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The *4P's Plus*© Screen for Substance Use in Pregnancy Research Background and Clinical Application

For the past several years, *NTI Upstream* has been involved in developing and validating a screening methodology that will identify pregnant women at risk for alcohol, tobacco, and illicit drug use. The *4P's Plus*© is a five-question screen specifically designed to quickly identify obstetrical patients in need of in-depth assessment or follow up monitoring. Taking less than one minute, it easily can be integrated into the initial prenatal visit and used for follow up screening through the pregnancy. The questions are broad-based and highly sensitive.

Development of the *4P's Plus*©

The first step in the development of the *4P's Plus*© was a three-year study, the goal of which was to identify risk factors for substance use during pregnancy. The results of this study were published in 2001.[1] Participants were 2,002 Medicaid-eligible pregnant women with two or less visits to prenatal care clinics in South Carolina and Washington State. Structured interviews were used to collect data. Logistic regressions and recursive partitioning classification and regression trees (CART analysis) identified predictors for pregnant women at high risk for substance use. Approximately 9% of the sample reported current use of either drugs or alcohol or both. Significant correlates of alcohol or drug use in pregnancy are documented in the following table.

Factors Correlated with Alcohol or Drug Use in Pregnancy (N=1949)

Characteristic	Adjusted odds ratio	
	Alcohol or drug use	Drug use only
Ever smoked cigarettes	6.03* (0.003)	4.06# (0.038)
Ever drank alcohol	7.68* (0.000)	4.53* (0.009)
Ever drank alcohol and ever smoked cigarettes	0.18* (0.004)	0.22# (0.018)
Smoked cigarettes in month before pregnancy	1.53 (0.176)	2.62# (0.034)
Drank alcohol in month before pregnancy	5.39* (0.000)	2.43* (0.003)
Another adult in household uses alcohol or illicit drugs	1.39 (0.175)	1.77# (0.041)
Moderate or severe depression	1.55# (0.046)	2.37* (0.001)
Lives alone or with small children	1.93# (0.014)	1.74 (0.098)

*Significantly different from 1 at $P = .01$ level, 2-tailed test
#Significantly different from 1 at $P = .05$ level, 2-tailed test

The regression results confirmed that past cigarette or alcohol use was significantly correlated with current drug or alcohol use. Furthermore, the effects of the various factors were cumulative; that is, women who had smoked and had ever used alcohol were 8 times more likely to use alcohol or drugs during pregnancy than women who had done neither. To refine the analysis and identify a small set of risk factors that could serve as the basis for a screening protocol for risk of alcohol or other drug use during pregnancy, a CART analysis was performed. Within the sample, the CART analysis generated three groups with increasing levels of risk for alcohol or illicit drug use during pregnancy:

1. **Low risk** – *those women who had never used alcohol*: 1.4 % of women in the low-risk group reported using either drugs or alcohol or both during the time they had been pregnant

2. **Average risk** – *those women who had used alcohol in the past but not in the month before pregnancy*: 8.7% of women in the average risk group reported using either drugs or alcohol or both during the time the y had been pregnant
3. **High risk** – *those women who used alcohol in the month before pregnancy*: 36% of women in the high risk group reported using either drugs or alcohol or both during the time they had been pregnant.

Entering cigarettes into the CART analysis, we found that the number of cigarettes smoked in the month before pregnancy helped to further distinguish the average risk and high risk groups. Of those women who had used alcohol in the past but did not smoke three or more cigarettes in the month before pregnancy, 3.4% reported using drugs during the time they had been pregnant. For those women who had used alcohol in the past *and* smoked three or more cigarettes in the month before pregnancy, 14.5% reported using drugs during pregnancy.

On the basis of these three levels of risk, we suggested 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?

