Alcohol, Tobacco and Illicit Drug Screening in Pregnancy

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Alcohol, Tobacco and Illicit Drug Screening in Pregnancy

Wright State University

By

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BSN, State University of New York College at Plattsburgh

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I HEREBY RECOMMEND THAT THE DISSERTATION PREPARED UNDER MY SUPERVISION BY Lisa R. Jasin ENTITLED Alcohol, Tobacco and Illicit Drug Screening in Pregnancy BE ACCEPTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF Doctor of Nursing Practice.

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ABSTRACT

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Intrauterine substance exposure is a nationally growing problem. A steady increase in neonates with neonatal abstinence syndrome in the state of Ohio was noted. Prenatal substance use presents a significant burden to society. Of infants exposed to intrauterine opiates, 55-94 percent develop signs of withdrawal. For example, the estimated lifetime cost for a neonate with fetal alcohol spectrum disorder is $2 million.

The purpose of this evidence based practice improvement project was to evaluate the utility of the 5Ps screening tool and brief intervention by community health workers during the first prenatal home visit. The Evidence-Based Practice Improvement (EBPI) model guided the project. The prenatal screening tools previously used by community health workers focused on only one substance and asked primarily direct questions. Evidence supports asking a combination of direct and indirect questions for improving recognition of risk. Screening followed by a brief intervention suggests improvement in patient outcomes. Community health workers caring for prenatal women were educated about the use of the 5Ps tool, motivational interviewing and practice of a brief intervention. Sixteen staff members were surveyed before and after the education. Staff outcome measures were ease of use, comfort with, and intention to use the 5Ps tool. Patient outcomes included use of the 5Ps, identification of risk, and documentation of
discussion or intervention. A significant difference was noted between total average score on the pretest ($M=27.12$, $SD=11.29$) and total average score on the posttest ($M=14.81$, $SD=9.99$) $p<.001$. Particularly, there was a significant difference in staff member’s knowledge of the 5Ps tool ($p<.031$). Retrospective chart review before and after staff education revealed a significant difference in the use of the 5Ps, $p<.022$. Individually, there was a significant difference in documentation of a substance intervention or discussion $p<.030$. Further study with a larger sample size is needed to determine the effect of the 5Ps tool on the prenatal population served by community health workers. Staff involved in treating pregnant women benefited from education in motivational interviewing and use of a brief intervention.
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Completion of a doctoral program is a labor of love, not only for the student, but also for the many people who helped the student along the way. I would like to take this opportunity to recognize the many people who made my doctoral program a success.

As with many things, there were changes along the way. I would like to acknowledge Dr. Bobbe Gray’s contribution to the beginning of my DNP project. Dr. Susan Batten who was willing to serve on my committee as the member from the University of Toledo and provided wonderful support and feedback. Dr. Sara Paton was the longest running member who was present during the conception of my project and stayed with me through the very end. Dr. Paton provided statistical support as well as a wonderful public health perspective.

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Dr. Tracy Brewer became my Committee Chair and without Dr. Brewer there would have been no DNP project completion. Dr. Brewer was a mentor, advisor, and the most supportive Committee Chair a DNP student could ask for. Dr. Brewer helped me make sense of the revisions needed to make my project a reality.
DEDICATION

To my husband Tom, your support of me and my never-ending pursuit of learning means the world to me. To my boys, Brian, Craig and Collin, you can do anything you set your heart on. To my mother and father, thank you for raising me to believe I can do anything I set my heart on and demonstrating that in real life.
I. INTRODUCTION

Problem Statement

Intrauterine substance exposure, which includes tobacco, alcohol and illicit drugs, is a growing problem nationally, including the state of Ohio, which demonstrates a steady increase in neonates requiring treatment for neonatal abstinence syndrome (Walsh et al., 2012). Intrauterine exposure to illicit drugs, tobacco and alcohol are associated with neonatal comorbidities such as intrauterine growth restriction, prematurity and low birth weight (Bada et al., 2005; Cornelius, Goldschmidt, Day, & Larkby, 2002; Ostrea et al., 2001). Comorbidities which arise from maternal substance use, regardless of the substance used, place an undue burden on the healthcare system and society as a whole (Hudak & Tan, 2012). The maternal substances used during pregnancy and related comorbidities are broad with varying neonatal manifestations.

Intrauterine exposure to marijuana may be associated with long term neurodevelopmental effects (Campolongo, Trezza, Palmary, Trabace, & Cuomo, 2009), as well as reduced height at 6 years of age (Cornelius, et. al, 2002). Whereas, intrauterine exposure to opiates may result in neonatal abstinence syndrome (NAS) requiring pharmacologic treatment and prolonged hospital stay (Hudak & Tan, 2012), as well as risk for mild developmental impairment (Bunikowski et al., 1998; Schuler, Nair, & Kettinger, 2003). Intrauterine exposure to cocaine and other stimulants may result in NAS like behavior that may last up to seven days, but may reflect the effects of the drug
as opposed to withdrawal from the drug (Hudak & Tan, 2012). Intrauterine exposure to alcohol is associated with fetal alcohol spectrum disorder (FASD), preterm birth, miscarriage, stillbirth and short stature (Centers for Disease Control and Prevention [CDC], 2013; Cornelius et al., 2002; March of Dimes, 2012). Intrauterine exposure to tobacco from 1995-1999 resulted in over 1000 infant deaths each year from prematurity related causes including respiratory distress syndrome, low birth weight, and increased risk of sudden infant death syndrome (CDC, 2002).

**Background and Significance**

Considering the myriad consequences of intrauterine substance exposure, in the absence of prematurity or other congenital defects, newborns facing withdrawal from intrauterine opiate exposure require the most immediate treatment. Of infants exposed to intrauterine opiates, 55-94 percent of neonates will develop signs of withdrawal (Hudak & Tan, 2012). From 2009 to 2011 there was an increase from 200 to more than 300 neonates treated for neonatal abstinence syndrome (intrauterine exposure to opiates) at four of the Ohio Children’s Hospitals (Walsh et al., 2012). Treatment of neonatal abstinence syndrome is variable with length of treatment in the Ohio Children’s Hospitals from 14.4 to 41.8 days (Walsh et al., 2012). This resulted in a range of cost per patient of approximately $18,922 to $54,925 for each hospital stay (R. McClead, personal communication, September 1, 2013).

Neonatal abstinence syndrome is a constellation of symptoms in a neonate exposed to opiates in utero. When the umbilical cord is cut and the neonate’s source of opiate is removed, withdrawal may result. Other substances may also cause symptoms similar to NAS, prolong the severity of symptoms or increase the time needed to treat
NAS. These substances include tobacco, cocaine, barbiturates, alcohol and hypnotic-sedatives (Hudak & Tan, 2012). Symptoms of NAS may require pharmacologic treatment and prolonged hospital stay beyond the typical 48 to 72 hour stay. NAS primarily affects the gastrointestinal and neurologic systems and may lead to difficulties in the neonate’s ability to sleep, eat, maintain temperature and gain weight. The most severe consequences of NAS, though rare, are seizure activity and/or death (Hudak & Tan, 2012).

In the six freestanding Ohio Children’s Hospitals from January 2012 to July 2013, 547 neonates requiring pharmacologic treatment for NAS were studied by the Ohio Children’s Hospital Association Neonatal Abstinence Working Group to determine the demographics of pregnant women using substances whose newborns required pharmacologic treatment for NAS. This study also collected data on the treatment plans for the newborns born to these women, and the lengths of stay associated with the treatment used to treat withdrawal in these infants (Walsh et al., 2012). Maternal demographics of the women studied included mothers who were primarily Caucasian and using public insurance. White, non-Hispanic women accounted for 91.5 percent of mothers in the study, and 79.5 percent of mothers used public insurance. Of the neonates studied, 81.5 percent were exposed to tobacco, 9.7 percent were exposed to alcohol, and 58 percent were exposed to any illicit substance. Any illicit substance included illicit drugs including marijuana, cocaine, methamphetamines, opiates obtained and used illegally, or abuse of prescription opiates. The most common opiates used were buprenorphine, oxycodone, heroin and methadone, which may have been used with a prescription or misused without a prescription (Walsh et al., 2012).
A proxy measure to identify the significance of potential intrauterine exposure to substances can be measured by the rate of unintentional death from drug overdose. The rate of unintentional death from drug overdose increased in Ohio from 3.6 per 100,000 deaths in 2000 to 16.59 per 100,000 in 2012 (Ohio Department of Health [ODH], 2014). The demographics for unintentional fatal overdose rate by sex include 43 percent females compared to 57 percent males, with females at highest risk for prescription opioid deaths (ODH, 2014). While the proportion of unintentional overdose in males decreased from 70 percent to 61 percent from 2000 through 2011, the unintentional overdose rate in females increased from 30 percent to 38 percent during those same years (ODH, 2013). The unintentional overdose death rate is used as a proxy measure for maternal drug use as there is not a good measure of general drug use in pregnancy (M. Walsh, personal communication, September 11, 2013).

A computerized anonymous survey is performed by SAMHSA annually to determine overall and maternal substance use in the United States. Nationwide, among pregnant women between the ages of 15 to 44, an average of 5.9 percent used illicit drugs, 8.5 percent reported alcohol usage, 15.9 percent reported cigarette use in the previous month, 2.7 percent reported binge drinking and 0.3 percent reported heavy drinking based on data obtained for 2011-2012 (Substance Abuse and Mental Health Services Administration [SAMHSA], 2013). Cigarette use in non-pregnant women has declined since 2003, but cigarette use in pregnant women has not declined significantly (SAMHSA, 2013). There is no universal screening of pregnant women for substance use. Most data is self-reported and estimated to be grossly underreported (M. Walsh, personal communication, September 11, 2013).
Maternal substance use and the sequelae associated with use present a significant burden to society. The national hospital charge to treat NAS in 2009 was $53,400 with an average length of stay of 16 days. This resulted in a daily cost of $3,337.50 (Patrick et al., 2012). In 2009, state Medicaid programs were responsible for 77.6 percent of charges for NAS treatment (Patrick et al., 2012). This is consistent with the Ohio Children’s Hospital findings in 2012-2013. In Columbus, Ohio the average allowed cost per day for Medicaid Managed care patients in 2012-2013 was $1,314 (R. McClead, personal communication, September 1, 2013). At an average length of stay of 20.5 days, this results in a cost of $26,937 per neonate treated for NAS in Ohio compared to the average Medicaid cost of $8,600 for a vaginal delivery without complications (Merrill & Steiner, 2006). The cost for fetal alcohol spectrum disorder is calculated as a lifetime cost by the Centers for Disease Control with a lifetime estimate of $2 million (CDC, 2012). The most recent data reported by CDC stated an average cost of $704 per maternal smoker in 1996 which accounted for 2.6 percent of total neonatal medical expenditures for 1996 (CDC, 2002). These data are old; however, no further current data has been reported.

Healthy People 2020 objectives, while not quality objectives, do offer guidance for quality initiatives to improve abstinence from alcohol, tobacco and illicit drugs during pregnancy. Healthy People 2020 guidelines are listed in the Maternal, Infant and Child Health (MICH) section. MICH section 11 targets increased abstinence from alcohol, tobacco and illicit drugs among pregnant women. The goal for MICH 11.1 is that 98.3 percent of pregnant women age 15 to 44 will report abstinence from alcohol for the past 30 days, which would result in a ten percent improvement from a baseline of 89.4 percent
reported in 2007-2008. MICH 11.2 targets 100 percent of pregnant women abstain from binge drinking in the past 30 days, a target with improvement from the reported baseline of 95 percent in 2007-2008. Objective MICH 11.3 targets 98.6 percent of pregnant women will report abstinence from tobacco use while pregnant, resulting in a ten percent improvement from the reported 89.6 percent baseline in 2007. MICH objective 11.4 targets 100% of pregnant women from age 15 to 44 will abstain from illicit drugs in the past 30 days, a target with improvement from the baseline of 94.8 percent in 2007-2008. (United States Department of Health and Human Services [USDHHS], 2013).

Prevention of NAS, FASD, and other sequelae of intrauterine substance exposure can only be accomplished with intervention prior to conception or during the antenatal period of pregnancy. Therefore, the focus of prevention needs to be directed toward the mother. Prenatal screening along with a brief intervention shows promise in the detection of pregnant women at risk for alcohol, tobacco and illicit drug use during pregnancy as well as those who are continuing to use substances (Chasnoff et al., 2005; Kennedy, Finkelstein, Hutchins, & Mahoney, 2004; Wong, Ordean, & Kahan, 2011; Wyble, 2013). Interaction with health care providers has been determined to be the number one incentive for women toward changing patterns of substance use during pregnancy (Office of Disease Prevention and Health Promotion [ODPHP], 2009). A single interaction with a health care provider who addresses the risk of substance use can make a difference in a woman’s use of substances while pregnant (ODPHP, 2009). There is a need to understand what screening tools are available to determine risk for and/or use of substances during pregnancy, as well as the types of brief intervention that have been proven to be effective to decrease maternal substance use in pregnancy. Through use of
the evidence-based practice (EBP) process, available maternal substance use screening tools were explored, including those tools that included a brief intervention.

**Purpose**

The purpose of this evidence based practice improvement project was to evaluate the use of a standardized screening tool and brief intervention by community health workers during intake interviews during the first prenatal home visit.

**Formulate Focused Clinical Question**

**PICOT question.** A clinical question was developed to enable the DNP student to conduct a directed literature search to obtain a body of evidence available regarding the clinical problem. The PICOT format is an acronym that identifies factors to assist in identification of the appropriate evidence, which is the most relevant evidence to answer the clinical question. The “P” stands for patient population or disease, “I” stands for intervention or issue of interest, “C” stands for the comparison intervention or issue of interest, “O” stands for outcome of interest, and “T” stands for time frame for evaluation of an outcome (Melnyk & Fineout-Overholt, 2011).

The following PICOT question was developed prior the literature review: “In pregnant women, how does a standardized screening tool compared to free form substance use questions affect disclosure of substance use within the first prenatal home intake visit?”

**Guiding Framework**

The guiding framework chosen for this project was the Evidence-Based Practice Improvement (EBPI) model (Levin et al., 2010). Levin’s EBPI model merges components of the evidence based practice process with steps of quality improvement for
implementation. The model consists of seven steps to guide the development and implementation of the evidence based practice improvement project. The steps of the EBPI model are shown in Figure 1.

The systematic approach of Levin’s EBPI model (Figure 1; Permissions to reprint Appendix A and B) provides clear direction to an evidence based practice change. The model also provides a systematic guide to implementation of the practice change that results in measurement of outcome through the PDSA cycle or small tests of change (Levin et al., 2010). The EBPI model begins with the description of the problem. The problem in this evidence based practice project is intrauterine exposure to substance during a woman’s pregnancy. This led to the second step and formulation of a focused clinical question, the PICOT question. The PICOT question informed and enabled the third step, which is the directed literature search.
Figure 1. The steps of the EBPI model by R. F. Levin, J. M. Keefer, J. Marren, M. Vetter, B. Lauder and A. Sobolewski, 2010. Evidence-Based Practice Improvement: Merging 2 Paradigms. *Journal of Nursing Care Quarterly*, 25, P. 122. Reprinted with permission
II. EVIDENCE

Search for Evidence

The literature search was conducted using the PubMed, CINAHL, and Cochrane databases. In addition, hand searching was performed from applicable references found in the “keeper articles” bibliographic section. Key words used included “drug use”, “illicit drug use”, “substance use”, “alcohol”, “tobacco”, “smoking”, “screening”, “screening tools”, “substance abuse detection”, “pregnancy”, “prenatal care”, “perinatal”, “expectant mothers”, and “SBIRT”. No publication date limit was placed on the search, as some prenatal substance screening tools were developed in the 1980’s and remain in use. Articles were included if they addressed a substance use screening tool used in a prenatal population or developed for a prenatal population.

