

Original Article

The 4P's Plus[®] Screen for Substance Use in Pregnancy: Clinical Application and Outcomes

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OBJECTIVE:

Determine the prevalence of substance use among pregnant women in five diverse communities utilizing the 4P's Plus[®] screen for alcohol, tobacco, and other drug use.

STUDY DESIGN:

Pregnant women enrolled in prenatal care clinics in five communities were screened for substance use with the 4P's Plus[®]. Those women with a positive screen underwent an assessment for substance use through a follow-up structured clinical interview conducted at the same prenatal visit.

RESULTS:

Among 7818 women in five communities, 2555 (32.7%) had a positive screen for substance use in pregnancy. Four of the communities

conducted a follow-up assessment on all women with a positive screen ($n = 1548$). Among these women, 717 (15% of the total population) had continued use after learning of the pregnancy. Overall, 21% of the pregnant women used alcohol prior to recognition of the pregnancy, and 11% continued use after knowledge of the pregnancy. Among the 512 women who continued to use alcohol, 2% were drinking daily, 7% were drinking 3 to 6 days per week, 27% were drinking 1 to 2 days per week, and 63% were drinking less than 1 day per week. The rates of marijuana use and other illicit drug use among the women were 7 and 2%, respectively, prior to knowledge of pregnancy and dropped to 3 and 1% after learning of the pregnancy.

CONCLUSION:

The 4P's Plus[®] identifies not only those pregnant women whose drinking or drug use is at a high enough level to impair daily functioning, but provides an opportunity for early intervention for the much larger group of women whose pregnancies are at risk from relatively small amounts of substance use.

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INTRODUCTION

Over the past two decades, substance abuse during pregnancy has become a major public health concern. A number of studies have found poor pregnancy and neonatal outcomes among women who used alcohol or illegal drugs during pregnancy,^{1–4} and the long-term impact of prenatal alcohol or illicit drug exposure on the development and behavior of the exposed child^{5–8} is now being documented. However, despite the concern over the consequences of prenatal exposure to alcohol and other drugs, substance use by the pregnant woman remains a frequently missed diagnosis. Legal, social, attitudinal, operational, and logistical barriers often come together to restrain open communication between physician and patient, resulting in a very low rate of screening or intervention for substance use in the prenatal care setting. This lack of screening occurs in spite of evidence that screening improves the accurate identification of substance abusing patients in primary care settings and that treatment of substance abusing adults identified in primary care settings decreases clinical morbidity.^{9,10}

By identifying women early in pregnancy, treatment, brief intervention, and prevention services for this special population can

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be made available, reducing risk for the pregnancy and the child. However, substance use and abuse in this country historically have been viewed as problems specific to men. This has resulted in screening, intervention and treatment protocols being developed with language and approaches that are not necessarily appropriate for addressing these problems in women, especially pregnant women. For example, the *CAGE* (Cut down, Annoyed by criticism, Guilty about drinking, Eye-opener),¹¹ although easy to administer and possessing very good validity (overall percent of individuals correctly identified as using or not using substances), sensitivity (percent of correct identification of true positives) and specificity (percent of correct identification of true negatives), primarily targets heavy, alcoholic drinking in men¹² and does not provide a method for identifying pregnant women for early intervention.

Similarly, the *NET* (Normal drinker, Eye-opener, Tolerance)¹³ does not identify early-stage risk drinkers or users of illicit substances. The *T-ACE* (Tolerance, Annoyed by criticism, Cut down, Eye-opener)¹⁴ and the *TWEAK* (Tolerance, Worry about drinking, Eye-opener, Amnesia, K/Cut down)^{15–17} have been validated as reliable screening instruments for obstetrical practice, but, again, heavy drinkers are the primary targets of these two instruments, and they do not identify more moderate or light drinkers or users of illicit drugs.

