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INDIRECT SCREENING: ENHANCING IDENTIFICATION OF ILLICIT DRUG USE
DURING PREGNANCY

A dissertation submitted in partial fulfillment of the requirements for the degree of
Doctor of Philosophy at Virginia Commonwealth University

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Abstract

INDIRECT SCREENING: ENHANCING IDENTIFICATION OF ILLICIT DRUG USE DURING PREGNANCY

By Courtney E. Smith, M.S.

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

Virginia Commonwealth University, 2012

Major Director: Dace S. Svikis, Ph.D.
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OBJECTIVE: Most drug use screening measures rely on and are validated against self-report. Fear of negative consequences often promotes denial of drug use. For pregnant women, social stigma and fear of legal consequences make underreporting of drug use even more likely. An indirect screener that could effectively identify pregnant women at risk for illicit drug use without reliance on disclosure would be clinically significant. The purpose of the current study was to develop and validate an indirect measure of prenatal drug use by comparing correlates of prenatal drug use to urinalysis results. **METHOD:** Pregnant women attending an OB appointment at the VCUHS Women's Health Clinic were recruited and consented to participate in an anonymous, two-phase study. In Phase 1, women completed a 20-minute computerized assessment which included a true/false index of items known to tap behavioral, medical,

psychological, experiential and demographic correlates of drug abuse and dependence. In Phase 2, participants were asked to provide a urine sample for drug testing. Women received a \$20 gift card after they participated in each phase. RESULTS: Two hundred and thirty-one women completed both Phase 1 and 2 (94% completion rate). Participants were primarily African-American (66%), single (75%) and receiving public assistance (70%). Urinalysis revealed that 16% of the sample tested positive for recent drug use, while only 5% of women self-reported past month drug use. After examining the univariate and multivariate relationships between each indirect item and drug status (i.e., positive or negative urinalysis), six indirect items were chosen to comprise the Wayne Indirect Drug Use Screener-Pregnancy (WIDUS-P). Cross-validation analyses resulted in a sensitivity of .90, specificity of .75, and AUC of .85. In comparison to direct screening approaches, the WIDUS-P was superior in identifying pregnant women who had used drugs recently. CONCLUSIONS: Findings support the use of an indirect screening tool to identify prenatal drug use, especially over currently-used direct methods. Such a measure could easily be implemented into regular clinic practice and result in more cost-effective and better identification of prenatal drug use.

Indirect Screening: Enhancing Identification of Illicit Drug Use during Pregnancy

Statement of the Problem

Drug use is common in today's society. A 2008 national survey found that almost one-tenth of study participants reported recent use of illicit drugs (SAMSHA, 2009). Although men used illicit drugs at a higher rate than women (9.9% versus 6.3%), the rate of drug use among women increased from 2007 to 2008 but remained stable for men. During pregnancy, the majority of drug-using women tend to abstain from substance use (SAMHSA, 2009; Ebrahim & Gfroerer, 2003), however a proportion of drug-using women continue to use during the prenatal period (Bailey, Hill, Hawkins, Catalano, & Abbott, 2008). This rate, which ranges from 5-14% depending on the study, is significant given the numerous negative consequences associated with prenatal drug use for both mother and offspring (SAMSHA, 2009; Chasnoff, Landress, & Barrett, 1990; Huestis & Choo, 2002). Unfortunately, current prevalence rates of prenatal drug use are likely underestimations because drug use is frequently underreported (Magura & Kang, 1996). Women face social stigma and negative consequences (e.g., loss of custody, legal charges) when they report prenatal drug use so it is not surprising that they minimize or deny using (Ondersma, Malcoe, & Simpson, 2000; Ondersma, Simpson, Brestan, & Ward, 2001; Lester, El Sohly, Wright, Smeriglio, Verter, Bauer, et al., 2001).

