

## ORIGINAL ARTICLE

Validation of the *4P's Plus*<sup>©</sup> screen for substance use in pregnancy validation of the *4P's Plus*

IJ Chasnoff, AM Wells, RF McGourty and LK Bailey

Children's Research Triangle, Chicago, IL, USA

**Objective:** The purpose of this study is to validate the *4P's Plus* screen for substance use in pregnancy.

**Study Design:** A total of 228 pregnant women enrolled in prenatal care underwent screening with the *4P's Plus* and received a follow-up clinical assessment for substance use. Statistical analyses regarding reliability, sensitivity, specificity, and positive and negative predictive validity of the *4P's Plus* were conducted.

**Result:** The overall reliability for the five-item measure was 0.62. Seventy-four (32.5%) of the women had a positive screen. Sensitivity and specificity were very good, at 87 and 76%, respectively. Positive predictive validity was low (36%), but negative predictive validity was quite high (97%). Of the 31 women who had a positive clinical assessment, 45% were using less than 1 day per week.

**Conclusion:** The *4P's Plus* reliably and effectively screens pregnant women for risk of substance use, including those women typically missed by other perinatal screening methodologies.

*Journal of Perinatology* (2007) 27, 744–748; doi:10.1038/sj.jp.7211823; published online 6 September 2007

**Keywords:** alcohol; tobacco; illicit drugs; pregnancy; screening

## Introduction

Prenatal use of alcohol, tobacco or illicit drugs can have a significant impact on pregnancy and neonatal outcome as well as long-term growth and development of the exposed child.<sup>1–5</sup> However, despite the high rate of morbidity and mortality associated with maternal substance use during pregnancy, appropriate screening rarely occurs in the prenatal care setting.<sup>6</sup> This lack of screening runs counter to 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.<sup>7,8</sup>

A major barrier to screening pregnant women for alcohol and illicit drug use is the lack of an adequate screening instrument that is validated specifically for pregnant women and that screens for all substances at all levels of use.<sup>9</sup> The *CAGE* (Cut down, Annoyed by criticism, Guilty about drinking, Eye-opener),<sup>10</sup> although easy to administer and with very good validity and specificity in nonpregnant populations, begins the conversation about alcohol use at the level of heavy alcoholic drinking<sup>11</sup> and has been validated only in the nonpregnant population. The *NET* (Normal drinker, Eye-opener, Tolerance),<sup>12</sup> designed for pregnant women, is similar to the *CAGE* in that it targets only heavy alcohol use. The *T-ACE* (Tolerance, Annoyed by criticism, Cut down, Eye-opener)<sup>13</sup> was developed specifically for detection of risky drinking among obstetric patients and has been validated as a reliable screening instrument for obstetrical practice, but it, too, focuses on heavy drinking. The *TWEAK* (Tolerance, Worry about drinking, Eye-opener, Amnesia, K/Cut down)<sup>14</sup> has demonstrated moderately high sensitivity (79%) and specificity (83%) in a sample of pregnant women when detecting consumption of at least one ounce of absolute alcohol per day<sup>15</sup> but does not identify lighter drinkers or users of illicit drugs. The *AUDIT-C*,<sup>16</sup> validated on a general population, is not appropriate for pregnant women because it focuses on very heavy drinkers and would miss light-to-moderate drinkers and illicit substance users.

In the field of chemical dependency treatment, the *DSM-IV* (Diagnostic and Statistical Manual of Mental Disorders)<sup>17</sup> guidelines are the current gold standard for diagnosing substance abuse and chemical dependency in the general population. While these guidelines are useful, they do not capture substance use at levels that do not meet the full criteria for a diagnosis of substance abuse; however, these lower levels of use can pose substantial risk in pregnancy.<sup>18</sup> The purpose of this study is to validate the *4P's Plus*<sup>19</sup> (Figure 1), a screening measure designed specifically to identify women whose substance-use levels fall below the *DSM-IV* criteria but who still are at risk from any level of use of alcohol or illicit drugs. By identifying women early in pregnancy, treatment, brief intervention and prevention services for this special population can be made available, reducing risk for the pregnancy and the child.

Correspondence: Dr IJ Chasnoff, Children's Research Triangle, 180 North Michigan Avenue, Suite 700, Chicago, IL 60601, USA.