The *4P's*⁹ is a four-question screen specifically designed to quickly identify obstetrical patients at risk for alcohol or illicit drug use. The four questions are broad-based and highly sensitive, and one positive answer to any question is considered a positive screen. However, the *4P's* has never been evaluated for validity, sensitivity, or specificity, and clinical application of the instrument in general obstetric clinics has not supported its usefulness as a screen for substance use.¹⁸

The purpose of this paper is to evaluate the performance of a new screening instrument, the *4P's Plus*[®],¹⁹ in five diverse populations of pregnant women enrolled in prenatal care. The *4P's Plus*[®] (Figure 1) is a five-question screen specifically designed to quickly identify obstetrical patients in need of in-depth assessment or follow-up monitoring for risk of alcohol, tobacco and/or illicit

drug use. Taking less than 1 minute, it is easily integrated into the initial prenatal visit and used for follow-up screening through the pregnancy.

MATERIALS AND METHODS

Development of the Screening Instrument

The first step in determining effective screening criteria was a 3-year study funded by the Health Care Financing Administration, the results of which were published in 2001.²⁰ The goal of the study was to identify risk factors for substance use during pregnancy.

Participants were 2002 Medicaid-eligible pregnant women with two or less visits to prenatal care clinics. Approximately 9% of the sample reported current use of either illicit drugs or alcohol or both.

Logistic regression analysis results confirmed that past cigarette or alcohol use was significantly correlated with current illicit drug or alcohol use. Further analysis via classification and regression trees (CART) confirmed that past alcohol and tobacco use are powerful predictive variables for substance use in pregnancy and that three groups with increasing levels of risk for alcohol or illicit drug use during pregnancy can be generated:

1. *Low risk* — those women who had never used alcohol: 1.4% of women in the low-risk group were found to be using either illicit drugs or alcohol or both during the time they were pregnant.
2. *Average risk* — those women who had used alcohol in the past but not in the month before pregnancy and did not smoke three or more cigarettes in the month before pregnancy: 9% of women in the average risk group were found to be using either illicit drugs or alcohol or both during the time they were pregnant.
3. *High risk* — those women who used any alcohol or smoked three or more cigarettes in the month before pregnancy: 34% of women in the high-risk group were found to be using either illicit drugs or alcohol or both during the time they were pregnant.

- *Parents* Did either of your parents ever have a problem with alcohol or drugs?
- *Partner* Does your partner have a problem with alcohol or drugs?
- *Past* Have you ever drunk beer, wine, or liquor?
- *Pregnancy*
 - In the month before you knew you were pregnant, how many cigarettes did you smoke?
 - In the month before you knew you were pregnant, how many beers/how much wine/how much liquor did you drink?

Figure 1. The *4P's Plus*[®]. Published with permission, NTI Publishing²⁷.

On the basis of these three levels of risk, it was suggested²⁰ that primary prenatal care providers could ask three questions in the context of the health evaluation:

- Have you ever drunk alcohol?
- How much alcohol did you drink in the month before pregnancy?
- How many cigarettes did you smoke in the month before pregnancy?

These three questions were integrated into the 4P's screening instrument⁹ and field tested over several years in a variety of settings and communities.²¹ Chart reviews and focus groups were conducted with all participating physicians, and through this field testing, the order of the questions was established and wording for the two key questions related to alcohol and tobacco use in the month prior to pregnancy was converted to an open-ended format.²¹ The final result was the 4P's Plus[®] screening instrument¹⁹ (Figure 1). As documented in the initial research,²⁰ in the context of screening, the woman's admission or denial of alcohol or tobacco use *during* pregnancy was not as an effective predictor of substance use during pregnancy as her acknowledgement of any alcohol or tobacco use in the month *prior* to knowledge of pregnancy.

Target Populations

Five populations of pregnant women were screened with the 4P's Plus[®] as part of routine prenatal care in obstetric clinics in Chicago, Illinois; in four rural counties of southern Illinois; and in Camden, NJ; San Luis Obispo County, CA; and Ventura County, CA. The communities in which the clinics are located represent diverse and different populations, as demonstrated in Table 1.