A PubMed search using the phrase and Boolean connectors “drug use AND screening tools AND prenatal” garnered 38 articles, of which six were appropriate to the topic. Phrases in PubMed included “substance use AND screening tools”, “pregnancy AND drug use screening tools”, “Illicit drug use AND pregnancy screening” resulted in the abstraction of ten additional articles. Further phrases and Boolean terms used in PubMed were “perinatal AND drug use AND screening”, “illicit drug use AND pregnancy screening”, “pregnancy AND drug use screening tools”, “drug use AND screening tools AND prenatal”, “substance use AND screening tools” revealed 31
articles, resulting in twelve articles not previously found. The phrase “substance use screening tool” led to 118 articles, of which five were appropriate.

A CINAHL search using the phrases and Boolean connectors “expectant mothers AND screening AND drug use”, “perinatal substance use AND screening”, and “prenatal substance use AND screening” returned 13 articles, three of which had not been previously obtained in the PubMed search. A search of the Cochrane Database using the phrase and Boolean connector “substance use screening AND pregnan*”, and “illicit drug use and prenatal” resulted in 16 results, 13 of which, were trials and one of which was the protocol for an upcoming trial. The final result was two randomized trials and one relevant Cochrane review. A total of 17 articles were abstracted and critically appraised to make the recommendation for change.

**Appraisal and Synthesis of the Evidence**

**Screening tools**

There are multiple screening tools available for use to screen for alcohol, tobacco and substance use. Not all were created for use with pregnant women (Screening Instruments for Pregnant Women, 2012). The Substance Use Risk Profile-Pregnancy Scale was developed for use with pregnant women. The scale has potential to predict women at high risk for alcohol or illicit substances, but does not screen for tobacco use or family violence (Yonkers et al., 2010).

The TWEAK and T-ACE screening tools were developed from alcohol abuse screening tools, and were designed to minimize guilt-associated questions in relation to alcohol use in pregnancy. The TWEAK and T-ACE screening tools were both based on the CAGE and Michigan Alcohol Screening tool and adapted to address alcohol use in
pregnancy (Sarker, Einarson, & Koren, 2010). The revised CAGE alcohol was revised for alcohol use and identifies heavy alcohol use, while the modified CAGE drug tool identifies heavy drug use (Midanik, Zahnd, & Klein, 1998). Neither the revised CAGE alcohol nor the modified CAGE drug tool is useful for identification of risk or light use (Midanik, Zahnd, & Klein, 1998).

The 4P’s Plus was developed by Ira Chasnoff based on Hope Ewing’s 4P’s screening tool (The Institute for Health and Recovery [IHR], n.d.) for use with pregnant women who may or may not be at risk for substance use. The 4P’s Plus was designed to be used with the general population, as opposed to only the identified at risk population, to avoid the pitfalls of targeted screening (Chasnoff et al., 2005). Chasnoff and colleagues (2005) found that the most highly educated and most affluent women had the highest rate of substance use. The 4P’s Plus uses four questions regarding parents, partner, past and pregnancy related use of alcohol or drugs. The 4P’s Plus also asks how many cigarettes were smoked in the month prior to learning of pregnancy. The 4P’s Plus identifies pregnant women at risk for substance use, but does not address family violence (Chasnoff et al., 2005). The 4P’s Plus identifies those women with light or infrequent alcohol use, as well as heavier alcohol users. The 4P’s Plus demonstrates high sensitivity, with good specificity and has a high negative predictive value, as well as low positive predictive validity (Chasnoff, Wells, McGourty, & Bailey, 2007).

The Drug Use Disorder (DUD) Questionnaire focuses on alcohol and drug use, and was not tested on pregnant women. When it was validated, the validation group was noted to be low risk. The DUD Questionnaire does not screen for tobacco use or physical violence (Scherer, Furr-Holden, & Voas, 2013). The CRAFFT questionnaire was
embedded in a general screening tool and found to be a useful tool in identifying risk for
alcohol or drug use in pregnant women. The CRAFFT did not screen for tobacco use.
The majority of women in the survey were older than 25 years (Braaten, Briegle, Hauke,
Niamkey, & Chang, 2008).

The Institute of Healthcare and Recovery’s 5P’s was developed based on Ewing’s
4P’s, but with the questions reversed to address parent’s, partner’s and peer’s alcohol and
drug use prior to asking the pregnant woman about individual alcohol or drug use. This
involves both indirect and direct questioning and proceeds from non-threatening to more
threatening questioning. In addition, the 5P’s includes questions concerning tobacco use
and family violence. Any positive response garners a brief intervention. While there was
a risk of over-identifying women at risk for alcohol or drug use, it is one of the few
screening tools that screens for any alcohol use (Kennedy, Finkelstein, Hutchins, &
Mahoney, 2004). Table 1 reflects evaluation of the literature regarding maternal
substance use screening tools.

The prenatal screening tools in use primarily focus on drugs, alcohol, or tobacco,
and ask the pregnant mother directly about use. The evidence supports asking a
combination of direct and indirect questions to reveal a higher number of mothers at risk
for alcohol, tobacco and illicit drug use (Ondersma et al., 2012).

Previous cigarette smoking or alcohol use is significantly correlated with present
alcohol or drug use (Chasnoff, Neuman, Thornton, & Callaghan, 2001; Slutsker, Smith,
Higginson, & Fleming, 1993). Pre-pregnancy alcohol and cannabis use is correlated with
use of pre-pregnancy alcohol and cannabis use is correlated with use of alcohol or
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<th>Quality of Evidence: Critical Worth to Practice</th>
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<td>(Kennedy et al., 2004)</td>
<td>Descriptive study. Staff trained and interviewed after training on ASAP tool and after training in brief intervention</td>
<td>118 prenatal staff trained on ASAP screening 175 prenatal staff trained on Brief Intervention No information as to attrition between training and completion of post training interview</td>
<td>Education of staff in use of ASAP tool. This is the intervention Use of tool for consistent screening for substance use. This is an outcome</td>
<td>36% of women screened were positive for at least one risk factor with 5P’s screening.</td>
<td>Percentages without statistical analysis</td>
<td>89% of respondents reported the tool as an effective method of identifying pregnant women at risk for alcohol/substance abuse. 74% of respondents reported they learned new info about risks of alcohol/drug use by pregnant women 95% of patients screened at initial prenatal visit. 77% received brief intervention if screened positive for &gt;1 risk factor</td>
<td>VI</td>
<td>Strengths: Tool was easily integrated into workflow as evidenced by 95% use rate. Staff felt tool would be effective. Screening for alcohol use and/or abuse as well as brief interventions for alcohol and substance use can be effectively delivered. Limitations: No statistical analysis of tool.</td>
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<td>(Chasnoff et al., 2005)</td>
<td>Descriptive</td>
<td>5 sites in CA, NJ, and Il used the 4 P’s Plus screening tool at the first prenatal intake visit. No exclusion criteria existed. 90% of women which totaled 7818 women across 5 sites were screened. No explanation as to attrition of 10% of eligible women. Camden NJ site performed only screening, no follow up.</td>
<td>Screening with 4P’s Plus Screen for substance use</td>
<td>Percentages were used to determine revelation of substance use in pregnancy</td>
<td>Chi Square test of independence for rates of substance use across four sites</td>
<td>Significant decrease in rates of substance use after knowledge of pregnancy. P&lt;0.0001</td>
<td>VI</td>
<td>Strengths: Verbal screening= higher rate substance use than clinically guided urine toxicology. &gt; than 90% of women screened. Identified small amounts of alcohol use as opposed to larger amounts of alcohol use. Designed for pregnant women. Limitations: Validity &amp; reliability not tested. Very feasible to implement</td>
</tr>
<tr>
<td>Citation</td>
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<td>Sample/Setting</td>
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<td>Outcome Measurement</td>
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<tr>
<td>(Chasnoff et al., 2007)</td>
<td>Validation/Descriptive</td>
<td>All pregnant women 18 years and older eligible. 228 women initially screened of 387 eligible. No exclusion criteria noted</td>
<td>No variables manipulated</td>
<td>Not noted</td>
<td>Percentage</td>
<td>Internal consistency 0.62 (low but acceptable)</td>
<td>VI</td>
<td>Strengths: Validity and Reliability data noted, but measures note noted. May be straight percentages. Limitations Internal consistency low at 0.62. Positive predictive value low, but negative predictive value high. Indicates excess clinical assessment performed</td>
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<tr>
<td>Validation of the 4P’s Plus screen for substance use in pregnancy validation of the 4P’s Plus.</td>
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<td></td>
<td>Sensitivity 0.871</td>
<td>Specificity 0.761</td>
<td>Positive predictive value 0.364</td>
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<td>(Braaten, Briegleb, Hauke, Niamkey, &amp; Chang, 2008) Screening Pregnant Young Adults for Alcohol and Drug Use: A Pilot Study</td>
<td>100 patients from Young Adult Reproductive Medicine Clinic 80 of 100 were pregnant and less than 25 years old (final focus of study)</td>
<td>CRAFFT screen questions about alcohol and drug use (embedded in health survey) One answer of yes is positive finding</td>
<td>Descriptive results as percentages, means with standard deviations, and medians. Chi square or t-tests to determine differences between two groups of women.</td>
<td>15 (18.75%) of women had at least one positive score Most frequently positive score was for “have you ever ridden in a CAR with someone (including yourself) who was high or had been using alcohol or drugs?” Trend toward lower gestational age with higher CRAFFT score. Trend toward higher number of positive women willing to participate in further research; older women more willing to participate in further research</td>
<td>VI</td>
<td>Addresses alcohol and drug use. Copyright by Boston Children’s Hospital. Embedded in another survey. Direct questions Does not address tobacco</td>
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<tr>
<td>Citation</td>
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<td>(Sarker et al., 2010)</td>
<td>Descriptive cohort study, comparison of two tools</td>
<td>202 candidates recruited – these were pregnant women who called the helpline to self-report use of alcohol at least 2 months prior to or during pregnancy. 175 women were enrolled, 75 problem drinkers and 100 non-problem drinkers. No explanation for women who did not enroll.</td>
<td>No variables manipulated Comparison of effectiveness of TWEAK and T-ACE tools at identifying at risk drinkers who called the Mother risk helpline. Validation of TWEAK using cut points of either 2 or 3, which is population dependent, however, the population was not defined. T-ACE has been validated with a cut point of 2 in the population on which it was tested. The population was not defined.</td>
<td>Higher number of single or divorced women who identified themselves as problem drinkers. TWEAK: Capture at risk drinkers with sensitivity of 99% CP &gt;/= 2 Sensitivity 100% Specificity 19% PPV 0.48 CP &gt;/= 3 Sensitivity 93% Specificity 34% PPV 0.51 T-ACE Cut point &gt;/= 2 Sensitivity 100% Specificity 36% PPV 0.54 Cut point &gt;/= 3 Sensitivity 99% Specificity 43% PPV 0.54</td>
<td>SPSS: Chi-square analysis to deter diff in women determined to be problem drinkers vs non-problem drinkers. Student t-test and/or Mann-Whitney U-test used to compare sensitivity and specificity rates between TWEAK and T-ACE tools.</td>
<td>VI</td>
<td>Weaknesses: TWEAK false positive 64% T-ACE false positive 81% Conclusions: TWEAK and T-Ace are not ideal alone to identify problem drinkers in a population of pregnant women seeking help from a helpline.</td>
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<td>(Yonkers et al., 2010)</td>
<td>Epidemiological survey</td>
<td>Convenience sample of all pregnant women who presented between 2005 and 2009 for obstetric care. 2,684 women screened. &gt;80% African American or Hispanic. 73% 20-34 years old No exclusion criteria</td>
<td>No variable manipulated</td>
<td>No reliability scale noted</td>
<td>Model fit characteristics – Akaike’s Information Criterion, (AI) Nagelkerke R (NR) Sensitivity Specificity</td>
<td><strong>SURP</strong> Low risk pop AI - 579.74 NR - 0.27 Sens - 91% Spec - 67% High-risk pop. AI - 616.93 NR – 0.2 Sens - 57% Spec - 88%</td>
<td>VI</td>
<td>Strengths: Most predictive of alcohol and illicit drug use. Identified women at high risk for cocaine, sedative and opiate use. Weakness: Validation group noted to be low risk and sensitivity and specificity may vary. No indication for tobacco risk</td>
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<td><strong>TWEAK</strong> AI – 610.69 NR - 0.22 Sens - 63% Spec - 86% 4P’s (2007) AI - 625.77 NR - 0.19 Sens - 82% Spec - 68%</td>
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<td><strong>4P’s (2005) (Mod=positive)</strong> AI - 647.25 NR - 0.15 Sens - 95% Spec - 45%</td>
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<td><strong>4P’s (2005) (mod=neg)</strong> AI - 625.10 NR - 0.19 Sens - 81% Spec - 69%</td>
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<td>(Scherer, Furr-Holden, &amp; Voas, 2013)</td>
<td>Descriptive/Survey Blood and oral fluid toxicology</td>
<td>Subset of US National Roadside Survey. Administered to day and night time drivers in 48 states. N=2,702 (stated positive use of at least one of three substances) of 10,909 drivers who were eligible to participate.</td>
<td>Questions regarding Substance abuse (use in the last year) and substance dependence</td>
<td>DUD questionnaire assessed substance abuse and dependence based on self report</td>
<td>Logistic regression analysis</td>
<td>1,940 marijuana use 239 (12.3%) met criteria for abuse 130 (6.7%) met criteria for dependence 1,266 cocaine use 97 (7.6%) met criteria for abuse, 59 (4.6%) met criteria for dependence 2,017 reported painkiller use 209 (10.3%) met criteria for abuse, 98 (4.8%) met criteria for dependence</td>
<td>VI</td>
<td>Not developed for, used with or validated in pregnant women</td>
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<td>Toxicology for oral fluid for use of marijuana, cocaine and extramedicinal painkillers</td>
<td>Screened with enzyme linked immune-absorbent assays with verification with liquid chromatography-mass spectroscopy (LC/MS)</td>
<td>Chi square</td>
<td>DUD showed adequate fit for all substances measured</td>
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<td>Blood toxicology for use of marijuana, cocaine and extramedicinal painkillers</td>
<td>Screened with enzyme linked immune-absorbent assays with verification with LC/MS</td>
<td>Comparative fit analysis</td>
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<td>Standardized root mean square error of appropriation</td>
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<td>Standardized root mean square error residual</td>
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Cronbach’s Alpha Subscale of substance abuse .71 to .84 Subscale of dependence .83 to .92
cannabis use during pregnancy (Chang et al., 2011). A woman’s revelation of alcohol or tobacco use in the month prior to pregnancy was a better predictor of substance use during pregnancy than admission or denial during pregnancy (Chasnoff et al., 2005). A combination of direct and indirect questioning showed more promise in detecting current drug use than either indirect or direct questioning alone (Ondersma et al., 2012).

