer participating), it is likely that the information presented here is biased toward the types of WIC programs that have chosen to implement these programs. Clinics that are not currently using the 5A's intervention may have experience difficulty recalling information regarding training provided by ODH. Therefore, it is impossible to draw conclusions about why programs might have chosen not to implement a smoking cessation program based on the data presented here. Interestingly, very few WIC programs located in metropolitan counties have chosen to participate; there may be factors related to the type of setting or to the number of participants that affect the ability of WIC programs to take on smoking cessation interventions, but these were not evaluated in this assessment.

Recommendations

As a result of this investigation, the team made the following recommendations to Ohio Department of Health for the improvement and expansion of perinatal smoking cessation interventions statewide.

1. Revise format and methods for smoking cessation training provided by ODH
 - a. Use a mixture of web-based and onsite training
 - b. Ensure that training is relevant to audience consisting of different types of health care workers with varied educational backgrounds
 - c. Provide opportunities for practice, role-playing, and feedback during training
 - d. Use trusted figure to provide training

- e. Ensure that clinic schedules can accommodate training by scheduling at least 4-6 months in advance

Example: Provide webinar overview of smoking effects during pregnancy and use of brief, evidence-based smoking cessation counseling interventions, followed by onsite training that would give opportunities for practice, role-playing, and feedback, then provide access to virtual clinic for additional practice. Use trainers with different background and expertise (physician, addiction counselor, nurse, etc) for different components of the training. Consider using optional modules for audiences with different backgrounds or roles in providing the intervention.

2. Revise and update content of smoking cessation training provided by ODH, keeping content current with clinical recommendations
 - a. Training should focus on developing self-efficacy around Assess, Assist, and Arrange steps of 5A's
 - b. Include detailed information about use of the Ohio Tobacco Quit Line, including eligibility, services provided, who is providing counseling, number of sessions included, and accessibility of Ohio Tobacco Quit Line to enrolled clients
 - c. Provide information about working with special populations, such as younger mothers, heavy smokers, or resistant clients
 - d. Include information on use of nicotine replacement therapy (NRT) and pharmacologic methods during pregnancy
 - e. Address the use of alternative tobacco products such as electronic cigarettes, providing up to date information as it becomes available
 - f. Justification for promoting the full 5A's intervention, rather than abridged interventions, should be clear to participating clinics
 - g. Provide clear message during training that harm reduction is not considered best practice

Examples: Provide yearly updates to training materials to ensure that information is current with clinical recommendations and tobacco use trends in the state; provide time during training to call the Ohio Tobacco Quit Line; focus on skills such as motivational interviewing to enhance self-efficacy for counseling; provide examples of how to talk with women about the importance of abstinence rather than harm reduction.

3. Support enhancement of community resources available for referral
 - a. Support expansion and advertisement of Ohio Tobacco Quit Line services to partners and family members of pregnant women
 - b. Sustain Ohio Tobacco Quit Line services to pregnant women
 - c. Support implementation of tobacco cessation counseling programs in local health departments and other health care settings
 - d. Identify internet-based and text-message-based smoking cessation programs specific to pregnancy

- e. Consider use of social media, video, and other technologies to enhance outreach and follow-up for clients trying to quit smoking

Examples: Collaborate with ODH Tobacco Use Prevention and Cessation Program (TUPCP) to ensure accessibility of Ohio Tobacco Quit Line to families of pregnant and postpartum women; collaborate with TUPCP to build connections between CFHS funded programs, including WIC, and TUPCP funded programs located in the same counties; maintain weblinks to internet and text-based programs on ODH website that could be shared with local programs.

- 4. Reduce burden of documentation of smoking cessation counseling
 - a. Consider integration of the documentation of smoking status and smoking cessation counseling (the 5A's) with existing clinic systems, where possible
 - b. Reduce redundancy of documentation between systems
 - c. Simplify documentation necessary for the 5A's

Example: Incorporate FAIR form into electronic data capture systems when possible; when developing data systems for expansion into other state programs, use existing infrastructure and procedures when possible.

- 5. Develop data systems and capacity for quality improvement projects at the clinic level
 - a. Develop methods for providing timely feedback on smoking rates and quit rates to clinics using the 5A's
 - b. Provide guidance on implementing quality improvement projects around smoking cessation in the clinic setting

Examples: Enable clinics to query their data system for smoking rates and quit rates, using a similar approach to the one used for tracking breastfeeding initiation rates in WIC; develop a standard data system query that could provide smoking rates and quit rates on a quarterly basis to clinics; provide feedback to WIC clinics on number of Ohio Tobacco Quit Line calls referred by WIC; provide technical assistance to clinics to use their data on smoking quit rates or 5A's intervention using quality improvement cycle.