Chicago. Four clinics that make up a PHS 330 community health center network in medically underserved Chicago neighborhoods conducted screening as part of routine prenatal care under the Federal *Healthy Start* initiative. Any patients with a positive substance abuse screen and assessment were offered

treatment services per routine prenatal care policies and procedures.

Southern Illinois. The Southern Illinois Healthcare Foundation, Inc. (SIHF) is a federally qualified health-care facility with 14 locations in the four southern Illinois counties of St. Clair, Madison, Marion and Fayette. Screening for substance use with the 4P's Plus[®] was conducted as a component of routine prenatal care in four clinic sites participating in the Federal *Healthy Start* program. All women with a positive screen underwent further assessment, and all were referred for appropriate treatment services.

Camden, NJ. The City of Camden is the fifth poorest city of its size in the United States. Five prenatal clinics and two regional perinatal centers are available to care for the many high-risk mothers and infants in Camden. In 2001, all prenatal providers were trained to use the 4P's Plus[®] to screen every prenatal client seen through the city's Federally funded *Healthy Start* initiative. Camden clinics do not conduct the follow-up assessments of women with a positive screen within the prenatal setting but refer the women for home and community-based risk reduction services including assessment and referral to treatment. Thus, follow-up assessment data were not available in the prenatal charts for women in Camden.

San Luis Obispo County, CA. A relatively wealthy community, most of San Luis Obispo County is unincorporated, ranking 24th in population in California. Of the 18 public and private obstetrical providers in the County, 15 are participating in screening their patients with the 4P's Plus[®]. Any patient with a positive screen is further assessed, and all are offered services for substance abuse, domestic violence, tobacco cessation, and mental health treatment.

Ventura County, CA. The 11th largest county in population in California, Ventura County screens for substance use with the 4P's Plus[®] in seven clinic sites scattered throughout the county. All

Table 1 Demographic and Background Characteristics of the Five Clinical Populations

	Chicago, IL	So. Illinois	Camden, NJ	SLO Co., CA	Ventura Co., CA
<i>Racial distribution (%)</i>					
African Am	80	58	50	4	1
White	—	42	17	76	10
Hispanic	20	—	33	17	83
Asian Am	—	—	—	3	3
Other	—	—	—	—	3
Medicaid eligible (%)	100	100	Unknown	80	94
Urban/rural	Urban	Rural	Urban	Rural	Urban/rural

women with a positive screen undergo full assessment and, if necessary, referral to a treatment program.

Approach

The 4P's Plus[®] (Figure 1) was utilized in standard prenatal care as the primary screening instrument at all sites and was administered by a perinatal health worker, nurse, or medical assistant in English or Spanish. The clinical sites administered the 4P's Plus[®] at the first prenatal visit, with more than 90% of women in the sites completing the screen.

In all sites except Camden, NJ, any woman who had a "positive" 4P's Plus[®] screen (i.e., admitted use of any alcohol or any tobacco in the month before she knew she was pregnant) underwent immediate *assessment* for substance use through a standardized, structured clinical interview that addressed frequency, dose and pattern of use of alcohol, marijuana, heroin, cocaine, and methamphetamines during the pregnancy, commencing with the month prior to knowledge of the pregnancy through current point in gestation. This assessment was conducted in the primary prenatal care setting immediately following screening.

Based on the assessment, any woman who had evidence of any alcohol or illicit substance use *during* pregnancy, including the month prior to knowledge of pregnancy, was defined as a substance user. All women with a positive screen, regardless of assessment outcome, had follow-up monitoring and was given substance use educational materials in the prenatal care setting through the rest of the pregnancy. All women with a positive assessment were provided information and education regarding substance use and its impact on pregnancy and child outcome and were offered a referral to a perinatal treatment program in the community. In no case was child protection services notified of a woman's substance use during pregnancy.