E-mail: ichasnoff@cr-triangle.org

Received 15 May 2007; revised 9 July 2007; accepted 1 August 2007; published online 6 September 2007

- 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?

*Published with permission, NTI Publishing*<sup>18</sup>

**Figure 1** The 4P's Plus screen for substance use in pregnancy.

## Methods

### Target population

For the current study, all pregnant women 18 years of age or older were screened with the 4P's Plus as part of routine prenatal care in two obstetric clinics that make up a community health center network in medically underserved metropolitan neighborhoods in Chicago. The target population comprised of 80% African-American and 20% Hispanic women. Within the target area, 40% of residents were under 185% of the poverty level at the time of the 1990 census. Medicaid or a Medicaid-managed care plan covered all the patients who were screened. Any patients found to be using tobacco, alcohol or illicit drugs were offered treatment services per routine prenatal care policies and procedures. No women were denied care on the basis of socioeconomic status, race or ethnicity.

### Method

The development of the 4P's Plus (Figure 1) has been described in previous works.<sup>9,20</sup> The instrument contains five questions that were chosen from factors identified in the previous research<sup>9</sup> to be most closely correlated with substance use in pregnancy. The last two questions, which had the greatest positive predictive validity, are based on alcohol or tobacco use in the month prior to pregnancy, similar to a study by Hutchins and DiPietro<sup>21</sup> that documented the strong relationship between maternal smoking and illicit drug use by the pregnant woman.

The 4P's Plus served as the primary screening instrument for substance use through three generations of evaluation of the clinics' larger behavioral health screening program. In the first generation, the entire set of questions was administered by a perinatal health worker, nurse or medical assistant in English or Spanish. In the second and third generations, the final two questions of the 4P's Plus were incorporated into the overall behavioral health screener. The only change in the clinics' standard operating procedures was the substitution of the 4P's Plus

for a variety of other substance abuse screening strategies that were being used in the clinics.

Each woman, whether she had a 'positive' 4P's Plus screen (that is, admitted use of any alcohol or any tobacco in the month before she knew she was pregnant) or 'negative' screen, 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 pregnancy, commencing with the month prior to knowledge of the pregnancy through current point in gestation. This assessment was conducted by a perinatal health worker in the primary prenatal care setting immediately following screening.

On the basis of the assessment, any woman who cited any alcohol or illicit substance use since knowledge of pregnancy was determined to have a positive assessment and was defined as a substance user. 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 licensed social worker in the clinic. Substance use during pregnancy is not reportable under Illinois Child Protection Legislation, and 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 the clinics' federally funded Healthy Start program. All providers were trained in the use of the 4P's Plus, and perinatal health workers were trained in conducting the standardized clinical assessment for substance use. After the screening instrument was implemented in the prenatal care sites, screening and assessment forms, in the absence of any individual identifiers, were collected, and data were entered into a secured database. Human subjects approval was granted through expedited review by the Illinois

**Table 1** Internal consistency results

Item	Mean	s.d.	Corrected item-total correlation
Did either of your parents ever have a problem with alcohol or drugs?	0.27	0.445	0.405
Does your partner have a problem with alcohol or drugs?	0.11	0.315	0.419
Have you ever drunk beer, wine or liquor?	0.32	0.468	0.605
In the month before you knew you were pregnant, how many <i>cigarettes</i> did you smoke?	0.15	0.360	0.221
In the month before you knew you were pregnant, <i>how many beers/how much wine/how much liquor</i> did you drink?	0.12	0.322	0.248

Office of Alcoholism and Substance Abuse Institutional Review Board.

### Data analysis

Each study subject's 4P's Plus screening questionnaire was categorized as positive or negative based on the responses to the last two questions on the screen. If either question were answered in the affirmative, that is, the woman responded with any level of use for 'In the month before you knew you were pregnant, how many *cigarettes* did you smoke?' and/or 'In the month before you knew you were pregnant, how much *beer/wine/liquor* did you drink?' the screen was classified as positive. Any other configuration of responses was considered negative for risk of substance use. On the follow-up clinical assessment, if the woman had any level of alcohol use at any time after realizing she was pregnant or if she had used any level of illicit substance either in the month prior to knowledge of pregnancy or after learning she was pregnant, she was considered to have a positive assessment for substance use in pregnancy. If there were no illicit substance use prior to knowledge of pregnancy and no alcohol or illicit substance use after learning of pregnancy, the woman's assessment was considered negative. Tobacco use after learning of pregnancy, in the absence of any alcohol or illicit drug use, was not considered a positive assessment.