- 6. Continue to use a systems-based approach to providing smoking cessation interventions within the clinic setting
 - a. Enhance integration of the 5A's counseling intervention into existing clinic activities, documentation, and priorities
 - b. Improve use of Arrange follow-up step by developing clinic systems to ensure opportunities for follow-up
 - c. Develop methods for spreading innovations among participating clinics

Examples: Continue adapting 5A's into clinic flow using team-based approach; provide smoking cessation counseling intervention at WIC mid-certification visits; highlight innovative practices in providing counseling, such as development of system for providing follow up phone calls on client's quit date, using webinars or periodic updates to training

7. Provide recognition to high-achieving clinics and/or providers
 - a. Create award or other state-level recognition for excellence in providing smoking cessation counseling intervention
 - b. Create recognition for completion of additional training

Examples: Provide plaque or other recognition to clinics with best documentation of all 5 steps; provide personalized certificates for completion of additional training (such as virtual clinic training); provide buttons or stickers for providers with additional hours of smoking cessation counseling with message “Ask me about how to quit smoking”

Improvement and expansion of perinatal smoking cessation interventions across Ohio has the potential to impact high-risk women and infants throughout the state. Efforts in this area support two strategic priorities of Ohio Department of Health: to decrease infant mortality and to curb tobacco use. Supporting the efforts of front-line clinicians and service providers and standardizing the provision of evidence-based tobacco cessation interventions will be critical to the success of this initiative.

Works Cited

- Adams, E. K., Miller, V. P., Ernst, C., Nishimura, B. K., Melvin, C., & Merritt, R. (2002). Neonatal health care costs related to smoking in pregnancy. *Health Econ*, *11*(3), 193-206.
- American College of Obstetrics and Gynecologists. (2010). Smoking Cessation During Pregnancy. Committee Opinion No. 471. *Obstetrics and Gynecology*, *116*, 1241-4.
- Centers for Disease Control and Prevention. (2004). *The Health Consequences of Smoking: A Report of the Surgeon General*. Atlanta: Department of Health and Human Services.
- Davis, C. F., Lazariu, V., & Sekhobo, J. P. (2010). Smoking Cessation in the WIC Program. *Maternal Child Health Journal*, *14*, 474-477.
- Dietz, P. M., England, L. J., Shapiro-Mendoza, C. K., Tong, V. T., Farr, S. L., & Callaghan, W. M. (2010). Infant Morbidity and Mortality Attributable to Prenatal Smoking in the US. *American Journal of Preventive Medicine*, *39*(1), 45-52.
- Fiore, M. C., Jaen, C. R., Baker, T. B., & et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update*. Rockville, MD: US Department of Health and Human Services, Public Health Service.
- Halcomb, E. J., & Davidson, P. M. (2006). Is verbatim transcription of interview data always necessary? *Applied Nursing Research*.
- Hoyert, D. L., & Xu, J. (2012). Deaths: Preliminary Data for 2011. *National Vital Statistics Reports*, *61*(6).
- Liu, S. T., Conrey, E. J., & Cartwright, W. L. (n.d.). Integrating a brief evidence-based smoking cessation intervention in WIC clinics.

- McLeroy, K. R., Bibeau, D., Steckler, A., & Glanz, K. (1988). An ecological perspective on health promotion programs. *Health Education Quarterly*, 15(4), 351-377.
- Ohio Department of Health and Ohio Children's Trust Fund. (2013). *Ohio Child Fatality Review Thirteenth Annual Report*.
- Ohio Department of Health. (n.d.). *Women, Infant and Children*. Retrieved October 2013, from Ohio Department of Health: <http://www.odh.ohio.gov/odhprograms/ns/wicn/wic1.aspx>
- Ohio Department of Health. (n.d.). *Women, infants, and children (WIC) fact sheet*. Retrieved 2013 October, from Ohio Department of Health: [http://www.odh.ohio.gov/~media/ODH/ASSETS/Files/ns/wic nutrition/wicfacts.ashx](http://www.odh.ohio.gov/~media/ODH/ASSETS/Files/ns/wic%20nutrition/wicfacts.ashx)
- Ohio Partners for Smoke-Free Families. (2007). *Ohio Partners for Smoke-Free Families Final Report*.
- Tong, V. T., Dietz, P. M., Morrow, B., D'Angelo, D. V., Farr, S. L., Rockhill, K. M., et al. (2013). Trends in Smoking Before, During, and After Pregnancy- Pregnancy Risk Assessment Monitoring System, United States, 40 Sites, 2000-2010. *Morbidity and Mortality Weekly Report Surveillance Summaries*, 62(6), 1-19.
- United States Department of Agriculture. (n.d.). *WIC eligibility requirements: Food and nutrition services*. Retrieved January 22, 2014, from United States Department of Agriculture: <http://www.fns.usda.gov/wic/wic-eligibility-requirements>
- Yunzal-Butler, C., Joyce, T., & Racine, A. D. (2010). Maternal Smoking and the Timing of WIC Enrollment. *Maternal Child Health Journal*, 14, 318-331.

Appendices

1. Five A's Intervention Record (FAIR) form
2. Semi-structured interview guide: CFHS clinics
3. Semi-structured interview guide: Active (trained and documenting with FAIR form) WIC clinics
4. Semi-structured interview guide: Inactive (trained but not documenting with FAIR form) WIC clinics
5. Staff survey
6. Ohio Partners for Smoke Free Families: Five A's Intervention Record Data Entry Codes