Marijuana use was revealed by interview more frequently than by chart review or toxicology testing (O’Campo et al., 1992; Ostrea et al., 2001). Table 2 shows pre-pregnancy correlations with prenatal substance use.

Interview alone regarding substance use did not encourage behavior change (Chang et al., 2011). Screening followed by a brief intervention involving at least one visit showed improvement in outcomes (Goler, Armstrong, Taillac, & Osejo, 2008). Recommendations have been made to screen all pregnant women for alcohol use (Clark, Dawson, & Martin, 1999; Floyd et al., 2008) followed by a brief intervention (Floyd et al., 2008). Further recommendations have been made to screen all pregnant women for substance use, provide brief intervention as needed and provide referrals as needed (American College of Obstetricians and Gynecologists [ACOG] Committee on Ethics, 2004; Floyd et al., 2008).

Staff involved in counseling pregnant women about behavior change would benefit from education and training in motivational interviewing and brief intervention (Chang et al., 2008). A Cochrane review discussed prenatal and postnatal home visits by certified community health workers and noted seven studies with 803 mother infant pairs. The home visits were primarily conducted after birth and thus are not compatible with the design of this evidence based project. Findings from the review suggest that there was
### Table 2. Correlations with substance use

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<tr>
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<tbody>
<tr>
<td>Chang et al., 2011</td>
<td>Cross-sectional study Survey followed by interview</td>
<td>30 pregnant young adults up to age 25</td>
<td>DSM-IV substance use disorder module Drinking within the six months prior to the interview Drinking in settings: intimate, socially, and negative coping Likelihood of behavior change</td>
<td>Self-report of drug and alcohol use as well as the context within which the alcohol or drugs would be used</td>
<td>Descriptive statistics using percentages, means and standard deviations. Fisher's exact test to compare demographics Wilcoxon's test Logistic regression to measure the area under the curve</td>
<td>90% of women were single While pregnant: 8 (27%) drank average of 1.8 drinks/day (4% of days were drinking days). 3 (10%) smoked an average of 4.3 marijuana cigarettes on days they smoked (88% of days). 1 woman used both alcohol and marijuana 7 women fit DSM-IV criteria for lifetime alcohol use disorders, 1 had a current disorder. 9 met criteria for lifetime cannabis use disorder.</td>
<td>VI</td>
<td>Pre-pregnancy alcohol and cannabis use was associated with prenatal alcohol and cannabis use. Small sample size limits generalizability. No women indicated they would change behavior based on the interview alone, leading the authors to recommend brief intervention or counseling.</td>
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<td>Ondersma et al., 2012</td>
<td>Descriptive Survey on computer Toxicology samples of hair and urine</td>
<td>Four hundred low income, post-partum primarily (92%) African American women. Convenience sample from an obstetrical unit – inpatients. 300 women in the development sample and 100 in the cross-validation sample</td>
<td>Direct questions regarding drug use Indirect questions regarding associated behaviors of drug use Semi-indirect questions regarding drug use</td>
<td>Drug use consequences in last year – 10 item. Questions re marijuana, other drug use in past 3 months Smoking, pain, mental health, married, violence, positive if cut point 3 or more Drug use in the 3 months prior to becoming pregnant Cocaine, marijuana, or stimulants (short window of detection)</td>
<td>Item reduction based on 10-90% endorsement rates. Tetrachoric correlation coefficients to retain top 30 items. Logistic regression resulted in 6 questions remaining. Drug use in the 3 months before pregnancy C Cocaine, marijuana, or stimulants (short window of detection)</td>
<td>54.8% of women testing positive for drug use reported drug use in 3 months before pregnancy In cross-validation, 10% of women testing positive for drug use reported drug use in the 3 months before pregnancy Area under the curve showed 0.74 (fair) with t-test with t-value 51.6 and p&lt;0.0001 (significant) compared to DAST-10 (direct questions). Combined indirect/direct approach: incr. accuracy - 72% in dev sample, 71% in validation sample</td>
<td>VI</td>
<td>Applicable to low income African American Postpartum women. Screener not tested on women who were pregnant at the time of survey</td>
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<tr>
<td>(Slutsker, Smith, Higginson, &amp; Fleming, 1993)</td>
<td>Descriptive/ Survey of birth attendants, birth certificate review</td>
<td>All women who delivered a singleton infant residing in Oregon during November 1989</td>
<td>Survey questions: Self-reporting of illicit drug use</td>
<td>Marijuana, cocaine, heroin, methamphetamine or others.</td>
<td>Fisher exact test, chi-squared test. Comparisons were made with t-tests.</td>
<td>5.2% (n-144) of 2791 women were recognized as having used illicit drugs.</td>
<td>VI</td>
<td>Attendants who routinely asked about drug use were twice as likely to identify drug use.</td>
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<tr>
<td>Recognizing Illicit Drug Use by Pregnant Women: Reports from Oregon Birth Attendants</td>
<td></td>
<td>3200 women gave birth. 2791 (87%) of mothers had surveys of birth attendants and birth certificate data that could be linked and were the final sample.</td>
<td>Mother/baby lab testing for illicit drugs during pregnancy or postpartum period</td>
<td>Laboratory tests alone identified 13 of the 125 drug users. Urine testing was done on 40 of the identified users.</td>
<td>Primarily percentages used OR = 2.1 CI = 1.2, 3.7</td>
<td>125 drug users were recognized by birth attendant survey. Birth certificates identified 59 users (40 of whom who were also identified by attendant survey)</td>
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<td>Tobacco use most highly correlates with drug use. Alcohol correlates with drug use.</td>
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<td>Drug use was recognized by 6% of attendants who routinely asked vs 3% in those who did not ask about drug use.</td>
<td>Birth certificate data</td>
<td>Univariate analysis. Illicit drug use reduced birth weight by estimated 80g (p=0.05)</td>
<td>Drug users were more likely than non-users to use alcohol (22%) and tobacco (74%) during the current pregnancy, tobacco use was most strongly associated with drug use.</td>
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<td>Decreased birth weight is associated with illicit drug use.</td>
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<td>(O’Campo et al., 1992)</td>
<td>Descriptive/Personal interview</td>
<td>Women attending first prenatal visit at Johns Hopkins Hospital Obstetrical Clinic for their first prenatal visit. Over 18 years old. 672 women recruited, 638 study participants. The first 301 women to deliver had data abstraction from charts.</td>
<td>Recent illicit drug use defined as drug use in the last year revealed in interview. Chart review. Urine toxicology done if drug use suspected and may be repeated during pregnancy. Marijuana, cocaine, heroin, barbiturates and amphetamines. Inquiry about drug use is routine clinical procedure. Medical record documentation, nurses and physician notes or toxicology screens for marijuana, cocaine, and heroin.</td>
<td>Marijuana, cocaine, heroin, barbiturates and amphetamines. Period prevalence rates calculated for drug use. Positive agreement between interview and chart review were determined by positive reports matched between both sources and Kappa statistics were used.</td>
<td>Period prevalence rates between marijuana and cocaine, with the percentage revealed in personal interview 28.7% and chart review 7.5%. Cocaine showed the greatest agreement with 12.2% revealed in interview vs 18.6% in chart review. Heroin use was documented in medical chart more frequently (9.7%) as compared to interview (5.8%), but this was not a significant difference.</td>
<td>VI</td>
<td>Marijuana use revealed almost 4 times as often in interview vs chart review. Limitation: Information about illicit drug use was collected at 2nd interview. Drug use included last 12 months in interview, chart review was for length of pregnancy. 1/2 women responded for &gt;/=6 months of pregnancy, the other 1/2 for the period that included &lt;/=5 months of pregnancy. Rec that labs alone not be used for evaluation of illicit drug use.</td>
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<td>(Ostrea et al., 2001)</td>
<td>Descriptive/Maternal interview</td>
<td>Toxicology of hair and meconium</td>
<td>75 women from a convenience sample of all women who presented for prenatal care at the Hutzel Hospital antenatal high risk clinic enrolled. Final sample of 58 mothers and 59 infants (one set of twins)</td>
<td>Maternal interview via questionnaire on first and subsequent visits, scripting used re: use of cocaine, opiates and cannabis. Maternal hair sample for drug analysis for cocaine, opiates, and cannabis. Infant meconium analyzed for cocaine, opiates, and cannabinoid</td>
<td>Amount and frequency of each substance used, cocaine, opiates and cannabis revealed by self-report Pencil shaft sized hair sample from mother. Analysis by radioimmunoassay with Gas chromatography/mass spectroscopy (GC/MS) Sample obtained from newborn and analyzed for cocaine, opiates, and cannabinoid. Analysis by radioimmunoassay. Positive results confirmed by (GC/MS)</td>
<td>3 methods of detection compared between 12 and 40 weeks gestation. Degree of agreement between 3 methods evaluated using 2 way &amp; 3 way kappa statistics. Sensitivity and specificity determined by comparing one positive with the other two methods for reference. Reference was positive if either of the other 2 methods was positive. Negative if both reference methods were negative.</td>
<td>VI</td>
<td>Interview has highest sensitivity for cannabinoids compared to meconium or hair analysis. Interview has a high degree of agreement with hair and meconium analysis for detection of cocaine and opiate use. All interviews done by the same person Infants born to drug using women were significantly small for gestation and significantly lower birth weight</td>
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a tendency toward mothers who received home visits to be more engaged in drug
treatment services, but further studies were needed (Turnbull & Osborn, 2012). Table 3
reflects behavior change studies.

**Aim statement**

By July 2014, community health workers will use the 5P’s substance use
screening tool in greater than or equal to 90% of initial prenatal visits.

**Recommendation for practice change**

A substance abuse screening tool that is made for pregnant women, with a focus
on risk, not just heavy use, is ideal. The tool used for screening pregnant women needs to
address past behavior as an assessment of risk, and not solely screen for current behavior.
Women with a history of previous use of alcohol or cigarette use should benefit from a
brief intervention that warns them of the consequences of beginning use again while
pregnant. The best tool is one that is used consistently and reveals light or intermittent
use as well as regular use of substance(s) and is easy to use (Chasnoff et al., 2005). Table
4 compares the substance use screening tools reported in the literature.

Therefore, the 5P’s screening tool was the ideal substance use screening tool for
this evidence based practice improvement project. The 5P’s substance use screening tool
is based on a validated tool, combines indirect and direct questioning, which has been
shown to reveal more substance use than either direct or indirect questioning alone. The
5P’s was designed for use with pregnant women, has been shown to be easy to use by
prenatal office staff, and was used in more than 90% of initial interviews in one study
(Kennedy et al., 2004). The 5P’s substance use screening tool is designed to assess risk
as well as use, and this leads to a brief intervention by the community healthcare worker
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<tr>
<td>(Chang et al., 2011)</td>
<td>Cross-sectional study</td>
<td>30 pregnant young adults up to age 25</td>
<td>DSM-IV substance use disorder module&lt;br&gt;Drinking within the six months prior to the interview&lt;br&gt;Drinking in settings: intimate, socially, and negative coping&lt;br&gt;Likelihood of behavior change</td>
<td>Self report of drug and alcohol use as well as the context within which the alcohol or drugs would be used</td>
<td>Descriptive statistics using percentages, means and standard deviations.&lt;br&gt;Fisher’s exact test to compare demographics&lt;br&gt;Wilcoxon’s test&lt;br&gt;Logistic regression to measure the area under the curve</td>
<td>90% of women were single&lt;br&gt;While pregnant: 8 (27%) drank average of 1.8 drinks/day (4% of days were drinking days).&lt;br&gt;3 (10%) smoked an average of 4.3 marijuana cigarettes on days they smoked (88% of days).&lt;br&gt;1 woman used both alcohol and marijuana&lt;br&gt;7 women fit DSM-IV criteria for lifetime alcohol use disorders, 1 had a current disorder.&lt;br&gt;9 met criteria for lifetime cannabis use disorder.</td>
<td>VI</td>
<td>Pre-pregnancy alcohol and cannabis use was associated with prenatal alcohol and cannabis use.</td>
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<td>Findings</td>
<td>Level of Evidence</td>
<td>Quality of Evidence: Critical Worth to Practice</td>
</tr>
<tr>
<td>----------</td>
<td>---------------</td>
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<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Clark, Dawson, &amp; Martin, (1999)</td>
<td>Randomized controlled trial</td>
<td>200 women screened with “old” procedure 400 women screened with “new” procedure</td>
<td>“old” screening approach – three check boxes for substance use, one for smoking/alcohol, and one for drug addiction/alcoholism  “new” screening approach - more detailed questions re: frequency of cigarette, alcohol, and illegal drug use during pregnancy</td>
<td>Any alcohol, cigarette or drug use.  Further information regarding frequency and amount of alcohol, cigarettes and/or drug use  Separation with new procedure of alcohol and smoking</td>
<td>Relative risk, confidence intervals.</td>
<td>21% of women with old procedure reported smoking/drinking alcohol  76% of women screened with new procedure reported smoking/drinking. Able to separate to 61% smoked 43% drinking</td>
<td>II</td>
<td>More detailed questions improves reporting as compared to yes and no questions  43% of women who revealed substance use or abuse may have been missed with old screening procedure</td>
</tr>
</tbody>
</table>