The hypothesis of this study was that the 4P's Plus would accurately identify those pregnant women who were using alcohol or illicit drugs. The hypothesis was tested by evaluating the validity of the 4P's Plus screening instrument through sensitivity and specificity analyses. Positive predictive value and negative predictive value were also computed. In addition, statistical analyses regarding reliability of the 4Ps Plus were conducted.

## Results

### Reliability data

During the first generation of the study, reliability data, that is, internal consistency information (Table 1), on the five items of the 4P's Plus were evaluated. The overall internal consistency for the five-item measure is 0.62, which is somewhat low but in the acceptable range for a screening measure.<sup>22</sup>

**Table 2** Classification table for positive and negative screens vs positive and negative clinical assessment

	Clinical assessment positive	Clinical assessment negative	Total
4P's Plus screen positive	27	47	74
4P's Plus screen negative	4	150	154
Total	31	197	228

Correct classification = 0.776 (overall correct classification into positive or negative).

Sensitivity = 0.871 (percentage of the correct identification of true positives).

Specificity = 0.761 (percentage of the correct identification of true negatives).

Positive predictive value = 0.364 (percentage of individuals classified as positive who actually were positive).

Negative predictive value = 0.974 (percentage of individuals classified as negative who actually were negative).

### Validity data

Over the course of the study, 387 women were eligible for screening. Of these women, 228 received an initial screen with follow-up assessment at the first prenatal visit, representing 60% of women enrolled in prenatal care in the two clinics. Failure to capture all eligible women was due to turnover in staff, who required training before screening procedures could be implemented. Among the 228 women screened with the 4P's Plus, 74 (32.5%) had a positive screen, and 154 (67.5%) had a negative screen. On the basis of follow-up clinical assessment, 78% of the 228 women were classified correctly on the 4P's Plus as positive or negative (Table 2). Sensitivity (the percentage of women correctly identified as positive) and specificity (the percentage of women correctly identified as negative) were very good, at 87 and 76%, respectively. Positive predictive validity (the percentage of individuals classified as positive on the 4P's Plus who actually were positive on the assessment) was low (36%), but negative predictive validity (percentage of individuals classified as negative on the 4P's Plus who actually were negative on the assessment) was quite high (97%).

### Patterns of use

The strength of the 4P's Plus lies in its ability to identify those women who use lower levels of alcohol or illicit drugs. As noted in the Introduction, other perinatal alcohol screening measures

identify only women who are classified as 'heavy' drinkers or drink on a daily basis. However, of the 31 women who had a positive clinical assessment, 5 (16%) used alcohol or illicit drugs 1 to 2 days per week and 14 (45%) were using less than 1 day per week, levels of use that would not be recognized by other screening instruments.

## Discussion

The *4P's Plus* is a five-question screen specifically designed to quickly identify obstetrical patients in need of in-depth substance-use assessment or follow-up monitoring. The five questions are broad-based, highly sensitive, and focus on social issues specific to women rather than physiologic measures such as tolerance. From the current study, it appears that the *4P's Plus* provides a clinically valuable methodology for integrating screening of pregnant women for risk from substance use and abuse into the primary prenatal care setting. The instrument has adequate internal consistency and is highly sensitive with good specificity. More important to clinical application, the positive predictive validity of 0.364 ensures that all women at risk will be identified, and, even if their follow-up clinical assessment is negative—indicating that they have ceased using alcohol and do not use illicit substances—they can be provided prevention/intervention information that will promote ongoing abstinence in pregnancy. The high negative predictive validity value (0.974) can assure the prenatal care provider with a high degree of certainty that if a woman screens negative, she is in fact not at risk for substance use or abuse.