Pregnancy has often been viewed as a "window of opportunity" as drug using women may be more motivated to reduce or eliminate use for the sake of the unborn baby (Daley, Argeriou & McCarty, 1998). Some women are able to do this on their own, while others may need assistance (Ebrahim & Gfroerer, 2003). Pregnancy is therefore an ideal time for screening and intervention, creating opportunities to positively impact public health. Unfortunately, prenatal drug screening often does not occur because of such barriers as lack of provider time and discomfort (Chasnoff, Neuman, Thornton, & Callaghan, 2001; Yarnall, Pollack, Ostbye,

Krause, Michener, 2003). Even if screening does occur, current screening methods fall short in adequately detecting prenatal drug use. Screening measures rely extensively on self-report, despite the documented issue of underreporting, and may lack utility in prenatal populations (Skinner, 1982; Midank et al., 1998; Chasnoff et al., 2005). Prenatal care providers often do not universally screen patients and face other barriers to identifying at-risk women (Chasnoff et al., 2001; Anthony et al., 2010). Biological methods, while not limited by self-report bias, are less useful because of their cost and level of invasiveness. The consequence of these limitations is that prenatal drug use is often not identified at what would be a key time for intervention. New strategies are needed to more accurately identify drug use during pregnancy.

Overall, the present study sought to compare different screening methods to a biological measure of prenatal drug use. Specifically, the purpose of this study was to develop and validate an indirect measure of drug use; one that would identify pregnant women who were continuing to use drugs, regardless of their willingness to disclose such use. The research built upon the recent work of Drs. Ondersma and Svikis who created the Wayne Indirect Drug Use Screener (WIDUS; Ondersma, Svikis, Grekin, Lam, & Connors, 2009), developed to identify post-partum women at risk for drug use during pregnancy.

Review of the Literature

In the following sections, I will introduce the issues of prenatal drug use and underreporting. In doing so, I will present research on prevalence rates of drug use in the general population and during pregnancy, factors commonly associated with drug use during pregnancy and maternal, fetal, and infant consequences of prenatal drug use. Then, I will describe both direct and indirect methods for detecting drug use during pregnancy, such as standardized screening measures and biological measures, and also highlight the limitations of these approaches. Next, I will elaborate on a recent study that utilizes an indirect method for

identifying prenatal drug use (i.e., the WIDUS) in order to provide a foundation for the current study. Finally, I will conclude with a discussion of the current study's aims and hypotheses.

Drug Use Prevalence

General population. Substance use is common in the general U.S. population. In a recent Substance Abuse and Mental Health Services Administration (SAMHSA) National Survey on Drug Use and Health (NSDUH), a representative sample of individuals ages 12 and older (N = 68,000) was interviewed about recent (past 30 days) and lifetime use of alcohol and other drugs. More than half of the sample (52%) reported consuming alcohol (beer, wine, liquor) in the 30 days prior to completing the interview. Almost a quarter (23%) reported binge drinking, defined as having five or more drinks on the same occasion on at least one day in the past 30 days. Heavy drinking or having five or more drinks on the same occasion on at least five days in the past month was reported by about 7% of respondents. Current (past 30 days) use of a tobacco product was also common, with over a quarter of respondents reporting use.

In this SAMHSA survey, "illicit drug use" focused on marijuana, cocaine, heroin, hallucinogens, and inhalants as well as nonmedical use of prescription-type pain relievers, tranquilizers, stimulants, and sedatives. Approximately 8% of the sample and 6% of female participants reported recent use of at least one illicit drug. The most common drug used was marijuana and was reported by three-quarters of current drug users and was commonly the only drug used (57% of marijuana-users used only marijuana; SAMSHA, 2009). Marijuana was also the most frequently used drug among women (4.4% of women reported using marijuana). After marijuana, non-medically-used drugs were most commonly used (2.5% of the total sample), followed by crack/cocaine (0.7%) and hallucinogens (0.4%; SAMSHA, 2009).

While not all individuals who use substances go on to develop or currently have a substance use disorder (SUD), a significant proportion of them do. Results from the same

NSDUH 2008 survey, indicated that almost 9% of respondents met Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition-Text Revision (DSM-IV-TR) criteria for alcohol and/or illicit drug abuse or dependence. Of these individuals, almost a third met criteria for illicit drug abuse or dependence, either in combination with alcohol abuse or dependence or alone. The rate of SUD for men was twice as high as the rate for women (12% versus 6%; SAMSHA, 2009).

Underreporting drug use. Prevalence rates of illicit drug use rely extensively on individual's self-report, as often only one method of data collection is used (i.e., paper-and-pencil questionnaire, interview). Individuals' disclosure of substance use is influenced by their perceptions of social desirability. If they perceive that disclosure will be viewed negatively and may result in negative consequences, they may underreport or minimize their drug use. Drug use is often considered a sensitive behavior and especially given its illicit nature, individuals may be uncomfortable admitting use (Fendrich, 2005). Individuals may also be more hesitant to admit use of certain types of drugs, for instance, "harder" drugs (e.g., cocaine, amphetamine, and heroin) that carry a much (remove) stronger stigma than marijuana (Weir, Stark, Flemming, He, & Tesselaar, 1998). Consequently, self-reported drug use may not be a valid representation of an individual's actual use.