40
which is a discussion about the importance of abstaining from alcohol, drugs and tobacco while pregnant. As well, if actual use is admitted, motivational interviewing is used as part of the brief intervention to discuss the pregnant mother’s feeling as to whether she can change behavior at the time of the interview. The 5P’s screening tool also assesses the associated factors with substance use such as family violence. Appendix C shows the 5P’s substance use screening tool and Appendix D shows the permission to use the 5P’s substance use screening tool.
<table>
<thead>
<tr>
<th>Tool</th>
<th>Length of use</th>
<th>Time period for assessment</th>
<th>Assesses drugs</th>
<th>Assesses alcohol</th>
<th>Developed or for use for pregnant women</th>
<th>Assesses associated factors ie: tobacco, violence</th>
<th>Cost for Use</th>
<th>Sensitivity and Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-ACE</td>
<td>4 items</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Tobacco</td>
<td>Free</td>
<td>Heavy use</td>
</tr>
<tr>
<td>TWEAK</td>
<td>5 items</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>High sens for heavy drinking</td>
<td>Free</td>
<td></td>
</tr>
<tr>
<td>AUDIT-C</td>
<td>3 items</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>67-95% Sens</td>
<td>Free</td>
<td>85% Spec</td>
</tr>
<tr>
<td>ASSIST</td>
<td>8 question (follow up – lengthy)</td>
<td>not for prenatal patients</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Tobacco</td>
<td>Free</td>
<td>54-97% sens</td>
</tr>
<tr>
<td>4 P’s Plus</td>
<td>5 question (brief)</td>
<td>Direct/ ind quest. prior to &amp; during preg</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Tobacco</td>
<td>Cost for use – permission</td>
<td>87% sens</td>
</tr>
<tr>
<td>5P’s</td>
<td>Brief</td>
<td>Ind/ direct questions prior to preg &amp; current use</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Free with permission</td>
<td>76% Spec</td>
<td>Assessment ongoing</td>
</tr>
<tr>
<td>CAGE</td>
<td>4 items</td>
<td>No</td>
<td>Yes</td>
<td>No developed for men</td>
<td>No</td>
<td>Not rec for pregnant women</td>
<td>Not rec for pregnant women</td>
<td></td>
</tr>
<tr>
<td>Revised CAGE: Alcohol (Midanik, Zahnd, &amp; Klein, 1998)</td>
<td>4 items</td>
<td>12 months prior to pregnancy</td>
<td>No</td>
<td>Yes</td>
<td>No, but has been used with pregnant women</td>
<td>No</td>
<td>Sens &lt;20 y.o. 12-73% &gt;= 20; 57-84% &gt;=20; 84-92% Spec 91-99%</td>
<td></td>
</tr>
<tr>
<td>Tool</td>
<td>Length of use</td>
<td>Time period for assessment</td>
<td>Assesses drugs</td>
<td>Assesses alcohol</td>
<td>Developed or for use for pregnant women</td>
<td>Assesses associated factors ie: tobacco, violence</td>
<td>Cost for Use</td>
<td>Sensitivity and Specificity</td>
</tr>
<tr>
<td>------------------------------------------</td>
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<td>-----------------</td>
<td>--------------------------------------</td>
<td>-----------------------------------------------</td>
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<td>----------------------------</td>
</tr>
<tr>
<td>Modified CAGE: Drug use</td>
<td>4 items</td>
<td>12 months prior to pregnancy</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>Sensitivity lighter drug use &lt;20 year old 10-37% &gt;/=20; 34-37% THC24-30% 20 and older 23-25% heavier drugs &lt; 20 year old 31-80% &gt;/=20; 84-92% Spec 91-99% for all groups/ages</td>
</tr>
<tr>
<td>Drug Use Disorder (DUD) Questionnaire</td>
<td>12 items</td>
<td>Previous 12 months</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
<td>Assesses for drug use and dependence, not for risk of use</td>
</tr>
<tr>
<td>CRAFFT</td>
<td>6 items</td>
<td>Lifetime use addressed</td>
<td>Yes</td>
<td>Yes</td>
<td>Validity/Reliability in pregnant population not ascertained</td>
<td>No</td>
<td></td>
<td>Used in one study; embedded in health questionnaire.</td>
</tr>
<tr>
<td>Substance Use Risk pregnancy Profile</td>
<td>5 items</td>
<td>Yes – THC only</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Free</td>
<td>91% sens 67% spec</td>
</tr>
</tbody>
</table>
III. IMPLEMENTATION

Project Setting/Population

The setting chosen for this evidence based practice project was the Clark County Public Health Department’s Healthy Mommy Healthy Baby, Help Me Grow and Healthy Families America programs. These programs serve almost 300 pregnant and postpartum women in Clark County, located in Southwest Ohio. The three prenatal and postpartum programs provide pregnant women between one and five prenatal visits. See Appendix E for the agency permission form.

Healthy Mommy Healthy Baby serves primarily African American women, teens and Hispanic women, from the prenatal period until the toddler is two years old. The Help Me Grow program serves first time mothers whose babies are less than six months old through the age of three years old. The Healthy Families America program serves women during the prenatal and postnatal period, and until the child is five years old.

Table 5. Clark County Health department Programs

<table>
<thead>
<tr>
<th>Program Title</th>
<th>Maternal population served</th>
<th>Child population served</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy Mommy Healthy Baby</td>
<td>Aimed at African American women, pregnant adults and teens</td>
<td>Fetus to two years old</td>
</tr>
<tr>
<td>Help Me Grow</td>
<td>First time mothers, no race limitations</td>
<td>Less than six months to two years old</td>
</tr>
<tr>
<td>Healthy Families America</td>
<td>No race limitations, pregnant women</td>
<td>Fetus through five years old</td>
</tr>
</tbody>
</table>
All programs serve those women, babies, and children found to be below 200% of the poverty level and eligible for Medicaid services. In addition, those served include teen mothers, transient or homeless individuals and women with unintended pregnancies.

The aforementioned programs in Table 5 fall under the Child and Family Health Services Program at the Ohio Department of Health. Staffing at the programs consisted of registered nurses, licensed social workers, and certified community health workers. The programs function to assist clients to incorporate life-changing behaviors and collaborate with other agencies for referrals with an overall aim of improving pregnancy and infant outcomes.

Upon admission to any of the three programs, the staff completed an initial intake form that asks each pregnant woman questions regarding tobacco, alcohol, and illicit drug use. At the time of the evidence based practice improvement (EBPI) project implementation, there was no standard evaluation tool to elicit information related to the use of alcohol, tobacco, or illicit drug use upon entry into any of the above mentioned maternal/infant health programs. Each staff member asked questions as to substance use as they saw fit, and checked three boxes that the subject of alcohol, tobacco, and illicit drugs had been discussed. For instance “I know you probably don’t use drugs, but I have to ask” or “Sorry we have to ask, but you don’t use drugs, do you?” Questions about alcohol and tobacco were asked in a similar manner.

If substance abuse was revealed, the drug treatment facility to which clients are referred is the McKinley Hall Women’s and Children’s Program. Inpatient and outpatient therapy are available at McKinley Hall’s Program for women with substance use problems (C. Parker, personal communication, September 2013). Outcomes of the
referral were not tracked at the beginning of the EBPI project, but anecdotal evidence suggested that women who disclosed substance use and sought treatment in Clark County had been treated by McKinley Hall and some took maintenance medications at the time of delivery (C. Parker, personal communication, September 2013). Pregnant women typically were given priority if inpatient treatment was needed (M. Walsh, personal communication, January 2014). Participation in any of Clark County’s prenatal programs is voluntary and the relationship was based on mutual trust. If a woman disclosed substance use, a referral may be made, but the mother was not obligated to follow through with the referral. Care and support continues to be provided by the certified community health workers (CCHW), nurses and social workers regardless of the mother’s participation in a substance use treatment program (C. Parker, personal communication, September 2013).

**Implementation plan**

The team involved in implementation of the EBPI project is listed in Table 6. The team was responsible for planning training times, obtaining contact hour credit, providing training on the standardized training tool, and providing printed material about substance use in pregnancy.

The DNP student project leader coordinated the education time, contact hour preparation and approval, IRB application, data collection and data analysis. The manager of the Healthy Mommy Healthy Baby program and Director of the Clark County Maternal/Child Division met with the DNP project leader multiple times over the year prior to implementation to provide information and facilitate a smooth implementation plan. Dayton Children’s Hospital employees sponsored the contact hour
preparation and approval as outreach education. The biostatistician provided statistical support for the DNP student after data collection and completion of the project.

Table 6. 5P’s Screening Implementation Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisa R Jasin</td>
<td>Project leader/DNP student</td>
<td>Wright State University</td>
</tr>
<tr>
<td>Carlissa Parker</td>
<td>Leader Healthy Mommy Healthy Baby</td>
<td>Clark County Public Health</td>
</tr>
<tr>
<td>Lori Lambert</td>
<td>Director, Clark County Maternal/Child Division Certified Community Health Workers, nurses and social workers</td>
<td>Clark County Public Health</td>
</tr>
<tr>
<td>Mary Ann Swank</td>
<td>Contact Hour preparation</td>
<td>Dayton Children’s Hospital</td>
</tr>
<tr>
<td>Caroline Michael</td>
<td>Contact Hour Approval</td>
<td>Dayton Children’s Hospital</td>
</tr>
<tr>
<td>Michele Walsh</td>
<td>Advisor</td>
<td>Ohio Children’s Hospital Neonatal Abstinence Working Group</td>
</tr>
<tr>
<td>Rick McLead</td>
<td>Advisor</td>
<td>Ohio Children’s Hospital Neonatal Abstinence Working Group</td>
</tr>
<tr>
<td>Adrienne Stolfi</td>
<td>Biostatistician</td>
<td>Wright State University and Dayton Children’s Hospital</td>
</tr>
</tbody>
</table>

**Plan Do Study Act.** Plan Do Study Act (PDSA) is a method of testing a change. PDSA is the implementation step in Levin’s EBPI model. The *Plan* step is the plan needed to test the change. The *Do* stage is carrying out the plan of change. *Study* indicates observation of results of the test of change and reflection on what was learned during the *Do* stage. *Act* is the step in which changes are made and preparation is made for the next PDSA cycle. The first PDSA cycle is typically tested on a small group in a real world setting on a small scale called a small test of change. After the first PDSA
cycle, the next PDSA cycle is performed based on the outcome of the small test of change. The subsequent PDSA cycles may be expanded to other parts of an organization or implemented on a larger scale (Institute of Healthcare Improvement [IHI], 2014).

Readiness for Change

**Barriers.** Overcoming skepticism and misperception was the biggest barrier to implementing change. Melnyk & Fineout-Overholt, (2011) discuss skepticism and misperception as a major barrier to any implementation of an evidence-based practice change. The Clark County Public Health staff, which included CCHW, social workers, and registered nurses (RNs), were open to changing their substance use data collection tool and providing information, but not necessarily the time commitment required to perform a new screening and brief intervention with clients.

During clinical time previously spent with the CCHW, the DNP student had informal conversations about screening for substance use in the prenatal population. The comments made by the CCHW included "It's hard to find time to fill out more paperwork" (community health workers, personal communication, September, 2013).

During the education session, the CCHW were trained with the 5P’s substance use screening tool using self-directed role-playing. Role playing is a process of active learning by which participants are immersed in the process being taught. The participants gain understanding and skill in the use of the tool when engaged in active learning as opposed to passive learning in which the participants are expected to absorb and memorize pre-processed information. Active learning provides a higher level of engagement and motivation in participants, which was evident during the role playing session (McCarthy & Anderson, 2000).
The CCHW self-selected pairs and each performed the role-playing exercise with peer evaluation and then switched roles. Role-playing demonstrated the rapidity with which the 5P’s substance use screening tool could be used in the context of patient screening. Appendix F refers to the role playing script and the peer evaluation of the education that was provided.

Facilitators. The manager of the Healthy Mommy Healthy Baby program had buy in for the project, through previous conversations and education provided to the Clark County Public Health staff regarding the implementation of the 5 Ps screening tool. The Director and manager voiced support for instituting consistent evaluation for substance use of clients at entry into any of the three programs.

There was one community health worker from the Clark County Healthy Mommy Healthy Baby program who expressed a positive attitude at the thought of having a consistent method to document the substance use assessment. This individual was the unit champion, was an informal leader, and was the person with the most seniority in the Healthy Mommy Healthy Baby Program. The unit champion provided support for fellow staff members and distributed information in the form of pamphlets for clients that were provided by the March of Dimes and Centers for Disease Control. Pamphlets were distributed to the staff by the unit champion to use during the implementation of the new 5 Ps screening process. However, a behavior change in the staff was not noted with the distribution of pamphlets, but did result in reinforcement of information previously discussed with the staff.

The Clark County prenatal programs serve approximately 300 pregnant and postpartum women. Entry into any of the three programs was primarily by word of
mouth. It was anticipated that between ten and twenty women would enter the three programs in a month (C. Parker, personal communication, September 2013). Therefore, the first two weeks of the new implementation by the Healthy Mommy Healthy Baby program were expected to include three to five pregnant women. The initial two weeks encompassed the first PDSA cycle.

**Methods**

The DNP student received training regarding the 5P’s screening tool for substance use in February 2013. The trainer was Enid Watson, Director of Screening and Early Identification, Massachusetts FASD State Coordinator, Institute for Health and Recovery. The DNP student provided the two-hour education program for CCHW, RNs and social workers. There was one education contact hour available for all who attended, provided by the local Children’s Hospital. The education method was a PowerPoint (Appendix G) lecture and a role playing activity. During the role-play, participants were able to use the 5P’s screening tool for assessing substance use and practice the discussion/intervention if risk of substance use was identified.

The EBPI project began with a training session for RNs, social workers and certified community health workers. Because of the barrier of time to commit to training, the entire staff from the three prenatal and postpartum programs were trained at the same time.

The PowerPoint used to educate the Clark County staff members contained history of the 5P’s substance use screening tool, Screening, Brief Intervention, and Referral to Treatment (SBIRT), and information about motivational interviewing. The role-playing activity took place between pairs of staff, one of whom played the part of the
pregnant mother, and the other who played the part of the interviewer. Peer evaluation took place using the tool in Appendix E to ensure all areas of the SBIRT process were addressed. After the first role-playing exercise, the staff members then switched roles. While the DNP student provided the initial training, subsequent training sessions were conducted by peer-to-peer teaching. The PowerPoint (Appendix G) and peer evaluation tool (Appendix F) was made available to the Clark County prenatal and postnatal staff after the initial training period to ensure consistency of the program.

**Plan Do Study Act.** The initial Plan Do Study Act (PDSA) cycle (small test of change) occurred with the certified community health workers from the Healthy Mommy Healthy Baby (HMHB) staff. The initial PDSA cycle and data collection occurred for two weeks. The plan proceeded as expected, with fewer than expected pregnant women entering the HMHB program. As well, one of the CCHWs used the 5P’s substance use screening tool with clients already in the program as opposed to new clients. This specific CCHW felt more comfortable using the screening tool with patients already enrolled in the program versus patients that were initial intakes. The DNP student learned of this unintentional change in protocol while talking with the CCHW during a data collection appointment.

The prediction the DNP student made for the first PDSA cycle was that there would be a change in substance use or violence risk revealed with the 5P’s substance use screening tool as opposed to free form questioning. During the first PDSA cycle, three CCHW’s saw three new intake clients. The DNP student predicted the CCHWs would find the 5P’s substance use screening tool easy to use, which was stated by the CCHW during the first data collection session. During the first PDSA cycle, one pregnant
A woman who was a current client revealed a risk factor for substance use on follow up when the CCHW used the 5P’s substance use screening tool for follow up, that was not revealed in the initial intake with free form questioning.

The second PDSA cycle was extended to the Healthy Families America program with no changes and continued for three total months of data collection. Figure 2 shows the timeline for the EBPI project. Appendix H shows the two PDSA cycles.

![Timeline for Evidence Based Practice Project](image)

Prior to beginning the staff education program, a pre-survey was given (Appendix I). Immediately after the staff education program, a post-survey was given (Appendix I). As questions included intent to use and ease of use, the immediate post-survey was used
to assess and compare the intent to use the 5P’s substance use screening tool immediately after the staff education session as well as the perception of ease of use. After the staff had the opportunity to use the 5P’s screening tool for two months, the post-survey was administered again to assess and compare ease of use, and continued intent to use the 5P’s screening tool (Appendix I). The staff members who took the pre survey and immediate post survey were the same staff members. However, the staff members who took the post survey eight weeks after the education program were not all the same staff members who took part in the pre and post survey due to staffing changes.