We integrated these three questions and field tested our new instrument, the *4P's Plus*©,[2] in a variety of settings and communities with over 100 physicians from around the country. Through this field testing, we learned:

1. Physicians and other providers feel most comfortable if substance use screening can be incorporated into routine prenatal care and flows naturally within the context of the prenatal interview. Thus, we made the *P* for *Parents* the first question and advised physicians to ask the question within the context of the family history. A positive response does not predict the woman's substance use, but it normalizes the following questions about substance use by making it clear that these are questions that are part of routine medical care.
2. The second *P*, for *Partner*, is similar to the first *P*, in that a positive response does not predict the woman's use of substances in pregnancy. However, a partner's alcohol or drug use was found to correlate with risk for domestic violence in the home.
3. A positive response to the third *P*, for *Past*, placed the woman at low risk for alcohol use during pregnancy (9.5%), an indication for prevention services to be instituted as part of primary prenatal care.
4. The two questions related to the fourth *P*, for *Present Pregnancy*, were converted to open-ended questions in an attempt to obtain an answer that most truthfully reflected the woman's substance use patterns prior to pregnancy. In addition, the questions were changed to "In the month before you knew you were pregnant…." This phrasing of the questions was found to be less threatening for the woman. As documented in the initial research,[1] 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 *prior* to pregnancy.
5. In administering the *4P's Plus*©, it is important not to use the term alcohol since many men and women do not recognize beer or wine to be alcohol. Thus, when administering the *4P's Plus*©, the terms *beer, wine or liquor* are used rather than alcohol. In addition, any forms of alcohol popular in the local community – such as daiquiris in Louisiana – should specifically be included in the questions.

6. Physicians and other providers, with training, gave strong support to the use of the *4P's Plus* as a screening instrument. The reasons the instrument gained this high level of approval were:
    a. Physicians appreciated the fact that they were not being asked to question the woman about illicit drug use, only alcohol and tobacco use prior to pregnancy. As shown in our previous research, the level of denial of illicit drug use was so high, questions about illicit drugs did not provide usable information for the primary care physician.
    b. The *4P's Plus*© is efficient, requires little training, and is easily interpreted.
    c. Providers more readily accepted screening responsibility if the procedures could be integrated into routine prenatal care and had a logical flow within the clinical interview of the pregnant woman. The screening easily flows from the family history, and, since the latter inquiries about past and present substance use are the more potentially threatening questions, they are less likely to elicit defensiveness or denial on the part of the patient if less personal questions are asked first.

Validity Data: *The 4P's Plus*©	
Correct classification (1,514/1,884)	80%
Sensitivity (310/375)	83%
Specificity (1,204/1,509)	80%
Positive predictive validity (310/615)	50%
Negative predictive validity (1204/1269)	95%

The *4P's Plus*© has been validated across a variety of populations. The first validity data were collected in a population of 1,884 pregnant women enrolled in community health centers and maternal and child health programs in Alameda County, California. The instrument demonstrated moderately high sensitivity (83%) and specificity (80%). In addition, the goal of the *4P's Plus*© is to identify women with risky drinking patterns prior to learning of pregnancy, not just those women drinking once they learned of pregnancy. This was accomplished, as demonstrated by excellent levels of positive and negative predictive validity (50% and 95%, respectively). These levels of predictive validity demonstrate that we are able to identify not only those pregnant women who are drinking heavily or whose alcohol use is at a high enough level to impair daily functioning, but also identifies those women whose pregnancies are at risk from relatively small amounts of alcohol use. Importantly, by identifying women with a positive screen for alcohol use but whose assessment is negative (meaning the woman stopped drinking once she found out she was pregnant), the pregnant woman can receive prevention materials and education regarding the impact of even low levels of alcohol use during pregnancy and be given a strong prevention message.

In 2004, the effectiveness of the *4P's Plus*© in identifying pregnant women at risk for alcohol or illicit drug use was compared to universal urine toxicology testing. In this study of close to 1,500 pregnant women enrolled in a managed care system in Southern Illinois, urine toxicologies were positive in 2% of the women; however, the *4P's Plus*© identified 20% of the population as using alcohol or illicit drugs during pregnancy.[3] In a similar study in Baton Rouge, Louisiana, the *4P's Plus* ©was compared to the *T-ACE*. Among 1,133 pregnant women, 42% of the women with a positive *4P's Plus*© were negative on the *T-ACE*. The *4P's Plus*© was able to identify women who were drinking 2 to 3 days per week and less, while the *T-ACE* identified only the heavier drinkers.