The results of the 4P's Plus[®] screen and the substance use assessment were gathered as part of routine tracking of prenatal care patients and as a component of required evaluation procedures for Healthy Start in those communities who received Federal funding for this program. Each community was responsible

for its data entry procedures. The databases for the communities included screening and clinical assessment results in all sites except Camden, which recorded only screening data. Data in each of the sites were analyzed by the sites for frequencies and distributions, then cumulative data, absent any individual identifiers, were submitted to Children's Research Triangle, which integrated and compared the blinded data. Human subjects protection issues were addressed individually by each community site, and human subjects approval for CRT's overall data collection and management protocols was granted by the Illinois Office of Alcoholism and Substance Abuse Institutional Review Board. Since blinded data were collected by chart review and were based in standard of care protocols at all sites, informed consent was deemed not to be necessary.

RESULTS

In response to the 4P's Plus[®] screening instrument, 21.9% of the 7818 women across the five sites admitted to tobacco use in the month prior to knowledge of the pregnancy, 20% admitted to alcohol use, and 9.3% admitted to both alcohol and tobacco use in the month prior to knowledge of pregnancy (Table 2). Eliminating duplicative counts, the rate of positive screens, that is, women at risk for substance use during pregnancy due to alcohol or tobacco use in the month prior to knowledge of pregnancy, ranged from 17 to 45% across the five sites, with an overall positive screen rate of 32.7% within the total population of 7818 women.

Follow-up substance use assessments (Table 3) were conducted on all women with a positive screen in all sites except Camden. In the four sites that gathered assessment data, 4865 women were screened with the 4P's Plus[®]. Within this population, 1548 women (32%) had a positive screen and underwent clinical assessment for substance use. This assessment process revealed that substance use rates decreased once the women learned of their pregnancies. Among the 4865 women who were in the four communities that performed a substance abuse assessment, 21% of

Table 2 Screening Results

	Chicago		So. Illinois		Camden		SLO		Ventura		Combined	
<i>N</i>	1528		1435		2953		744		1158		7818	
Parents	214	14%	281	20%	769	26%	210	28%	255	22%	1729	22.1%
Partner	122	8%	185	13%	299	10%	74	10%	31	3%	711	9.1%
Past	550	36%	812	57%	1574	53%	546	73%	518	45%	4000	51.2%
Cigarettes*	275	18%	427	30%	770	26%	147	20%	94	8%	1713	21.9%
Alcohol*	183	12%	389	27%	564	19%	280	38%	151	13%	1567	20.0%
Cigarettes and alcohol*	47	3%	217	15%	327	11%	89	12%	45	4%	725	9.3%
Positive screen*	411	27%	599	42%	1007	34%	338	45%	200	17%	2555	32.7%

*Indicates use in month prior to woman's knowledge of pregnancy.

Table 3 Assessment Results

	Chicago		So. Illinois		SLO		Ventura		Combined	
Total N	1528		1435		744		1158		4865	
Positive screen	411		599		338		200		1548 32%	
Alcohol in month before known pregnant	183	12%	389	27%	280	38%	151	13%	1003	21%
Alcohol since known pregnant	137	9%	84	6%	203	27%	88	8%	512	11%
Mj only in month before known pregnant	110	7%	136	9%	55	7%	24	2%	325	7%
Mj only since known pregnant	60	4%	67	5%	25	3%	14	1%	166	3%
Other illicit drug in month before known pregnant	20	1%	11	1%	35	5%	11	1%	77	2%
Other illicit drug since known pregnant	15	1%	2	0%	11	1%	11	1%	39	1%
Alcohol/illicit drug use since known pregnant	212	14%	153	11%	239	32%	113	10%	717	15%
Alcohol/illicit drug use in pregnancy	313	20%	536	37%	370	50%	186	16%	1405	29%

Mj = marijuana.