Inspection of the patterns of use of women who were positive on the screen reveals that the measure identifies women across a broad spectrum of light-to-heavy use. Of the women identified on the clinical assessment as using alcohol or illicit drugs during pregnancy, 45% were using less than 1 day per week, a level of use that would not have been elicited through other forms of screening, including urine toxicologies.<sup>20</sup>

This is the first published validity study of the *4P's Plus*. Although the sample size is relatively small, the use of a population from an urban clinic helps make the findings generalizable to other urban settings. The greatest advantage the *4P's Plus* has over other screening instruments is that it identifies light and infrequent drinkers, including those women who drank in early pregnancy before they knew they were pregnant, as well as those women who continue to drink at heavier levels. In addition, the *4P's Plus* identifies both infrequent and frequent users of illicit substances, women who typically are missed by the other perinatal screening instruments.

The issue of screening pregnant women for substance use is especially pertinent to primary prenatal care since there is good evidence that early identification of the substance using pregnant woman and linkage to interventions significantly improves birth outcome. Infants whose alcoholic mothers entered treatment and

became alcohol-free by the third trimester have been shown to have substantially improved outcome at birth.<sup>23,24</sup> Rates of preterm labor, intrauterine growth retardation and neonatal morbidity are significantly reduced for cocaine-using women, who are identified early in pregnancy and cease use by third trimester.<sup>25</sup> A study of 6774 pregnant women receiving prenatal care through Kaiser Permanente Managed Care Plan demonstrated that pregnant women, who screened positive for alcohol and other drug use and received even a single brief intervention had a reduced rate of low birth weight infants, preterm infants and infants who required ventilation.<sup>26</sup> Identification of the lighter drinker takes on added importance in that research into the effects of alcohol as a teratogen have revealed that even low doses of alcohol may have serious long-term consequences for children.<sup>18,27</sup>

Over the last few years, physicians' attitudes toward intervening in their patients' drug and alcohol problems have become more positive,<sup>28</sup> and the American College of Obstetricians and Gynecologists recently stated that obstetricians are ethically obligated to address substance use as a part of routine prenatal care with all patients.<sup>29</sup> Taking less than 1 min, the *4P's Plus* easily can be integrated into the initial prenatal visit and used for follow-up screening through the pregnancy.

## Acknowledgments

This work was supported in part by a grant from Maternal and Child Health Bureau, Health Resources and Services Administration, US Department of Health and Human Services no. D63MC00053.

## References

- Lester BM, Corwin MJ, Sepkoski C, Seifer R, Peucher M, McLaughlin S *et al*. Neurobehavioral syndromes in cocaine-exposed newborn infants. *Child Dev* 1991; **62**: 694–705.
- Chasnoff IJ, Griffith DR, MacGregor S, Dirkes K, Burns KA. Temporal patterns of cocaine use in pregnancy. *J Am Med Assoc* 1989; 741–1744.
- Finnegan LP, Connaughton JF, Kron RE, Samuels SJ, Batra KK. Neonatal abstinence syndrome: assessment and management. In: Harbison RD (ed). *Perinatal Addiction*. Spectrum Publications: New York, 1975 pp 141–158.
- Streissguth AP, Sampson P, Barr H. Neurobehavioral dose—response effects of prenatal alcohol exposure in humans from infancy to adulthood. *Ann NY Acad Sci* 1989; **562**: 145–158.
- Fried PA, Watkinson B. 36- and 48-month neurobehavioral follow-up of children prenatally exposed to marijuana, cigarettes, and alcohol. *J Dev Behav Pediatr* 1990; **11**(2): 49–58.
- American College of Obstetricians and Gynecologists. Substance abuse in pregnancy. *ACOG Technical Bulletin No. 195*. American College of Obstetricians and Gynecologists: Washington (DC), 1994.
- Perl HI. *Numerous Studies Demonstrate Effectiveness of Brief Interventions*. NIAAA: Frontlines Washington DC, 2000.
- US preventive services task force ratings: strength of recommendations and quality of evidence. *Guide to Clinical Preventive Services, Third Edition: Periodic Updates 2000–2003*. Agency for Healthcare Research and Quality: Rockville, MD#http://www.ahrq.gov/clinic/3rduspstf/ratings.htm.