Staff were instructed that if substance use was revealed by the expectant mother, a brief intervention was to be performed with the staff member stating the need for abstinence and/or treatment for the substance use. If the disclosure consisted of illicit substance use, referral was supposed to be made to McKinley Hall Treatment Center and the woman was encouraged to disclose the substance use information to the obstetrician. Both of these actions on the part of the pregnant woman were voluntary.

Each staff member was given a tool kit which contained a copy of the 5P’s screening tool for substance use and pamphlets from the March of Dimes and the Centers for Disease Control that consisted of information about alcohol, tobacco and illicit drug use in pregnancy. The pamphlets were given to all expectant mothers. However, if risk of substance use was revealed, the written information was to be accompanied by verbal discussion initiated by the CCHW, RN or social worker. The pamphlets from the March of Dimes were “Alcohol and Pregnancy”, “Smoking and Pregnancy” and “Drugs and Pregnancy.” Each of these pamphlets detailed the effect of alcohol, tobacco and drugs on the fetus. The Centers for Disease Control pamphlet was “Think Before you Drink” and
detailed prevention of Fetal Alcohol Syndrome. Included in the tool kit was also a copy of the power point lecture (Appendix G) for reference.

The DNP student accomplished retrospective data collection of client demographics to include race, age, number of pregnancies, number of living children, weeks of pregnancy, education, and intent to breastfeed. The DNP student also collected data to include use of the 5P’s substance use screening tool, risk revealed, referrals for treatment for substance use or domestic violence, and documentation of discussion about substance use or documentation of written information about substance use being given, for the three months prior to implementation after IRB approval. Data collection for intake interviews after implementation was accomplished on an every other week basis (Appendix J).

The expected outcomes of increased use of a standardized screening tool for the identification of risk for substance use while pregnant was expected to lead to an increased discussion of abstinence of substances while pregnant. The data collection included whether the 5P’s screening tool or the “old” tool was used in the initial interview, whether risk was identified, if referral was made, and documentation of brief intervention, discussion and written information took place.

Instruments

Staff pre and post survey. Outcome measures included both staff and client outcomes. Staff was surveyed prior to education in the use of the 5P’s substance use screening tool and immediately following the education (Appendix I). The staff was surveyed with the same questions two months after education, which allowed the staff time to use the 5P’s substance use screening tool with clients at intake appointments.
The staff included certified community health workers (CCHW), social workers and nurses. Staff were surveyed prior to the staff education session to determine the baseline knowledge about the 5P’s substance use screening tool. Then the staff were surveyed immediately following the staff education session to determine the change in knowledge about the 5P’s substance use screening tool. Lastly, the staff were surveyed (Appendix I) eight weeks following the initial staff education session to determine if the change in knowledge about the 5P’s substance use screening tool was retained. The staff surveyed at eight weeks after the staff education session may not have been the original staff members who received the education due to staffing changes.

The DNP student created the pre and post survey tool used with the staff. The questions used by the Institute of Health and Recovery in previous evaluations of the 5P’s substance use screening tool were not available. However, Enid Watson, from the Institute of Health and Recovery, discussed the themes of the questions during the DNP student’s training in the use of the 5P’s substance use screening tool. The themes were used to develop nine questions and a Likert scale was used as a response. The Likert scale of 1 indicated strong agreement with the statement, and 5 indicated strong disagreement with the statement. There was no established validity or reliability for the DNP created pre and post education survey tool.

The staff survey consisted of nine questions along four themes. The themes were knowledge, ease of use, comfort level, and intent to use the tool. The knowledge questions asked if the staff knew what the 5P’s substance use screening tool was, if the staff knew how to use the tool, and if the staff knew what to do if a mother had a positive screen. The ease of use question asked the staff if the 5P’s substance use screening tool
was easy to use. The comfort questions asked if the staff was comfortable asking the questions on the 5P’s substance use screening tool, if the staff was comfortable questioning a pregnant woman about substance use, and if the staff was comfortable performing a brief intervention. The intent to use question asked if the staff planned to use the 5P’s substance use screening tool at intake interviews. See Appendix I for staff evaluation tools.

There were a total of nine questions with an individual score of a minimum of 1 and a maximum of 5. Therefore, the total score would be a minimum of 9 and a maximum of 45. The lower score indicated a positive response and was more desirable. All questions were asked in a positive fashion with strong agreement (score of 1) as the goal. The change in score of each individual question that was desired from the pre survey to the post survey was an increase in agreement and thus a score on each individual question closer to 1 and a total score closer to 9.

**Staff role playing and peer evaluation.** The staff revealed a concern for the time it would take to perform the 5P’s substance use screening tool. To demonstrate the rapidity with which the 5P’s substance use screening tool could be used, the DNP student planned a role playing session. The staff practiced role playing in self-selected pairs and used a checklist that was created to ensure all the steps of the 5P’s substance use screening tool were followed. Both members of the pair were given the opportunity to play the role of the pregnant woman and of the interviewer. The role of the pregnant mother provided answers to each question on the 5P’s substance use screening tool and the checklist provided a place to check off each step of the screening process. Appendix E shows the role playing and peer evaluation tools.
Client Outcomes. Client outcomes were obtained for the three months prior to implementation of the 5P’s substance use screening tool. Client outcomes were collected by retrospective chart review every other week for three months after implementation of the 5P’s substance use screening tool. The client outcomes were collected for the Healthy Mommy Healthy Baby program initially for two weeks (during the first PDSA cycle) and then implementation and data collection was expanded to all three prenatal programs in the second PDSA cycle. Outcomes collected were de-identified and included demographic data to include race, age, number of pregnancies, number of living children, weeks of pregnancy, education, and intent to breastfeed, documentation of use of the standardized screening tool, identification of risk for substance use and documentation of discussion about identified risk for substance abuse. See Appendix J for the data collection tool.

IRB

The Wright State University Institutional Review Board was approached for expedited review for the EBPI project. In any intervention there are risks and benefits to participation. Risk to clients was non-existent from a health standpoint. However, there was potential risk related to privacy issues in relation to clients who were identified as at risk for substance use. The privacy risk to any one client was decreased by de-identification of all data at the time the data was collected. The risk to staff members was a potential loss of privacy if the answers to the pre and post surveys were revealed. The risk of privacy was decreased by de-identification of pre and post surveys at the time of the staff education session and again at the eight week post survey session.
The benefit to client participants included possible decrease in health behaviors that contribute to preterm birth. As well, there was potential for a possible increase in client referral for cessation services concerning alcohol, tobacco and illicit drug use related to increased assessment and discovery. The benefit to staff members included possible improvements in future education based on the changes in the response to pre and post survey questions. IRB approval for data collection is found in Appendix K. IRB declaration of staff survey as quality improvement not requiring oversight of the IRB is found in Appendix L.

**Project Costs**

Financial resources needed to implement the EBPI project required minimal funding, see cost projection Appendix M. Personnel resources included the Clark County Public Health Director, and Healthy Mommy Healthy Baby manager. There were no personnel needed to perform the data collection, data entry, or staff training since the DNP student performed these duties. Data analysis, review of integrated screening tool and data advice was provided free of charge by a biostatistician who is an employee of Wright State University. The March of Dimes and Centers for Disease Control provided the educational handouts free of charge.
IV. PROJECT EVALUATION

Outcomes of Project

Outcomes of the evidence based practice improvement project were measured in three categories. The first outcome was measured by staff pre implementation, and post implementation survey. The second outcome measure was peer evaluation in combination with a role playing exercise. The third outcome measure was a measure of the 5P’s substance use screening tool use and risk revealed related to its use. Statistical significance was defined as p<0.05.

**Staff pre and post implementation survey.** The total score of the staff survey could range from nine to 45, with a lower score indicating agreement with the survey statements. The mean total score of the staff pre survey was 27. The mean total score of the immediate staff post survey was 14. A paired samples t-test was conducted to evaluate whether the pre test results with a range of 9 to 42 (M=27.12, SD=11.29), were significantly greater than the post test results with a range of 9 to 42 (M=14.81, SD=9.99), t (15) =4.25, p<.001. The paired sample t-test demonstrated statistical significance in the change of total score on the staff survey from pre survey to immediate post survey.

The staff post survey eight weeks after implementation demonstrated a continued improvement in individual mean scores when compared to the pre survey mean scores and the immediate post survey mean scores. The knowledge of the 5P’s substance use
screening tool decreased from a mean score of 3.3 on the pre survey to a mean score of 1.43 on the post survey. The mean score on the eight week post survey was 1.75 which remained lower than the pre survey. The question that addressed comfort asking the questions on the 5P’s tool demonstrated a decreased mean score from 3.12 on the pre survey to 1.56 on the post survey and remained lower than the pre survey on the eight week post survey at a mean score of 1.75. Comfort with questioning a pregnant woman about substance use indicated a mean score of 2.25 on the pre survey and a decreased mean score of 1.62 on both the immediate post survey and the eight week post survey. Knowledge of how to use the 5p’s tool for screening for substance use decreased from a mean score of 3.5 on the pre survey to a mean score of 1.87 on the immediate post survey and showed further decrease to a mean score of 1.75 on the eight week post survey. Planning to use the 5P’s tool on the pre survey showed a mean score of 2.5 which decreased on the post survey to a mean score of 1.56. The plan to use the 5P’s tool mean score increased to 1.87 on the eight week post survey. Knowledge of what to do if a pregnant woman had a positive screen with the 5P’s tool had a mean score of 3 on the pre survey and decreased to a mean score of 1.56 on the immediate post survey and an increase to a mean score of 2.12 on the eight week post survey. Confidence in using the 5p’s screening tool had a mean score of 3.25 on the pre survey and a mean score of 1.75 on the post survey. The mean score increased to 2 on the eight week post survey. Comfort performing a brief intervention had a mean score of 1.75 with no change in mean score post survey and an increased mean score of 2 on the eight week post survey results. Table 7 shows mean scores and standard deviation of staff pre and post surveys.
Table 7. *Staff Member Survey Change pre and post implementation*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Pre implementation Mean (SD)</th>
<th>Post implementation Mean (SD)</th>
<th>8 weeks post implementation Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I know what the 5Ps screening tool is</td>
<td>3.3 (1.62)</td>
<td>1.43 (1.2)</td>
<td>1.75 (.88)</td>
</tr>
<tr>
<td>I am comfortable asking the questions on the 5Ps tool</td>
<td>3.12 (1.58)</td>
<td>1.56 (1.2)</td>
<td>1.75 (.88)</td>
</tr>
<tr>
<td>I am comfortable questioning an expectant mother about substance use</td>
<td>2.25 (1.23)</td>
<td>1.62 (1.02)</td>
<td>1.62 (.74)</td>
</tr>
<tr>
<td>I know how to use the 5Ps tool for screening for substance use</td>
<td>3.5 (1.59)</td>
<td>1.87 (1.25)</td>
<td>1.75 (1.03)</td>
</tr>
<tr>
<td>I plan to use the 5Ps screening tool for substance use at all new intake interviews</td>
<td>2.5 (1.31)</td>
<td>1.68 (1.25)</td>
<td>2.12 (1.24)</td>
</tr>
<tr>
<td>The 5Ps screening tool for substance use is easy to use</td>
<td>3.25 (1.43)</td>
<td>1.56 (1.2)</td>
<td>1.87 (1.12)</td>
</tr>
<tr>
<td>I know what to do if an expectant mother has a positive screen with the 5Ps’s substance use screening tool for substance use</td>
<td>3 (1.54)</td>
<td>1.56 (1.03)</td>
<td>2.12 (1.12)</td>
</tr>
<tr>
<td>I feel confident using the 5Ps screening tool</td>
<td>3.25 (1.48)</td>
<td>1.75 (1.29)</td>
<td>2 (.92)</td>
</tr>
<tr>
<td>I am Comfortable performing brief intervention</td>
<td>1.75 (1.48)</td>
<td>1.75 (1.29)</td>
<td>2 (.92)</td>
</tr>
</tbody>
</table>

Each statement in the survey was looked at individually to compare the pre and immediate post survey. The distribution of answers was not in a bell curve, but was a
skewed distribution. Therefore, an exact McNemar’s test was performed to determine statistical significance of the number of staff members who changed from disagree on the pre survey to agree on the post survey. The responses were rated with a five point Likert scale; strongly agree, agree, neutral, disagree, and strongly disagree. The exact McNemar’s test required changing all strongly agree and agree responses to agree, and all strongly disagree and disagree responses to disagree. Neutral responses were counted as missing data. Table 8 shows the results of the staff pre and post survey with statistical significance.

The exact McNemar’s test determined there was a statistically significant difference in the individual staff survey question “I know what the 5P’s screening tool is?” pre- and post-implementation (p<.031). Several questions demonstrated close to clinical significance. The questions concerning comfort asking the questions on the 5P’s tool (p<.07), knowledge how to use the 5P’s (p<.063), ease of use of 5P’s (p<.063), and knowledge of what to do with a positive screen (p<.063). The remainder of the individual questions showed no statistically significant difference.

The staff was evaluated with a post survey eight weeks after the implementation of the 5P’s substance use screening tool. The mean total score of the post survey was 17 with a standard deviation 8.23 (N=8) on the same scale of minimum nine and maximum 45. This was a decrease from the pre survey mean 27.12 with standard deviation 11.29 (N=16) and slightly increased from the immediate post survey mean of 14.81 with standard deviation 11.29 (N=16).

**Staff peer evaluation and role playing.** Peer evaluation of the staff took place during the education class when community health workers divided into pairs and
performed evaluation of each other with a role playing exercise (Appendix F) involving screening with the 5Ps tool, brief intervention and motivational interviewing. All participants verbally stated comfort with the role-playing exercise and evaluation in pairs.

The staff members retained their role-playing exercise and evaluation papers.

Table 8. *Staff Member Evaluation Results*

<table>
<thead>
<tr>
<th></th>
<th>Change from disagree to agree</th>
<th>Change from agree to disagree</th>
<th>Statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>I know what the 5Ps screening tool is</td>
<td>N-6</td>
<td>N-0</td>
<td>P&lt;.031</td>
</tr>
<tr>
<td>I am comfortable asking the questions on the 5Ps tool</td>
<td>N-7</td>
<td>N-1</td>
<td>P&lt;.07</td>
</tr>
<tr>
<td>I am comfortable questioning an expectant mother about substance use</td>
<td>N-2</td>
<td>N-0</td>
<td>P&lt;.5</td>
</tr>
<tr>
<td>I know how to use the 5Ps tool for screening for substance use</td>
<td>N-5</td>
<td>N-0</td>
<td>P&lt;.063</td>
</tr>
<tr>
<td>I plan to use the 5Ps screening tool for substance use at all new intake interviews</td>
<td>N-2</td>
<td>N-0</td>
<td>P&lt;.5</td>
</tr>
<tr>
<td>The 5Ps screening tool for substance use is easy to use</td>
<td>N-5</td>
<td>N-0</td>
<td>P&lt;.063</td>
</tr>
<tr>
<td>I know what to do if an expectant mother has a positive screen with the 5Ps substance use screening tool for substance use</td>
<td>N-5</td>
<td>N-0</td>
<td>P&lt;.063</td>
</tr>
<tr>
<td>I feel confident using the 5Ps screening tool</td>
<td>N-5</td>
<td>N-0</td>
<td>P&lt;.125</td>
</tr>
<tr>
<td>I am Comfortable performing brief intervention</td>
<td>N-4</td>
<td>N-0</td>
<td>P&lt;.125</td>
</tr>
</tbody>
</table>
**Client evaluation.** The prenatal programs enrolled seventeen new clients in the three-month period following implementation of the 5P’s substance use screening tool. The prenatal groups, when compared, were unequal in number. There were 43 women enrolled as new intakes prior to implementation and 27 women enrolled after implementation across the three groups. However, in light of the third prenatal group declining to use the 5P’s tool, those clients were removed from statistical analysis. There were 57 remaining clients for evaluation of use of the 5P’s within the first two prenatal groups. Demographic data is demonstrated in Table 9. Site 1 was Healthy Mommy Healthy Baby, which had a 100% population of African American women. This was appropriate for this group due to the focus of Healthy Mommy Healthy Baby to target African American women for enrollment.