Biased self-reported drug use is problematic. When individuals distort their drug use it leads to inaccurate prevalence rates, which may in turn negatively impact screening and intervention efforts, as well as jeopardize the legitimacy of study conclusions (Macleod, Hickman, & Smith, 2005). The validity of self-reported drug use has been examined by comparing self-report to one or more biological measures of drug use (e.g., urinalysis, hair analysis, meconium testing). Magura and Kang (1996) conducted a meta-analysis of 24 studies involving self-report and biological measures of drug use in various high risk populations (e.g.,

individuals involved in the legal system, psychiatric inpatients, post-partum women referred to drug treatment). Results indicated significant underreporting of self-reported drug use. While underreporting may be expected in high-risk populations given the potential for negative consequences of reporting drug use (e.g., legal charges), research has also provided support for underreporting in general populations (Fendrich, Johnson, Wislar, Hubbell, & Spiehler, 2004; Ledgerwood, Goldbeger, Risk, Lewis, & Price, 2008). In a random sampling of households in Chicago (N = 627), biological testing revealed higher rates of heroin and cocaine use than self-report estimated. Of those testing positive by biological measures (i.e., a positive hair, urine, or saliva screen), only a quarter of individuals self-disclosed past year cocaine use and only one-fifth disclosed past year heroin use. Interestingly, most individuals (78%) testing positive for marijuana reported use in the past year, possibly reflecting the idea that marijuana is a less-stigmatized drug. Additionally, Fendrich and colleagues (2004) found that participants were more willing to disclose lifetime drug use than recent use (i.e., past month, past year), suggesting that lifetime drug use prevalence rates may be a more valid measure of drug use. Together, this research underscores the need to acknowledge the impact of underreporting on rates of self-reported drug use.

Pregnant women. Although many women reduce or stop substance use during pregnancy (SAMHSA, 2009; Ebrahim & Gfroerer, 2003), a significant proportion continue to use substances during the prenatal period (Bailey, Hill, Hawkins, Catalano, & Abbott, 2008). According to recent epidemiological data (2008 NSDUH), of pregnant women interviewed, ages 15 to 44 years, 11% reported current (past month) alcohol use, 4.5% reported binge drinking (five or more drinks on one occasion) at least one day in the past month, and 0.8% reported heavy drinking (having five or more drinks on one occasion on at least 5 days in the past month). Cigarette smoking was more common than alcohol consumption among pregnant women: 16%

of respondents reported smoking at least one cigarette in the month prior to being interviewed. Rates of drug use were lower with 5% of pregnant women reporting use of illicit drug in the past month. Although the NSDUH did not break down prevalence of prenatal illicit drug use by type of drug used, marijuana was the most commonly used drug by women of childbearing age (SAMSHA, 2009). Research using an earlier version of the NSDUH survey also confirms this finding (Ebrahim & Gfroerer, 2003). Overall, in considering NSDUH data, it is important to recognize that these are conservative estimates of prevalence as the interviews focused only on the past 30 days rather than the entire prenatal period.

Other studies focusing on specific samples (i.e., pregnant and postpartum women) and utilizing a range of methodologies (i.e., self-report, biological testing, review of hospital records) have found higher prevalence rates of prenatal substance use, specifically illicit drug use. Based on a review of hospital records of all births occurring in a county hospital in San Francisco during a 4-year period (July 1995-June 1999; N = 5940), 7% were determined to be drug-exposed. Classification was based on maternal self-report of drug use, positive toxicology screens during pregnancy, and/or positive toxicology screens in the newborn (Wolfe, Guydish, Santos, Delucchi, & Gleghorn, 2007). Additional research utilizing toxicology screens at delivery have documented even higher rates of prenatal illicit drug use (14%; Chasnoff, Landress, & Barrett, 1990; Vega, Kolody, Hwang, & Noble, 1993).