Table 4 Alcohol Use Patterns during Pregnancy

	Chicago		So. Illinois		SLO		Ventura		Combined	
Alcohol since known pregnant	137		84		203		88		512	
Every day	4	3%	2	2%	4	2%	1	1%	11	2%
3–6 days/week	8	6%	4	5%	21	10%	3	3%	36	7%
1–2 days/week	36	26%	21	25%	63	31%	20	23%	140	27%
<1 day/week	89	65%	57	68%	115	57%	64	73%	325	63%

the women admitted to alcohol use in the month prior to knowledge of the pregnancy and 11% admitted to alcohol use only (no illicit substances) after they learned of the pregnancy (Table 3). Thus, about half of the women who used alcohol in the month prior to knowledge of pregnancy ceased use once they learned of the pregnancy, but the remaining half continued to drink. As demonstrated in Table 4, of the 512 women who continued to drink alcohol 9% were heavy drinkers, with 7% drinking 3 to 6 days per week and 2% drinking daily. Importantly, however, well over half (63%) of the women who continued to drink alcohol fell into the lightest level of drinking (<1 day/week) and another 27% were drinking 1 to 2 days per week. These are levels at which recent studies indicate substantial risk for the child,⁸ but these are women who most often are missed in routine prenatal care and through other forms of screening.

The rate of admitted marijuana use only in the month prior to knowledge of pregnancy among the population of 4865 women in the four clinics was 7%, and 3% of the total population continued to use marijuana after knowledge of pregnancy (Table 3). This number reflects only those women who used marijuana but did not use any alcohol or other illicit drugs. The rate of use of cocaine, heroin, and/or methamphetamines with or without alcohol and/or marijuana in the month prior to knowledge of pregnancy was 2%. This rate dropped to 1% after the women learned of the pregnancy. Eliminating all duplicative counts and including women who used illicit substances prior to knowledge of pregnancy, the overall rate

of illicit drug use in pregnancy among the population of women in the four communities was 9%. In sum, including women who used substances during early pregnancy when they were unaware of the pregnancy and excluding duplicate counts, the rate of alcohol and/or illicit drug use during pregnancy was 29%, dropping to 15% after women learned of their pregnancy. It should be noted that all prevalence rates of substance use in pregnancy reported here exclude the 21.9% of women who admitted to tobacco use in the month before they realized they were pregnant, almost all of whom continued smoking through the rest of the pregnancy.

A χ^2 -test of independence was conducted to compare the rates of substance use during pregnancy across the four sites presented in Table 3. An α level of 0.05 was used for this test. Rates of overall substance use differed significantly: $\chi^2 (3, N = 4865) = 352.70, P < 0.001$. San Luis Obispo, the wealthiest community in the study, had the highest rate of substance use (50%) during pregnancy, followed by Southern Illinois (37%), Chicago (20%), and Ventura (16%).

D-STAT software²² was used to compare rates of substance use prior to knowledge of pregnancy vs rates of substance use after learning of pregnancy for all women included in Table 3. The test of correlated proportions was significant ($P < 0.0001$), indicating that there was a significant decrease in substance use among this sample of pregnant women after they learned they were pregnant.

In the clinics in Southern Illinois, clinical policies instruct physicians to obtain urine toxicologies on all pregnant women

suspected of substance use based on clinical criteria. These criteria include no prenatal care and/or *abruptio placentae*, preterm labor, or intrauterine growth retardation due to no apparent reason. Of the 1435 pregnant women seen in the prenatal clinics, 651 (45%) had a urine toxicology ordered. Among these urine toxicologies, 2.6% (17) were positive, giving a positive urine toxicology rate in the overall population of 1.2%. However, 37% of the women admitted to the use of alcohol or illicit drugs during pregnancy when administered the 4P's Plus[®] screening with follow-up assessment. Thus, the verbal screening and assessment process uncovered a significantly higher rate of alcohol or illicit drug use than did the use of clinically guided urine toxicologies.