In 2007 the team at NTI Upstream published a validity study in the *Journal of Perinatology* which confirmed previous findings.[4] This was followed by the completion of a four-year study funded by NIAAA that validated the *4Ps Plus*© in a population of women enrolled in Kaiser Permanente's managed care plan. The excellent results achieved through this study were recently presented at the national meeting of the American Public Health Association.[5]

Depression and domestic violence

Work to expand the application of the *4P's Plus*© to include screening for depression and domestic violence was begun in 2000. Preliminary data among a population of approximately 10,000 women in Fresno, California, had demonstrated a 65% correlation between substance abuse and domestic violence. High rates of depression also were found in the clinical populations. It was thus decided to add straightforward, nonjudgmental questions regarding risk for domestic violence and depression to more fully explore these areas and to give the woman an opportunity to talk with her provider about her experiences with abuse or depression. Such an approach through routine and multiple screenings by skilled health care providers, when conducted face to face, markedly increases the identification of domestic violence and depression.

In developing questions for depression screening, there were several depression screening instruments available, most of which were easy to use and could be administered in less than five minutes. However, a study on a hospitalized population of armed services veterans demonstrated that simply asking two questions about depressed mood and anhydonia detected a majority of depressed patients, and, in some cases, performed better than the original instrument from which they were derived. However, these two areas of questioning had never been validated in pregnant women. Through a series of three generations of questions, tested against the *Edinburgh Postnatal Depression Scale* and a comprehensive psychosocial clinical interview, we were able to validate two questions regarding depression and two questions regarding risk for domestic violence.

Depression

	Edinburgh Positive	**Edinburgh Negative**	**Total**
***4P's Plus*© Screen Positive**	15	21	36
***4P's Plus*© Screen Negative**	0	83	83
Total	15	104	119

Sensitivity = 1.00
Specificity = .798
Positive Predictive Value = .417
Negative Predictive Value = 1.00

Domestic Violence

	DV Assessment Positive	**DV Assessment Negative**	**Total**
***4P's Plus*© Screen Positive**	10	2	12
***4P's Plus*© Screen Negative**	2	103	105
Total	12	105	117

Sensitivity = .833
Specificity = .981
Positive Predictive Value = .833
Negative Predictive Value = .981

By incorporating the questions for domestic violence and depression into the original substance abuse screen, The *4P's Plus Screen for Behavioral Health Risk in Pregnancy*© (still called the *4P's Plus*©)is the first validated instrument that has been developed to screen for alcohol, tobacco, and illicit drug use, depression, and domestic violence in pregnant women.[6]

Brief intervention

Brief intervention strategies were integrated into the screening process in 2000. Grounded in motivational interviewing techniques, *"I am concerned…"* is an interactive, multisensory psychoeducational approach that takes about five minutes and is administered to all women who are found through the screening process to be using alcohol, tobacco, or illicit drugs. In San Bernardino County, California, over a period of three years, close to 20,000 women were screened with the *4P's Plus*© and those women with a positive screen underwent the brief intervention in the prenatal care provider's office. A follow up study demonstrated that among those women receiving prenatal care in offices that used the *4P's Plus*© and *"I am concerned…",* there was a *decrease* in the low birth weight rate of 18%, a statistically significant drop as compared to the *increase* in low birth weight rate of 1% among women whose physicians did not use the *4P's Plus*©. Similar findings emerged in a study in Solano County, California. It was estimated that use of the *4P's Plus*© and "*I am concerned…"* as a universal screening and brief intervention strategy saved the county $1.8 million in costs related to low birth weight infants over a two year period.[7]

Finally, the *4P's Plus*© is a successful prevention strategy. Among six California counties who implemented universal screening of pregnant women for substance use, the rate of substance use in pregnancy has *decreased* an average of 27%. This is a statistically greater decrease in rates compared to rates of substance use in pregnancy in California and in the U.S. as a whole, both of which have demonstrated no changes in rates of substance use in pregnancy over the same period of time. From focus groups with providers and patients, it appears that administration of the *4P's Plus*© in the target pregnancy impacts a woman's use of substances in subsequent pregnancies.

Screening with the *4P's Plus*© has now been instituted in over 100 communities around the nation, and several states have developed state-wide initiatives for universal screening with the instrument. The *4P's Plus*© has been used in a wide range of populations and has been translated into five languages. The research, development and clinical experience with the *4P's Plus*© has shown it to be a viable procedure for instituting universal substance use screening in pregnant women. An outside review of the *4P's Plus*© published in the *Journal of Perinatology* supported the clinical usefulness of the instrument, providing an opportunity for successfully integrating screening into primary prenatal care.

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