Underreporting in pregnant women. Prevalence rates of illicit drug use during pregnancy likely differ given the variability in methodologies used to detect use (e.g., interview, questionnaire, biological testing of mother and/or infant), which is discussed in a later section, and the types of populations studied (e.g., national, pregnant vs. postpartum, patients attending prenatal care, treatment-seeking). In addition, the high-risk nature of prenatal drug use may also lead women to underreport their use, making it difficult to obtain accurate prevalence rates

(Huang & Reid, 2006). Women who use drugs during pregnancy face social and legal consequences, including social stigma, child protective services involvement, and loss of custody, which leads them to underreport or minimize their drug use (Ondersma et al., 2000, 2001). Their fears of negative consequences are not unjustified. In South Carolina, child protection laws include “viable fetuses” and thus pregnant women can be criminally prosecuted with such charges as child abuse/endangerment and/or illegal drug delivery to a minor. In 1989, the Medical University of South Carolina adopted policies which, in cooperation with a local prosecutor, selectively screened urine samples from medically indigent obstetric patients for cocaine metabolites. Those who screened positive were taken to the police, who then arrested the pregnant women on charges of possession of an illegal drug and either delivery of drugs to a minor and/or child abuse (Harris & Paltrow, 2003).

Not surprising given these consequences, there is often discrepancy between self-report and biological measures of prenatal drug use. In a large, multi-site study of in utero cocaine and/or opiate exposure, rates of maternal self-report of prenatal drug use differed from rates of positive meconium analysis (Lester et al., 2001). Over 8,500 women were recruited shortly after delivery from four sites, varying in race, ethnicity, social class, and geographic region. Based on a maternal interview of past and current substance use, 661 (7.5% of the sample) women self-reported prenatal cocaine and/or opiate use. However, testing of infant meconium and subsequent confirmation of positive screens identified an additional 254 drug-using mothers (2.9% of the sample) who denied prenatal drug use. Therefore, based on a combination of maternal self-report and meconium assays, 10.7% of all women used cocaine and/or opiates during their pregnancy. Earlier studies utilizing large samples of pregnant women have also noted discrepancies between self-report and toxicology screens (Frank, Zuckerman, Amaro,

Aboagye, Bauchner, Cabral, et al., 1988, Ostrea, Brady, Gause, Raymundo, & Stevens, 1992, NIDA, 1996).

Drug Use and Pregnancy

Patterns of abstinence during pregnancy. As stated earlier, most women reduce their use of illicit drugs during pregnancy, either by abstaining completely or decreasing the frequency and/or quantity of their use (Ebrahim & Gfroerer, 2003). In addition, pregnant women may engage in other harm reduction approaches, such as switching to a less potent type of drug (e.g., from hashish to marijuana; el Marroun, Tiemieier, Jaddoe, Hofman, Mackenbach, Steegers, et al., et al., 2008). Data from the 1996-1998 National Household Survey on Drug Abuse (NHSDA; now known as the NSDUH), suggests that cessation does not occur immediately after women realize they are pregnant, but rather, during the third trimester most drug-using women report abstinence. The proportion of drug-using women reporting abstinence increased by trimester: 28% were abstinent in their first trimester, 76% in their second trimester, and 93% in their third trimester. The remaining 7% of drug-using pregnant women continued illicit drug use during their third trimester. These statistics exemplify that although a small, but meaningful nonetheless, percentage of women continued drug use throughout pregnancy; almost a quarter of all drug-using women did not ultimately abstain until late in their pregnancy.

Frequency of drug use during pregnancy. When women continue using drugs into their pregnancy they tend to be frequent users. In a study of prenatal care patients attending urban healthcare centers in Minnesota (N = 1492), women who reported drug use at their first prenatal visit typically reported weekly or daily use of illicit drugs, as opposed to rare or monthly use (Harrison & Sidebottom; 2009). Researchers in the Netherlands (el Marroun et al., 2008) found similar results in their population-based study of pregnant women (N = 7531). Women who self-reported prenatal cannabis use (the drug of interest in this study) were most often

frequent users (80% used daily or weekly). Women who did not report prenatal use were likely monthly users. Additionally, pregnant women with a history of cannabis dependence were almost three times more likely to use prenatally (OR = 2.77, $p < .001$) than women with no history. Together, these findings of frequent use highlight the dependent nature of drug use during pregnancy and the difficulty of abstaining.