- 9 Chasnoff IJ, Neuman K, Thornton C, Callaghan MA. Screening for substance use in pregnancy: a practical approach for the primary care physician. *Am J Obstet Gynecol* 2001; **184**: 752–758.
- 10 Ewing J. Detecting alcoholism: the CAGE questionnaire. *JAMA* 1984; **252**: 1905–1907.
- 11 Kitchens JM. Does this patient have an alcohol problem? *JAMA* 1994; **272**: 1782–1787.
- 12 Bottoms SF, Martier SS, Sokol RJ. Refinements in screening for risk drinking in reproductive-aged women: the 'NET' results. *Alcohol Clin Exp Res* 1989; **13**: 339.
- 13 Sokol RJ, Martier SS, Ager JW. The T-ACE questions: practical prenatal detection of risk-drinking. *Am J Obstet Gynecol* 1989; **160**: 863–868.
- 14 Russell M, Martier SS, Sokol RJ, Mudar P, Bottoms S, Jacobson S *et al*. Screening for pregnancy risk-drinking: TWEAKing the tests. *Alcohol Clin Exp Res* 1991; **15**: 368 abstract no. 338.
- 15 Chan AW, Pristach EA, Welte JW, Russell M. Use of the TWEAK test in screening for alcoholism/heavy drinking in three populations. *Alcohol Clin Exp Res* 1993; **17**: 1188–1192.
- 16 Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. *Arch Intern Med* 1998; **158**: 1789–1795.
- 17 American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders: DSM-IV: International Version with ICD-10 Codes* 1995.
- 18 Sood B, Delaney-Black V, Covington C, Nordstrom-Klee B, Ager J, Templin T *et al*. Prenatal alcohol exposure and childhood behavior at age 6–7 years: I. Dose–response effect. *Pediatrics* 2001; **108**: e34.
- 19 Chasnoff IJ, Hung WC. *The 4P's Plus*. NTI Publishing: Chicago, 1999.
- 20 Chasnoff IJ, McGourty RF, Bailey GF, Hutchins E, Lightfoot SO, Pawson LL *et al*. The 4P's Plus<sup>®</sup> screen for substance use in pregnancy: clinical application and outcomes. *J Perinatol* 2005; 368–374.
- 21 Hutchins E, DiPietro J. Psychosocial risk factors associated with cocaine use during pregnancy: a case–control study. *Obstet Gynecol* 1997; **90**: 142–147.
- 22 Center for Substance Abuse Prevention. *Maternal Substance Use Assessment Methods Reference Manual: A Review of Screening and Clinical Assessment Instruments for Examining Maternal Use of Alcohol, Tobacco, and Other Drugs*, (DHHS Publication no. (SMA) 93–2059) Division of Communication Programs: Rockville, MD, 1993.
- 23 Larsson G. Prevention of fetal alcohol effects: an antenatal program for early detection of pregnancies at risk. *Acta Obstet Gynecol Scand* 1983; **62**: 171–178.
- 24 Little RE, Young A, Streissguth AP, Uhl CN. Preventing fetal alcohol effects: effectiveness of a demonstration project In: *CIBA Foundation Symposium 105, Mechanisms of Alcohol Damage In Utero*. Pitman Press: London, 1984 pp 254–274.
- 25 Chasnoff IJ, Griffith DR, MacGregor S, Dirkes K, Burns KA. Temporal patterns of cocaine use in pregnancy: perinatal outcome. *JAMA* 1989; **261**: 1741–1744.
- 26 Armstrong MA, Osejo VG, Lieberman L, Carpenter DM, Pantoja PM, Escobar GJ. Perinatal substance abuse intervention in obstetric clinics decreases adverse neonatal outcomes. *J Perinatol* 2003; **23**: 3–9.
- 27 Huizink AC, Mulder EJJ. Maternal smoking, drinking, or cannabis use during pregnancy and neurobehavioral and cognitive functioning in human offspring. *Neurosci Behav Rev* 2006; **30**: 24–41.
- 28 Roche AM, Richard GP. Doctors' willingness to intervene in patients' drug and alcohol problems. *Soc Sci Med* 1991; **33**: 1053–1061.
- 29 ACOG Committee on Ethics. At-risk drinking and illicit drug use: Ethical issues in obstetric and gynecologic practice. ACOG Committee Opinion No. 294. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2004; **103**: 1021–1031.