Evaluation of the first prenatal program demonstrated three of eight intake evaluations performed using the 5P’s substance use screening tool after the implementation took place. This equates to a 38 percent use in the initial intake. There were nine new clients in the second prenatal group, of which four had the 5P’s tool used in the post implementation period. This equated to a 44 percent use rate post implementation. Combined, there was a 47 percent use rate of the 5P’s tool after implementation took place.

Data analysis of the first two combined prenatal groups was completed pre and post education using Pearson Chi Square. There was a significant difference (defined as \( p<0.05 \)) between pre and post education when comparing the use of the 5P’s tool \( p=0.022 \). There was not a significant difference in identification of risk pre and post education \( (p=0.654) \), substance use disclosure \( (p=0.5) \), referral to treatment \( (p=0.473) \),
Table 9. Demographics of Clients

Demographics of clients in the first and second prenatal groups pre and post education

<table>
<thead>
<tr>
<th></th>
<th>Pre implementation of 5P’s tool</th>
<th>Post implementation of 5P’s tool</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Site 1</td>
<td>Site 2</td>
</tr>
<tr>
<td>Subjects</td>
<td>N=26</td>
<td>N=14</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>N=0 (0%)</td>
<td>N=6 (42%)</td>
</tr>
<tr>
<td>African American</td>
<td>N=26 (100%)</td>
<td>N=1 (7%)</td>
</tr>
<tr>
<td>Gravida</td>
<td>2.7(1.52)</td>
<td>1.6(.89)</td>
</tr>
<tr>
<td>Para</td>
<td>.87(1.02)</td>
<td>1.3(.51)</td>
</tr>
<tr>
<td>Years of school</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 12 years</td>
<td>N= 5 (19%)</td>
<td>N=1 (7%)</td>
</tr>
<tr>
<td>12 years or &gt;</td>
<td>N= 21 (81%)</td>
<td>N=6 (42%)</td>
</tr>
<tr>
<td>Age</td>
<td>24(5.9)</td>
<td>24.3(4.8)</td>
</tr>
<tr>
<td>Weeks of pregnancy</td>
<td>21.4(8.7)</td>
<td>33.4(12.6)</td>
</tr>
<tr>
<td>Marital status</td>
<td>N=21(81%)</td>
<td>N=7 (50%)</td>
</tr>
<tr>
<td></td>
<td>N=3 (12%)</td>
<td>N=0 (0%)</td>
</tr>
<tr>
<td>Planning to breastfeed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>N=13 (50%)</td>
<td>N=2 (14%)</td>
</tr>
<tr>
<td>No</td>
<td>N=7 (27%)</td>
<td>N=2 (14%)</td>
</tr>
</tbody>
</table>

Numbers do not add up to 100% due to missing data

documentation of discussion or intervention (p=.109), or written information given to clients (p=.908).

One of the certified community health workers decided to use the 5P’s tool as a follow up with current clients after the implementation. This certified community health worker had twenty total clients in the six months before and after the implementation,
and two were new clients after the education session. Of the eighteen current clients, sixteen were screened with the 5P’s tool after the education session. This equated to 80 percent use of the 5P’s tool overall for this particular certified community health worker. Of the sixteen clients, nine clients had risk identified with the 5P’s substance use screening tool. Of those, eight clients had risk identified with the 5P’s tool that was not identified during intake. This equated to a risk identification with the 5P’s substance use screening tool of 56% compared to 6% with free form questioning. The risk was related to violence (n=2), parental use of drugs (n=2), and smoking (n=4). Post implementation, there was an increase in documentation of discussion as well as increased documentation of written information given. Table 10 shows data related to risk identification post implementation with a single CCHW.

Table 10. Pre and post implementation risk identification of a single CCHW

<table>
<thead>
<tr>
<th></th>
<th>Initial Intake N=16</th>
<th>Use on follow up visits N=16</th>
</tr>
</thead>
<tbody>
<tr>
<td>5P’s tool used</td>
<td>N=0</td>
<td>N=16 (100%)</td>
</tr>
<tr>
<td>Risk identified</td>
<td>N=1 (6%)</td>
<td>N=9 (56%)</td>
</tr>
<tr>
<td>Disclosure substance use</td>
<td>N=0</td>
<td>N=0</td>
</tr>
<tr>
<td>Referral made</td>
<td>N=0</td>
<td>N=1 (6%)</td>
</tr>
<tr>
<td>Documentation of discussion</td>
<td>N=4 (25%)</td>
<td>N=14 (88%)</td>
</tr>
<tr>
<td>Written information given</td>
<td>N=12 (75%)</td>
<td>N=16 (100%)</td>
</tr>
</tbody>
</table>
V. DISCUSSION

Findings from this evidence based practice improvement project were expected to demonstrate increased use of a standardized screening tool after education in the use of the tool. Increased use of the standardized screening tool was demonstrated and it was statistically significant. A clinically increased revelation of risk at initial intake interview was demonstrated after implementation, but this was not statistically significant.

Staff pre and post survey evaluation

Sixteen staff members participated in the pre-implementation education program about use of the 5Ps substance use screening tool, motivational interviewing, and brief intervention. The staff members were representatives of three separate departments of the public health department that provide services for pregnant women. The staff members were certified community health workers who were required to have a minimum education level of a High School education, nurses who were licensed practical nurses at a minimum, and social workers. A pre-survey and post survey were obtained before and after the education session. A post survey was obtained again eight weeks after the education session (Appendix I).

Eleven staff members took part in the post survey eight weeks after the education and implementation. Of those, the two staff members who used the 5Ps substance use screening tool in the first PDSA cycle had resigned and were not present. Of the eleven, there were three staff members who were newly hired and who did not participate in the
 Those three new staff members post surveys were not included in the statistical analysis.

The mean total score decreased from the pre to the immediate post evaluation of staff and was statistically significant. However, the individual evaluation showed a difference only in the knowledge of what the 5P’s tool was. The remainder of individual questions pre and posttest did not have a statistically significant difference. The difference between significant and insignificant change was impacted by the small sample size. Statistical significance for this project was defined as \( p < 0.05 \). Several individual questions approached statistical significance with a \( p < 0.1 \). These were the questions related to comfort asking the questions on the 5P’s tool, knowledge of how to use the 5P’s tool, ease of use of the 5P’s and knowledge of what to do if there was a positive screen using the 5P’s tool. The difference between statistical significance and lack of statistical significance in these questions was one staff member changing to agree from disagree on the post survey.

**Strengths.** The staff members were very receptive to “anything that improves the care we provide.” The Healthy Mommy Healthy Baby manager was responsible for that quote and the statement was echoed by the remainder of the staff. The entire staff was available for the education session prior to implementation of the 5P’s substance use screening tool. The Director of the prenatal services arm of the Public Health Department was supportive and ensured the education took place by scheduling it on the day of a district meeting to ensure staff attendance.

This was the first documented use of the 5P’s substance use screening tool in a home visiting population with staff members who were certified community health
workers. Previously, the 5P’s substance use screening tool was implemented with private and public health obstetrical services by nurses, physicians, nurse practitioners and certified nurse midwives (Watson, 2010). This type of implementation may have been impacted by reimbursement as noted by Enid Watson in “The Evolution and Application of the 5P’s Behavioral Risk Screening Tool” (Watson, 2010). Screening for substance use is part of the initial intake interview in all prenatal departments of the public health department. Substance use screening in the public health department is not tied to reimbursement and because CCHWs as well as nurses perform initial intake assessments at the public health department, it was reasonable for the staff of the public health department to use the 5P’s substance use screening tool. The CCHWs demonstrated the ability to successfully use the 5P’s substance use screening tool and expose risk in clients that could then be addressed with brief intervention and referral.

**Barriers.** A small sample size limited statistical significance. Staffing changes had a large impact on the sample size due to resignations and new hires. The pre and post survey was not a validated tool, but did ask questions along the same themes as the Institute for Health and Recovery had previously asked when implementing the 5P’s substance use screening tool.

Further impact on statistical significance was due to one of the three prenatal programs using the 5P’s substance use screening tool at the direction of the state department of health. The staff that was already using the 5P’s tool was not calling it by the same name. The Director who was helping the DNP student coordinate the education and implementation was unaware that the tool was in use. There had been no training for
the staff using the tool prior to its implementation approximately six months before the education session offered by the DNP student.

**Staff role playing and peer evaluation**

The staff role-playing and evaluation was a successful way to have peers practice using the 5P’s evaluation tool. The staff members self selected the pairs for the role playing exercise. All staff present at the education session completed the role-playing evaluation on the first attempt.

**Strengths.** The staff members immersed themselves in the role playing exercise as evidenced by direct observation by the DNP student. Staff members stated comfort with the use of the 5P’s substance use screening tool after the role playing exercise in response to direct questioning by the DNP student. The staff members kept the role playing exercise and evaluation checklist for future reference. Active learning in addition to lecture encourages not only passive absorption of information, but application of new knowledge for better recall.

**Barriers.** There was no formal documentation of success of the role playing exercise. Successful completion was self reported via verbal response to direct questioning after completion of the exercise. Staff stated comfort with performing the brief intervention after the role playing exercise during the staff education session. Staff also verbalized the referral center that a client would be referred to if the client revealed illicit drug use. This stated comfort was consistent with the increased comfort found in the Massachusetts ASAP Program after role playing exercises, scripting and knowledge of the local referral center for substance use (Kennedy, et al, 2004).

**Client evaluation**
The intent of the evidence based practice improvement project was to use a standardized screening tool in the first prenatal intake evaluation. Data was collected retrospectively for three months pre implementation and also for three months post implementation. The first prenatal group only had data collection for two months post implementation. This was due to the resignation of two of three staff members after two months of data collection.

The second prenatal program was already using the 5P’s tool. However, the staff was not using the tool as a prenatal screening tool, but within thirty days of the baby’s birth. This defeated the purpose of the 5P’s screening tool as a prenatal screening tool. This concern was discussed with the manager of the second prenatal program. However, it was found to be at the direction of a state level government agency that the 5P’s screening tool be used as a postpartum tool. The staff of the second prenatal program had been using the 5P’s screening tool for several months, however, the staff had not received previous education about the use of the 5P’s, brief intervention, or motivational interviewing prior to the education offered by the DNP student. The third prenatal program elected not to participate in the 5Ps screening for new clients, primarily because they were closed to new clients during the project implementation time frame.

Evaluation of the use of the 5Ps screening tool compared to free form substance use questions took place retrospectively every two weeks for three months after the education. Comparison was made between substance use screening in the three months prior to education and for the three months post education.

The staff of the prenatal programs did not achieve a 90% use of the 5P’s screening tool after education during intake interviews. One certified community health
worker achieved an 80% use of the 5P’s screening tool. This was not done on initial intake, but primarily with clients who had previously had an intake interview. While not the intent of the EBPI project, it showed that use of a standardized screening tool does reveal more risk than use of free form questioning, and increases screening of clients in this population.

There were two comments made by the certified community health workers in the first prenatal program to the DNP student during data collection. Both certified community health workers were present during data collection approximately one month after the education session. The statements made were, it’s “a little more uncomfortable with first time clients” and it’s “easy with clients you’ve been with for a while.”

There was a significant difference in the use of the 5P’s tool post education. While the tool was not available for the first prenatal program prior to the education, the second prenatal program did have the tool available for use. This does show an increase in the use of the 5P’s tool post education. There was not a significant increase in risk revelation, substance use disclosure, referral for treatment, documentation of discussion or intervention, or distribution of written information. Small numbers of post education clients impacted the data analysis.

There were an unequal number of participants pre and post education, almost twice as many pre as post. When evaluating demographic data, totals in each category do not add up to the total of 57 due to unavailable data during chart review. Race was unequal pre and post implementation and was primarily African American. This was due to the prenatal programs designated service population. There were a higher number of pregnancies in the pre implementation population, but no statistical difference in the
number of living children. There was no difference in the years of education, but pre implementation, women were older. There was no difference in the marital status or plans to breastfeed pre and post education.

Further impact on the use of the free form questioning and documentation may have been impacted by the way in which documentation was accomplished. Evaluation of the free form questioning used prior to the education session showed that community health workers were required to flip a piece of paper to visualize the check boxes to document free form questioning and then turn a six sided folder upside down to document the discussion. The 5Ps standardized substance use screening tool was a one page document that required no additional movement beyond turning a page to obtain access to the documentation.

**Unintended results.** The certified community health worker who used the 5Ps substance use screening tool as a follow up for current clients was the same certified community health worker who made the statement it’s “easy with clients you’ve been with for a while.” Of the twenty clients who this certified community health worker interviewed, eight had no screening on intake, twelve clients had free form questioning on intake. Sixteen of the clients had screening with the 5Ps substance use screening tool. Seven of the clients with no previous screening were subsequently screened with the 5Ps screening tool. Two of these clients revealed smoking that was previously unknown and two revealed risk for substance use that was previously unknown. Of the thirteen clients who were screened with free form questioning, ten were subsequently screened with the 5Ps tool. One client revealed risk for alcohol use, and domestic violence that was previously unknown, this client was known to use tobacco, which was discovered with
free form questioning. One client revealed domestic violence that was previously unknown.

The use of the 5P’s substance use screening tool enabled referral to counseling for domestic violence that would not have taken place if only the free form questioning had been used. When the 5P’s substance use screening tool was used in the ASAP 2 project, 36% of the women on whom it was used had a positive screen and received a brief intervention (Fogerty & Finkelstein, 2005). This is consistent with a 56% positive screen in the clients in this evidence based practice improvement project. The low number of clients in this study impacts the percentage with a positive screening, but it does indicate a higher rate of risk being revealed with use of the 5P’s substance use screening tool.

**Strengths.** In this evidence based practice improvement project, use of the standardized screening tool revealed a higher percentage of risk than use of free form questioning, although this was not statistically significant. This is consistent with the findings by Clark, Dawson, & Martin (1999) that free form questions reveal less smoking and drinking than more detailed questioning. The small number of new clients who were interviewed at intake impacted the statistical significance.

**Barriers.** There was a lower than expected number of clients who had intake interviews post education. This was the result of several unanticipated variables.