Patterns of substance use. Not only does the frequency of substance use change during pregnancy, patterns in the type of substance used from pre-pregnancy to pregnancy may also differ. This has been shown specifically among low-income populations. Harrison and Sidebottom (2009) interviewed women attending their first prenatal care appointment (N = 1,492) about their pre-pregnancy and prenatal (use that occurred after a woman found out she was pregnant) use of substances. The majority of participants were non-Caucasian (43.7% African American), young (mean age = 22.6 years), and low-income (90% received services through Medicaid or a state-funded program). Pre-pregnancy (12 months prior to pregnancy) substance use rates indicated that alcohol use was almost twice as common as drug use (41.1% vs. 24%). Interestingly, prenatal use showed the opposite pattern: almost twice as many women reported recent illicit drug use as recent alcohol use (10.7% vs. 5.6%). More specifically, drug use alone, as opposed to alcohol use alone or concurrent alcohol and drug use, was the most common substance use pattern reported during pregnancy. Further, the rate of women continuing substance use after they discovered they were pregnant was higher for drugs than alcohol (44% vs. 13%). In a smaller sample of prenatal patients (N = 130) with comparable demographics, the same pattern was true: women tended to report prenatal marijuana use more often than alcohol use (17% vs. 7%; Jesse, Graham, & Swanson, 2006). Overall, these findings underscore the need to address illicit drug use during pregnancy. Moreover, as with all self-reported rates, it is

important to consider the possibility that these percentages may be even higher because of underreporting.

Factors associated with prenatal drug use. In an attempt to improve screening and identification of drug-using pregnant in prenatal care clinics, a growing body of research has examined factors associated with prenatal drug use. Unfortunately, the majority of these studies relied on women's self-reported drug use to identify risk factors. As previously mentioned, this reliance on self-report is problematic given the frequency of underreporting by pregnant women. Nonetheless, the research is still informative as a first step towards better identification of prenatal drug use.

Researchers have utilized both nationally representative and convenience (e.g., university-based obstetrics clinic, county hospitals) samples of pregnant women to identify correlates of drug use. A variety of factors have been examined, including demographic, social, psychological, experiential and pregnancy-related factors (Havens, Simmons, Shannong, & Hansen, 2009; Ebrahim & Gfroerer, 2003; Marcenko & Spence, 1995; Kelly, Zatzick, & Anders, 2001; Horrigan, Schroeder, & Schaffer, 2000; Jesse et al., 2006).

While studies have used different methodologies, common correlates of prenatal drug use have been identified. Demographically, pregnant drug-using women are more likely than non-users to be unmarried (Havens et al., 2009; el Marroun et al., 2008; Wolfe et al., 2007; Huang & Reid, 2006; Ebrahim & Gfroerer, 2003), older (Harrison & Sidebottom, 2009), unemployed or never worked (Havens et al., 2009; Huang & Reid, 2006), receiving public assistance (Huang, & Reid, 2006; NIDA, 1996) and have less education (Ebrahim & Gfroerer, 2003). Prenatal drug-users are also more likely to be experiencing current psychopathology, including depression, anxiety and suicidality (Havens et al., 2009; Jesse et al., 2006; Chasnoff, Neuman, Thornton, & Callaghan, 2001; Horrigan et al., 2000). They also often live with another adult who uses illicit

substances, have a family member with a drug or alcohol problem (Chasnoff et al., 2001; Marcenko & Spence, 1995), and have experienced some form of abuse and/or childhood trauma in their lifetime (Horrigan et al., 2000; el Marroun et al., 2008; Marcenko & Spence, 1995). Delinquent behavior (i.e., having ever been arrested or having a criminal record) was also found to be a significant predictor of prenatal drug use (el Marroun et al., 2008). Additionally, women's past and current substance use may be a useful indicator of current drug use. Pre-pregnancy and current cigarette smoking and alcohol use (Harrison & Sidebottom, 2009; Svikis, Henningfield, Gazaway, Huggins, Sosnow, Hranicka et al., 1997; Chasnoff et al., 2001; el Marroun et al., 2008), as well as pre-pregnancy drug use (Harrison & Sidebottom, 2009), have been found to be significantly associated with prenatal drug use.