SIGNIFICANCE

Use of a simple screening instrument, the 4P's Plus[®] in five diverse communities effectively identified pregnant women at highest risk for substance use in pregnancy. The overall rate of illicit drug use of 9% in the total population of women in this study is higher than the rate of prenatal illicit drug use of 5.5% documented in the National Institute on Drug Abuse *Pregnancy and Health Survey*.²³

The development of the 4P's Plus[®] was an attempt to address the many barriers to screening that have been documented through a variety of studies,^{18,21} not the least of which is targeted screening. When screening for alcohol or drug use is implemented in clinical practice, it often focuses on targeted populations rather than the general population.²⁴ In addition, many prenatal care providers hesitate to implement screening procedures because they immediately assume urine toxicologies to be the most appropriate methodology for screening.¹⁰ However, use of urine toxicologies does not, for the most part, pick up alcohol use and limits identification of illicit drug use to only those women who used drugs in the 48 hours prior to testing. The limitations of the clinically defined use of urine toxicologies were demonstrated in the Southern Illinois population.

In this study, it is important to note that half of all women who were using alcohol or illicit drugs prior to knowledge of pregnancy continued to use after learning of their pregnancies. This is a previously unrecognized phenomenon. In addition, the wealthiest — and most likely best-educated — of the communities in this study, San Luis Obispo, had the highest rates of substance use in pregnancy. San Luis Obispo is situated in the midst of California's wine producing country, and it was the alcohol use rates that drove the finding of high substance use rates among pregnant women in this community.

From a prevention perspective, the high rate of alcohol use in the earliest part of pregnancy — the month before the woman knew she was pregnant — is of concern, given the

documented structural changes in the fetal brain that can be induced by early alcohol exposure.²⁵ Thus, public education campaigns must focus on pre-conceptional as well as post-conceptional health. Failing alcohol abstinence in early pregnancy, several studies have demonstrated that many of the maternal and child complications associated with the prenatal use of alcohol or illicit drugs are preventable with early identification of the pregnant, substance-using woman and referral into treatment. Infants whose alcoholic mothers enter treatment and become alcohol free by the third trimester have been shown to have substantially improved outcome at birth.²⁶ Studies of cocaine use in pregnancy have found that cessation of cocaine use by the third trimester significantly reduces the rate of low birth weight infants and prematurity.²⁷ In addition, a recent study at Kaiser Permanente Medical Care Program documented the cost savings accrued when pregnant substance using women are identified early in pregnancy and provided substance abuse interventions.³

A highly sensitive screening instrument addresses the need to identify all women at risk. It identifies not only those pregnant women who are drinking heavily or whose drug use is at a high enough level to impair daily functioning, but also identifies those women whose pregnancies are at risk from tobacco use as well as relatively small amounts of alcohol, marijuana or other drugs. Specifically, women with a positive 4P's Plus[®] screen but whose assessment is negative can receive prevention materials and education regarding the impact of even low levels of tobacco use, drinking or illicit drug use during pregnancy. Much research has demonstrated that educational input provided by the prenatal care provider significantly increases the woman's likelihood to make healthy decisions during pregnancy.²⁸ In addition, interventions in the current pregnancy are likely to influence the woman's behavior in subsequent pregnancies.

A recent report by the *U.S. Preventive Services Task Force*²⁹ recommended screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings. The *USPSTF* concluded that the benefits of behavioral counseling interventions to reduce alcohol misuse by adults outweigh any potential harms. A recent ACOG publication¹⁰ emphasized the importance of addressing risk for substance abuse within the context of primary prenatal care, and in May 2004, the *ACOG Committee on Ethics* issued a statement that noted that "(p)hysicians have an ethical obligation to learn and use techniques for universal screening questions . . ."³⁰

As documented in this evaluation of clinical experience with the 4P's Plus[®], effective identification of pregnant women at highest risk for substance use can be accomplished within the context of routine prenatal care. Even if resources are limited, the screening strategy allows for efficient identification of pregnant women who need a full assessment for substance use and further education or,

perhaps, treatment intervention. The positive return on investment in early intervention for substance using pregnant women and their children has been clearly documented. Appropriate screening strategies can support that investment.

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