The timing of the implementation of the 5P’s substance use screening tool coincided with the 2014 grant cycle. At that time, there were changes made to several programs and it was unclear what effect the grant approval or disapproval would have on the third prenatal program that was planned to implement the 5P’s tool. This resulted in closing of the third prenatal program to new intake clients.
The first prenatal program that implemented the 5P’s tool had staffing changes related to funding immediately prior to implementation and had a loss of the Spanish speaking CCHW and stopped new client intakes of Hispanic women. The first prenatal program shifted entirely to African American women in compliance with the grant that funded the program.

The second prenatal program was already using the 5P’s screening tool; however, it was being used as a postnatal screening as opposed to a prenatal screening tool. When this was discovered, a discussion took place with the manager of the second prenatal program. The manager reviewed the need for the 5P’s screening tool to be used prior to the infant’s birth. Though there was not enough time to demonstrate a change in practice, this is considered a positive outcome by both the manager of the second prenatal program and the director of the public health department.

There were staffing changes in the first prenatal program, with one staff member being down-sized immediately prior to education. Two of the remaining staff members resigned two weeks prior to the completion of the three month post education data collection.

**Future Recommendations and Conclusion**

The 5P’s substance use screening tool is able to be used successfully in a public health setting by certified community health workers. Peer to peer role playing and evaluation is a successful strategy to teach use of the 5P’s screening tool. Staff involved in treating pregnant women benefit from education in motivational interviewing and use of a brief intervention.
There was added value in using the 5P’s substance use screening tool in follow up interviews with clients. Follow up interviewing using the 5P’s tool demonstrated increased risk detection, increased documentation of discussion and increased documentation of written information given. Further study with a larger sample size is needed to determine the effect of the 5Ps tool on the prenatal population served by community health workers.
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(2004). ACOG Committee opinion No 294. At-risk drinking and illicit drug use:

http://dx.doi.org/10.1038/sj.jp.7211378


http://dx.doi.org/10.1097/AOG.0b013e3181ed8290
Appendix A

Permission to use Evidence-Based Practice Improvement Model by Author

Hello Dr Levin,

I am a DNP student at Wright State University in Dayton Ohio. I am working with Tracey Brewer to implement an evidence based practice project in the public health arena.


Of course, appropriate credit would be given.

Please let me know if you give permission.

Thank you for your time,

Lisa R. Jasen, MSN, NNP-BC (DNP Student)
Wright State University
Dayton Ohio
### Appendix B

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<td>Rona Levin, Jeffrey Keefer, Joan Marren, et al</td>
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<td></td>
<td>DAYTON, OH 45458</td>
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United States
Appendix C

Institute for Health and Recovery: SP's Screening tool

| Screening introduction: Women & their children’s health can be affected by emotional problems, alcohol, tobacco, other drug use & violence. Women & their children’s health are also affected when those same problems are present in people close to us. Alcohol includes beer, wine, wine coolers, liquor & spirits. Drugs include marijuana and prescription drugs taken other than directed. |

<table>
<thead>
<tr>
<th>Parents</th>
<th>Did any of your Parents have a problem with alcohol or other drug use?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peers/friends</td>
<td>Do any of your Peers/friends have a problem with alcohol or other drug use?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Partner</td>
<td>Does your Partner have a problem with alcohol or other drug use?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Past</td>
<td>In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Present</td>
<td>In the past month, how often did you drink beer, wine, wine coolers or liquor or use illegal drugs? How many days per month do you drink? ____ How many drinks on any day? ____ How many days did you have 4 or more drinks per day? ____</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Smoking</td>
<td>Have you smoked any cigarettes in the past three months?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Emotional Health</td>
<td>Over the last few weeks, has worry, anxiety, depression, or sadness made it difficult for you to do your work, get along with people, or take care of things at home?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Violence</td>
<td>Are you currently or have you ever been in a relationship where you were threatened, controlled, physically hurt, or made to feel afraid?</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

Advising for brief intervention

| Did you state your medical concern? | Y | N | NA |
| Did you ADVISE to abstain or reduce use? | | | |
| Did you Check patient’s reaction? | | | |
| Did you refer to further assessment | | | |

At risk drinking:

- Non-pregnant: >7 drinks/week or >3 drinks/day
- Pregnant/planning pregnancy: Any use is risky drinking

For the best health of babies & mothers, women who are pregnant or planning to become pregnant should not use alcohol, illegal drugs, or tobacco during their pregnancy.

Used with permission by Institute of Health and Recovery
Appendix D

Permission to use 5P’s

Enid Watson
Institute for Health and Recovery
349 Broadway
Cambridge, MA 02139

December 9, 2013
Lisa Jasin
Wright State University
3640 Colonel Glenn Hwy
Dayton, OH 45435

Dear Ms. Jasin,

This letter acknowledges that you received training on the Institute for Health & Recovery 5 P’S screening tool, and that you have permission to utilize it in the Alcohol, Tobacco and Illicit Drug Screening in Pregnancy Project. We understand that the goal of the project is to standardize the screening process in the public health department working with pregnant women. Certified community health workers, RNs and social workers have potential to use the tool, but it will primarily be certified community health workers. We applaud the implementation of the tool with community health workers, in addition to the more traditional staff, and trust that all staff will be trained in Brief Interventions, Motivational Interviewing, and develop a familiarity with local substance use disorder assessment/treatment resources.

While we do not charge for the use of the 5 P’S, we ask that; 1) you submit your screening tool to us for our files; 2) IHR is clearly cited on the form; and 3) that you submit unidentified data to us on your outcomes.

Best wishes to you in your Doctor of Nursing Practice program. Please do not hesitate to contact me should you have any comments.

Enid Watson, MDiv
Director, Screening & Early Identification Projects
Appendix E

Wright State University-Miami Valley College of Nursing and Health

AGENCY PERMISSION FOR CONDUCTING DOCTORAL PROJECT

THE Clark County Combined Health District GRANTS TO Lisa R Jasir, MSN, NNP-BC, a student enrolled in the joint Doctor of Nursing Practice Program at Wright State University—University of Toledo, the privilege of using its facilities in order to conduct the following project:

Alcohol, Tobacco and Illicit Drug Screening in Pregnancy

The conditions mutually agreed upon are as follows:

1. The agency (may) (may not) be identified in the final report.

2. The names of consultative or administrative personnel in the agency (may) (may not) be identified in the final report.

3. The agency (wants) (does not want) a conference with the student when the report is completed.

4. Other:

Date: 2/24/14

Signature of Agency Personnel/Title

(Student Signature)

Project Chair Signature
Appendix F
Education Role Playing and Peer Evaluation

Role Playing Exercise

Role of pregnant mother:
Parents drank alcohol, but didn’t have a problem
Several friends have a problem with alcohol
Partner does not have a problem with alcohol or drugs
No problems for you in the past with alcohol or drugs
Currently not using alcohol or drugs
Smoker of tobacco
No depression
No issues with violence

Role of interviewer:
State screening preamble
Review the 5P’s questions for risk
Assess: positive answer (Yes answer) according to 5P’s tool
Advise: Recommend abstaining – provide written information
Work with mother’s reaction
Motivational interviewing:
  Ask open ended question? ie: What do you think you want to do about your use?
  Affirming: recognize strength or behavior that leads to positive change
Ie: “I appreciate that you are willing to meet with me today” “You are a resourceful person”
  Reflective listening: Use simple reflection, paraphrase or repeat emotional meaning
  Summarize the major points of the conversation/interview
Develop a change plan
## Peer Evaluation for 5P’s Substance Use Screening Tool/SBIRT

**Interviewer_________________**

**Evaluator  _________________**

**Instructions:** Please take turns with your partner role playing using the attached scenarios. Role playing will be done twice, with each person playing the interviewer once and playing the pregnant mother once. Please evaluate interviewer behaviors as a “Yes” or “No” based on whether they were performed. Circle the appropriate response as the role playing progresses.

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduces self</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Uses screening preamble</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Asks questions from parents (non-threatening) to present use (more threatening)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Asks about smoking</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Asks about emotional health</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Asks about intimate partner violence</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Assesses for risk - Any positive response</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Advises abstaining</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Offers pamphlets</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Uses open ended questions</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Affirmation of mother’s ability to make change</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Reflects statements made by mother</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Summarizes the major points discussed</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Develop a change plan and asks for commitment: What do you intend to do?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Appendix G
Power Point presentation for staff education

2/5/14

The Institute for Health & Recovery’ s 5 P’ S

SBIRT
- Screening: identification of risk
- Brief Intervention/ Treatment: provide to identified patients
- Referral to Treatment

Potential SBIRT Benefits
- Reduces alcohol, other drug and tobacco use during pregnancy and post-partum
- Improves medical conditions that are worsened by unhealthy use of substances (e.g., diabetes, high blood pressure)
- Prevents medical conditions that emerge with unhealthy use or addiction (e.g., cancer, heart and lung disease)
- Improves family life and workplace performance

Screening, Brief Intervention, Referral and Treatment – SBIRT

What is SBIRT?
- National initiative to detect and intervene with patients in healthcare settings who use substances in a manner that may adversely effect their health
- Screening: Quickly and accurately identifies unhealthy substance use and risk
- Brief Intervention: Raises awareness of risks and motivation towards behavioral change
- Referral to Treatment: Access to specialty care

Screening Women for Multiple Risks

Women are at risk for multiple problems:
- Substance use
- Mental health – including prenatal and postpartum depression
- Intimate partner violence
- Trauma
- Other health problems

Identify “risky” substance use before it becomes problem or dependent use
- Prevent Fetal Alcohol Spectrum Disorders: no drinking during pregnancy
Alcohol and Women’s Health

Women have...
- Higher rate of psychiatric co-morbidities, especially depression and anxiety
- 50-100% higher death rates from:
  - Alcohol Use Disorders
  - Cross-addiction to prescription drugs

Physiological Consequences of Female Alcohol Use

- Intoxication with less alcohol than men
- More severe hangovers than men
- 50-100% higher death rate than men
- > Alcohol Use Disorders than men
- > Cross-addiction to prescription drugs than men
- Greater vulnerability to brain damage, heart disease and cancer

Physiological Consequences of Female Alcohol Use, cont.

- Liver disease after shorter periods of drinking and lower level of daily drinking
- Psychiatric co-morbidities, esp. depression and anxiety
- Eating disorders
- Greater risk of infertility, menstrual abnormalities, adverse pregnancy outcomes

Fetal Alcohol Spectrum Disorders (FASD)

- Umbrella term describing range of effects that can occur to a child whose mother drank alcohol during pregnancy
  - Fetal Alcohol Syndrome (FAS)
  - Alcohol Related Neurodevelopmental Disorders (ARND)
  - Alcohol Related Birth Defects (ARBD)
  - Partial FAS
    - ARBD > common than Autism and Down’s Syndrome
    - Organic effects are not reversible
    - Effects of FASD last a lifetime
    - People with an FASD can grow, improve and function well in life

Corpus Callosum Effects

Normal | FAS

Dysgenesis of the Corpus Callosum (DCC) often result in problematic behaviors in the social/personal domains
FASD is 100% Preventable

- Leading known cause of preventable, non-genetic mental retardation
- Caused solely by alcohol consumption by pregnant women

IHR 5 P’s Behavioral Health Risk Screening Tool

- Smoking
- Parents: Problem Use
- Peers: Problem Use
- Partner: Problem Use
- Past
- Present/Pregnancy
- Emotional Health
- Violence

Based on Ewing’s 4 P’s, 1990

Screening Preamble

Women & their children’s health can be affected by emotional problems, alcohol, tobacco, other drug use & violence. Women & their children’s health are also affected when those same problems are present in people close to us. Alcohol includes beer, wine, wine coolers, liquor & spirits. Drugs include marijuana and prescription drugs taken other than directed.

Outcomes

ASAP II
- Prenatal staff found screening 33 more hazardous
- Most SU risk factors (51% of risk factors) captured in first screen (97%) &
- Later screens showed increased number of women reporting depression (29%) & violence (11%)

Screening

- Identifies full spectrum of use (risky to dependent)
- Can be done by existing or special personnel
- Rough estimates of unhealthy use by setting:
  - Primary Care – 10-40%
  - OB-GYN – 10-20%
  - Emergency – 20-40%
  - Trauma – 40-60%
The 5 P’s Behavioral Risk Screening Tool

- Did any of your Parents have a problem with alcohol or other drug use?
- Do any of your Peers/friends have a problem with alcohol or other drug use?
- Does your Partner have a problem with alcohol or other drug use?
- In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?
- In the past month (present) how often did you drink beer, wine, wine cooler or liquor or use illegal drugs? Quantity/Frequency? How many days did you have 4 or more drinks per day?

The 5 P’s Behavioral Risk Screening Tool

- Have you smoked any cigarettes in the past three months?
- Emotional Health
  - Over the last few weeks, has worry, anxiety, depression, or sadness made it difficult for you to do your work, get along with people, or take care of things at home?
- Violence
  - Are you currently or have you ever been in a relationship where you were threatened, controlled, physically hurt, or made to feel afraid?

Substance Use Among Positive Screens (report from IHR)

- Ask: Screen using 5 Ps
- Assess: Is there a current problem? How severe is it? Patient’s response?
- Advise: Recommend abstaining. Work with patient’s reaction
- Monitor: Follow-up on use; provide support

Brief Intervention

Strategies for talking about problems of use and abuse

- Talk in a private setting
- Point out specific observations that you have noticed
- Be non-judgmental
- Listen
- Identify strengths

Pre-Conception/Pregnancy Recommendation

For the best health of babies & mothers, women who are pregnant or planning to become pregnant should not use alcohol, illegal drugs, or tobacco during their pregnancy.
SBIRT
Referral to Treatment

Utilizing Motivational Interviewing

Old Change Paradigm
- Give them Insight - if you can just make people see, then they will change
- Give them Knowledge - if people just know enough, then they will change
- Give them Skills - if you can just teach people how to change, then they will do it
- Give them Hell - if you can just make people feel bad or afraid enough, they will change

Motivational Approaches
- Help individual set achievable goals
- Support any positive attempts to change
- Empathize with person’s struggle
- Convey a clear interest in the person & his/her effort
- Explore person’s capacity rather than incapacity
- Avoid arguments

MI is…
- A communication style
- Client-centered
- An intentional direction towards change
- Simple, but not easy
- Requires practice, practice, practice
- When used, results in positive student change

Stages of Change

Precontemplation
Contemplation → Preparation
Relapse → Action
Maintenance
What does the individual want to do about the problem?

- Nothing
- Unsure, ambivalent
- Change behavior, but how?
- Take specific action
- Maintain new behavior
- Test need for new behavior

Core MI Strategies

- Precontemplation
- Contemplation
- Preparation/determination
- Action
- Maintenance
- Relapse

Four Strategies: OARS
- Open-Ended Questions
- Affirming
- Reflective Listening
- Summarizing

OARS: Open/Closed Ended Questions

Affirmations are like salt, a little goes a long way. Be genuine.

OARS: Affirmations

OARS: Reflective Listening: All Ears

Reflective Listening

1. Words the Speaker Says
2. Words the Listener Hearts
3. What the Listener Thinks
   What the Speaker Means

Communication can go wrong because:
1. The speaker does not say exactly what is meant
2. The listener does not hear the words correctly
3. The listener interprets differently than speaker intended
4. Speaker benevolence (empathy, nonjudgmental listening)
I lost my job. I don’t know how I am going to support my family.