Research has also demonstrated associations between prenatal drug use and factors associated with low socio-economic status, including lack of transportation (Harrison & Sidebottom, 2009), housing instability (Chasnoff et al., 2001), and food insecurity (Harrison & Sidebottom, 2009). Some studies also suggest an association between prenatal drug use and sexually transmitted diseases (Horrigan et al., 2000; Berenson, Wilkinson, & Lopez, 1995). Additionally certain pregnancy-related factors, such as number of previous live births (Bendersky, Alessandri, Gilbert, & Lewis, 1996; Marcenko & Spence 1995), history of preterm birth (Jesse et al., 2006;), unintended pregnancy (el Marroun et al., 2008; Hunay & Reid, 2006), and seeking prenatal care later in pregnancy (Marcenko & Spence, 1995) have been associated with prenatal drug use. However, the correlates of age and previous live births/number of children are confounded by the length of time a woman has used drugs and therefore, may act as a proxy for substance use disorder chronicity (Johnson, McCarter, & Ferencz, 1987). Lastly, women who used drugs during pregnancy compared to those who did not more often reported that the father of their baby also used drugs (el Marroun et al., 2008).

In utero effects of illicit drug use. When a pregnant woman consumes drugs, the substance crosses the placenta thereby exposing the fetus. Consequently, in addition to the general health risks associated with drug use for the mother, prenatal drug use poses risk to the developing fetus. Prenatal exposure is associated with a variety of perinatal complications including higher rates of spontaneous abortion, stillbirth, placental insufficiency, eclampsia, gestational diabetes, fetal growth retardation, low birth weight and premature labor (Finnegan, 1994; Kennare, Heard, & Chan, 2005; Burns, Mattick, & Cooke, 2006). Not surprising given these consequences, drug-exposed infants tend to require more significant medical attention than non-exposed infants and are a greater socio-economic cost to society (Finnegan, 2000; Huestis & Choo, 2002). Prenatal drug exposure not only affects the fetus and infant, but can also impact the later cognitive and behavioral development of the child. While the specific long-term consequences vary by type of drug, prenatal exposure has been associated with lower IQ scores, increased behavioral problems, poor attention, impulsivity, impaired executive functioning and poor state control (Huestis & Choo, 2002; Behnke & Eyler, 1993).

Research has shown that the link between prenatal drug use and negative outcomes is more complicated than direct causation. The effect of prenatal drug use on fetal and infant outcomes varies as a function of the type of drug use (i.e., type of drug, quantity, frequency, and duration) and individual characteristics (i.e., how an individual responds physiologically and psychologically to drugs). Environmental factors associated with prenatal drug use (e.g., low SES, poor prenatal care, poor nutrition) also contribute to negative outcomes, making it difficult to disentangle the unique effects of prenatal drug exposure (Anthony, Austin, & Cormier, 2010; El-Mohandes, Herman, Nabil El-Khorazaty, Katta, White, & Grylack, 2003). In addition, poly-substance use further complicates researchers' ability to identify specific adverse consequences of specific drugs (Kandall, Doberczak, Jantunen, & Stein, 1999). Despite the many confounding

factors, there is still a great need for early detection and intervention of prenatal substance use in order to improve negative fetal/infant/child outcomes. Early work by Chasnoff and colleagues (1989) highlights this window of opportunity: drug-using women who become abstinent by their third trimester have been found to significantly reduce the risk of medical complications.

Unique circumstances of pregnancy. Pregnancy is a unique time for identification and intervention of problematic substance use. Most women stop using substances while they are pregnant, but often return to drug use during the postpartum period (SAMSHA, 2009; Ebrahim & Groerer, 2003). For those women who continue using into and throughout their pregnancy, their use of illicit drugs may be considered problematic and may even reflect addictive behavior (el Marroun et al., 2008). It is well known that most individuals with a substance use disorder do not seek treatment (SAMSHA, 2005). Thus, during pregnancy, when women are accessing health services more regularly than if they were not pregnant, is an ideal time to detect problematic drug use and to intervene. Motivation to seek help may be greater during this time because of women's concerns about the health of their fetus (Grella, 1999), their own health (Gehshan, 1995) and fear of negative consequences (e.g., the legal implications of testing positive at delivery; Howell & Chasnoff, 1999). In a retrospective study utilizing county hospital and drug treatment service records, Wolfe and colleagues' (2007) results support the notion of increased motivation during pregnancy. They found that significantly more women engaged in some form of drug treatment (i.e., outpatient, residential, methadone maintenance, or detoxification) during or after delivery than they did one year prior to becoming pregnant. Further, during pregnancy, substance-using women have the opportunity to reduce the harm to their fetus by quitting or cutting down whereas after delivery that window of opportunity expires. Although pregnancy is an ideal time for intervention, many drug-using women are not identified by their prenatal care providers, resulting in missed opportunity. Consequently, the ability to

refer and engage drug-using women in treatment rests on how well screening methods identify prenatal drug use.