- **Level 1** Simple Reflection
  - You lost your job. You don’t know how you are going to support your family.
- **Level 2** Reframe Reflection (paraphrase)
  - “You are unsure about how you are going to pay the bills now that you’ve lost your job.”
- **Level 3** Affective Reflection (repeating emotional meaning)
  - “You take your responsibilities to your family seriously, and you worried about taking care of them without an income.”

OARS: Summarize

- Repeat the major points that have been made during the interview.
- Emphasize student’s reasons for behavior change.

MI Decisional Matrix

<table>
<thead>
<tr>
<th>What do you like about...?</th>
<th>What do you like less about...?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What would you like if you changed...?</td>
<td>What would you like less if you changed...?</td>
</tr>
</tbody>
</table>

Developing a Change Plan

- **Commitment:** What do you intend to do?
- **Activation:** What are you ready or willing to do?
- **Taking Steps:** What have you already done?

  - E: Ask for Elaboration/Example
  - A: Offer an Affirmation
    - agree, encourage, advise, support
  - R: Reflect what the person has said

Role Playing

- Break into groups of two for role playing
- Please use role playing scenarios and peer evaluation tool.
Appendix H
PDSA CYCLE 1

PLAN:
All Certified Community Health Workers (CCHWs) will be trained in use of The Institute of Health and Recovery 5P’s tool and brief intervention. The Healthy Mommy Healthy Baby CCHWs will then use the tool with all clients at new intake appointments.

How will you know that the change is an improvement?
If the 5P’s tool is used in >90% of intake appointments with pregnant women.
If the CCHWs find the tool easy to use, and intend to continue its use.

What do you predict will happen?
I predict the 5P’s tool will result in a change in revelation of risk for substance use.
I predict the 5P’s tool will result in a change in the use of written information about smoking cessation, alcohol abstinence, and need to not use illicit drugs – during pregnancy.
I predict the CCHWs will find the 5P’s tool easy to use and that it does not take any more time than the current system.

PLAN

<table>
<thead>
<tr>
<th>List the tasks necessary to complete this test (what)</th>
<th>Person responsible (who)</th>
<th>When</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Outline for continuing education credit</td>
<td>Lisa</td>
<td>Feb 2014</td>
<td>Dayton Children’s</td>
</tr>
<tr>
<td>2. Complete continuing education credit application</td>
<td>Mary Ann Swank</td>
<td>Feb 2014</td>
<td>Dayton Children’s</td>
</tr>
<tr>
<td>3. Approve ce application</td>
<td>Caroline Michel</td>
<td>Mar 2014</td>
<td>Dayton Children’s</td>
</tr>
<tr>
<td>4. IRB application</td>
<td>Lisa</td>
<td>Feb 2014</td>
<td>WSU</td>
</tr>
<tr>
<td>5. Schedule training session</td>
<td>Carlissa</td>
<td>Feb 2014</td>
<td>Clark County Public Health</td>
</tr>
<tr>
<td>6. Conduct training session</td>
<td>Lisa</td>
<td>Apr 2014</td>
<td>CCPH</td>
</tr>
<tr>
<td>7. Conduct survey pre/post education</td>
<td>Lisa</td>
<td>Apr 2014</td>
<td>CCPH</td>
</tr>
<tr>
<td>8. Collect data from intake records</td>
<td>Lisa</td>
<td>Apr 2014 X 2 weeks</td>
<td>CCPH</td>
</tr>
<tr>
<td>9. Second Cycle: Review initial data and make changes if needed</td>
<td>Lisa</td>
<td>Apr 2014</td>
<td>CCPH</td>
</tr>
<tr>
<td>10. Collect data from intake records</td>
<td>Lisa</td>
<td>Apr 2014 X 3 months</td>
<td>CCPH</td>
</tr>
<tr>
<td>11. 2 month post test</td>
<td>Lisa</td>
<td>Jun 2014</td>
<td>CCPH</td>
</tr>
</tbody>
</table>

Plan for collection of data:
Chart review at the Public Health Dept. of all new intake patients. CCHWs will keep list of new intake clients, charts are in file folders. File folders will be made available for review in the Public Health Dept. Review will be hand collected, data de-identified by date of intake and age of client. Records will be assigned a number and names will not be recorded.

DO: Test the Changes
Was the cycle carried out as planned?  Y / N
Record data and observations:

What did you observe that was not part of our plan?

There were fewer new clients than expected.

STUDY:
Did the results match your predictions? Y / N

Compare the result of your test to your previous performance:

There was a follow up client in the first prenatal group who had risk of substance use identified that was not identified on previous screening with free form questioning.

What did you learn?

The CCHWs felt the 5P’s screening tool was easier to use with clients who they had a previous relationship.

ACT: Decide to Adopt, Adapt, or Abandon

Adapt: Y / N
Improve the change and continue testing the plan:
Plans/changes for next test.

Adopt: Y / N
Select changes to implement on a larger scale and develop an implementation plan and plan for sustainability
Will continue to use the 5P’s tool in the first prenatal program. The 5P’s program will be used in the second prenatal program (Healthy Families America)

Abandon: Y / N
Discard the change and try a different one.
PDSA CYCLE 2

PLAN:
The Healthy Mommy Healthy Baby CCHWs will continue to use the tool with all clients at new intake appointments. The Healthy Families America staff will use the 5P’s tool with all clients at new intake appointments.

How will you know that the change is an improvement?
If the 5P’s tool is used in >90% of intake appointments with pregnant women.
If the CCHWs find the tool easy to use, and intend to continue its use.

What do you predict will happen?
I predict the 5P’s tool will result in a change in revelation of risk for substance use.
I predict the 5P’s tool will result in a change in the use of written information about smoking cessation, alcohol abstinence, and need to not use illicit drugs – during pregnancy.
I predict the CCHWs will find the 5P’s tool easy to use and that it does not take any more time than the current system.

PLAN

<table>
<thead>
<tr>
<th>List the tasks necessary to complete this test (what)</th>
<th>Person responsible (who)</th>
<th>When</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Discuss start of use with Health Families America Director to begin use of 5P’s tool with intake appointments</td>
<td>Lisa</td>
<td>Apr 2014</td>
<td>CCPH</td>
</tr>
<tr>
<td>2. Collect data from intake records</td>
<td>Lisa</td>
<td>Apr 2014 X 3 months</td>
<td>CCPH</td>
</tr>
<tr>
<td>3. 2 month post survey of staff</td>
<td>Lisa</td>
<td>Jun 2014</td>
<td>CCPH</td>
</tr>
</tbody>
</table>

Plan for collection of data:
Chart review at the Public Health Dept. of all new intake patients. CCHWs and home visitors will keep list of new intake clients, charts are in file folders. File folders will be made available for review in the Public Health Dept. Review will be hand collected, data de-identified by date of intake and age of client. Records will be assigned a number and names will not be recorded.

DO: Test the Changes
Was the cycle carried out as planned?  Y / N

Record data and observations:
What did you observe that was not part of our plan?
There were fewer new clients than expected. One CCHW used the 5P’s tool as a follow up for previous clients, as this was more comfortable. The Healthy Families America (second group) used the 5P’s tool within 30 days of the baby’s birth and were using it as a post partum tool.

STUDY:
Did the results match your predictions?  Y / N

Compare the result of your test to your previous performance:
There were eight follow up clients in the first prenatal group who had risk of substance use identified that was not identified on previous screening with free form questioning.

What did you learn?
The CCHWs felt the 5P’s screening tool was easier to use with clients who they had a previous relationship. The 5P’s substance use screening tool revealed more risk for substance use that resulted in more brief interventions with clients.
ACT: Decide to Adopt, Adapt, or Abandon

Adapt:  Y / N
Improve the change and continue testing the plan:
  Plans/changes for next test.

Adopt:  Y / N
Select changes to implement on a larger scale and develop an implementation plan and plan for sustainability.

Abandon:  Y / N
Discard the change and try a different one.

The first and second prenatal programs (Healthy Mommy Healthy Baby and Healthy Families America) will continue to use the 5P’s substance use screening tool as a prenatal tool at initial intake appointments. New staff will be oriented using the power point and role playing exercise to sustain the use of the 5P’s substance use screening tool.
Pre/Post survey for 5P’s substance use screening and brief intervention

Please circle your role:

| RN | CCHW | Social Worker | Other |

**Instructions:** This pre and post survey will be used to determine understanding of information given, knowledge of the 5P’s screening tool and intention to use the 5P’s screening tool before and after the educational program, and again 2 months after the education program.

The scale used is a Likert scale with categories from 1 to 5. Please circle 1 response for each of the following questions.

1. Strongly agree  
2. Somewhat agree  
3. Neutral/no opinion  
4. Somewhat disagree  
5. Strongly disagree

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I know what the 5P’s screening tool is</td>
<td>○ 1</td>
<td>○ 4</td>
</tr>
<tr>
<td>2. I feel comfortable asking the questions on the 5P’s tool</td>
<td>○ 1</td>
<td>○ 4</td>
</tr>
<tr>
<td>3. I am comfortable questioning an expectant mother about substance use</td>
<td>○ 1</td>
<td>○ 4</td>
</tr>
<tr>
<td>4. I know how to use the 5P’s tool for screening for substance use</td>
<td>○ 1</td>
<td>○ 4</td>
</tr>
<tr>
<td>5. I plan to use the 5P’s screening tool for substance use at all new intake interviews</td>
<td>○ 1</td>
<td>○ 4</td>
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<tr>
<td>6. The 5P’s screening tool for substance use is easy to use</td>
<td>○ 1</td>
<td>○ 4</td>
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<tr>
<td>7. I know what to do if an expectant mother has a positive screen with the 5P’s screening tool for substance use</td>
<td>○ 1</td>
<td>○ 4</td>
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<tr>
<td>8. I feel confident using the 5P’s screening tool</td>
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<tr>
<td>9. I am comfortable performing a brief intervention</td>
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**Appendix J**

Data Collection Tool (Retrospective and Prospective)

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<th>Client number</th>
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<th>Race</th>
<th>Gender</th>
<th>Years of school</th>
<th>Age</th>
<th>Weeks of preg.</th>
<th>Screening tool used (standardized 5P’s)</th>
<th>Risk identified (Y/N)</th>
<th>Illicit drug use disclosed (Y/N)</th>
<th>Referral to Treatment (Y/N/NA)</th>
<th>Documentation of intervention/discussion (Y/N)</th>
<th>Documentation of written information given (Y/N)</th>
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</table>
Appendix K

IRB Protocol
**DATE:** 3-19-14

**TO:** Lisa Jasim

**RE:** SC# 5452 – Alcohol, Tobacco and Illicit Drug Screening in Pregnancy

The above-listed project was reviewed by the Chair of the IRB/authorized designee. Certain categories of research involving human subjects are exempt from IRB oversight. It has been determined that your study is exempt from IRB oversight per the federal category checked below.

Projects involving human subjects research activities in exemption categories allowed under 45 CFR 46.101(b):

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</td>
</tr>
<tr>
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<tr>
<td>(2)</td>
<td>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.</td>
</tr>
<tr>
<td></td>
<td><strong>Note: interview or survey research involving children does not qualify for exemption.</strong></td>
</tr>
<tr>
<td>(3)</td>
<td>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>(4)</td>
<td>Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.</td>
</tr>
<tr>
<td></td>
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<tr>
<td>(5)</td>
<td>Research and demonstration projects which are conducted by or subject to the approval of [Federal] Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>(5)</td>
<td>Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.</td>
</tr>
</tbody>
</table>
It is the Principal Investigator's responsibility to ensure that the consent form contains the required elements and accurately reflects the protocol. Please see http://www.wright.edu/rsp/subjects.html for a guide on the Required Elements of Informed Consent. Further, IRB consent form templates are available on this site and we encourage their use.

Should the protocol design change in the future, the study may no longer meet exemption criteria. Therefore, material revisions to the protocol must be reviewed by the IRB. Otherwise, no additional action is required.

If you have questions about this determination, please call the WSU IRB Office at (937) 775-3974.

Best wishes for a successful study.

Signature of IRB Chair/authorized designee Date

Please note:
The Data Collection Tool 1 will be removed from the submission packet as this appears to be part of the staff training for the project, which is not part of the research.
Appendix L
DATE: April 1, 2014

TO: Lisa R. Jasin, M.S. Doctoral Student

FROM: Wright State University IRB

RE: SC 5484
  Alcohol, Tobacco and Illicit Drug Screening in Pregnancy – Expedited Study

The above-listed project was reviewed by the Chair of the IRB/authorized designee. The project was determined to be “Not Human Subjects Research (NHSR)” per the federal definition checked below. Projects that do not meet the definition of research or human subject do not fall under the purview of the IRB.

Projects that do not meet the definition of research involving human subject under 45 CFR 46.102:

☒ IRB review of the project is not required because it does not meet the definition of research in 45 CFR 46.102(d) which defines ‘research’ as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Examples of projects that may not be research include quality improvement programs or required program evaluations that will not be published or disseminated formally.

☐ IRB review of the project is not required because it does not involve human subjects as recognized by 45 CFR 46.102(f) which defines a ‘human subject’ as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

If you are consenting participants for your project, please remove all references to research and the IRB so as not to confuse the participants.

If you have questions about this determination, please call Jodi Blackledge at (937) 775-3974.

Best wishes for a successful project.
# Appendix M

## Budget Projection

<table>
<thead>
<tr>
<th>Budget Item</th>
<th>Cost</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Training (in monthly staff meeting)</td>
<td>Avg CCHW salary $12/hr X 20 staff</td>
<td>$240</td>
</tr>
<tr>
<td>Initial training</td>
<td>DNP student (no cost)</td>
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</tr>
<tr>
<td>Contact hour for staff education</td>
<td>Free – Pro Bono by Dayton Children’s Hospital</td>
<td>$0</td>
</tr>
<tr>
<td>Use of tools</td>
<td>No charge</td>
<td>$0</td>
</tr>
<tr>
<td>- 5P’s substance use screening tool</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- EBPI model</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pamphlets</td>
<td>- Donated by the March of Dimes</td>
<td>$0</td>
</tr>
<tr>
<td>- Centers for Disease Control (CDC)</td>
<td>- No charge from CDC</td>
<td></td>
</tr>
<tr>
<td>Paper (provided by Clark County Public Health)</td>
<td>$3 X 250 sheets X 1</td>
<td>$3</td>
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<tr>
<td>Ink (provided by Clark County Public Health)</td>
<td>$20 X 1 cartridge</td>
<td>$20</td>
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<tr>
<td>Data Collection (by DNP student)</td>
<td>Avg CNP salary in Ohio $44 X 4 hr/wk X 12 weeks</td>
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<tr>
<td>Data Analysis (by biostatistician at Dayton Children’s)</td>
<td>Pro bono</td>
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<tr>
<td>Total projected cost for implementation</td>
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<td>$2,363</td>
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<td>- $263 paid by Public Health</td>
<td></td>
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<tr>
<td></td>
<td>- $2,100 no cost r/t DNP student</td>
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