Detecting Drug Use during Pregnancy

A variety of methodologies, including biological testing and self-report questionnaires, have been developed to screen for problematic substance use. The purpose of screening is not to diagnose substance abuse or dependence, but rather to identify individuals who may be at-risk for these problems in order to facilitate referral for additional assessment and intervention. Given this purpose, priority is often given to sensitivity, the true positive rate of a screening tool, over specificity, the true negative rate. No matter the type of method used, accurate identification is extremely important as brief intervention and treatment efforts can only occur following proper identification of problematic drug use. Health care providers, particularly primary care providers, are in a unique position to screen for substance use problems because of their regular access to patients over time and because such questions are relevant to their health. In addition, because a woman's obstetrician or gynecologist may function as her primary care physician (Klock, 2004), screening for prenatal drug use in OB/GYN clinics is ideal. During pregnancy, universal substance use screening at the first prenatal care visit (ACOG, 2006; Welch & Sokol, 1994), as well as throughout pregnancy (Svikis & Reid-Quinones, 2003) is recommended. When screening occurs, providers rely on a variety of methods.

Biological screening methods. Drug screening or "drug testing" has become somewhat synonymous with biological methods, where a biological specimen (i.e., urine, hair, blood, saliva) is analyzed for the presence of different kinds of drugs and their metabolites. To identify prenatal drug use, both maternal and infant specimens can be analyzed. For instance, testing of infant meconium (i.e., the first stool of the newborn infant) post-delivery has been used to determine whether a woman used substances during her pregnancy (Bessa, Mitsuhiro, Chalem,

Barros, Guinsburg, & Laranjeira, 2010). Screening for illicit drugs often consists of an initial test using an immunoassay to determine whether or not a drug or its metabolite is present and then confirmatory testing that is qualitatively different from the initial test (e.g., chromatography/mass spectrometry) is conducted. The Substance Abuse and Mental Health Services Administration (SAMSA) established drug-specific cut-off points to standardize the results of drug testing. Methods vary with respect to their window of drug detection, the amount of time after ingestion during which the substance can be detected, whether results are qualitative (positive or negative for a particular drug) or quantitative (the level of the substance used) and their level of invasiveness. Consequently, each method has strengths and limitations (Wolff, Farrell, Marsden, Montiero, Ali, Welch, et al., 1999). Unfortunately, biological screening is often used when a provider suspects a pregnant woman is using drugs, but denies such use (Svikis & Huggins, 1996).

Urine testing. Urinalysis is a well-accepted method for detecting drug use because urine samples are easy to collect in sufficient quantities necessary for testing. In addition, drugs and their metabolites are usually present in urine in high concentration. Relative to other methods, urinalysis has a short window of detection (i.e., 1-3 days) for most drugs, with the exception of marijuana, and therefore only identifies recent drug users. Use of marijuana can be detected in urine for weeks after last use. Another drawback to urine screening is that the sample can be easily adulterated to produce a false negative; however, temperature and pH tests can be used to determine the authenticity of samples (Wolff et al., 1999).

Hair testing. Hair analysis is another biological method to detect drug use and provides a “retrospective calendar” of use (Kintz, Villain, & Cirimele, 2006). Hair grows approximately one cm/month and so different sections of hair can be analyzed to create a timeline of use during pregnancy. Thus, hair analysis is considered advantageous over urinalysis because of its longer

window of detection. Research has also shown this method to have excellent sensitivity in detecting perinatal drug use (Ostrea, Knapp, Tannenbaum, Ostrea, Romero, Salari, et al., 2001). However, this method is not without limitations. Although collecting a hair sample may be less invasive than collecting urine or blood, some women may be opposed to providing a hair sample because of cosmetic concerns or taboos (Eyler, Behnke, Wobie, Garvin, & Tebett, 2005). In addition, the results of hair analysis can be affected by individual and racial differences (i.e., hair color and texture), with coarser, darker hair incorporating more of a drug than thinner, lighter hair (Ebrahim & Gfroerer, 2003). Chemical processing (i.e., coloring, bleaching, straightening), and external exposure to drugs (e.g., hair tests positive for marijuana because of passive exposure to smoke rather than active ingestion) also impact test results.

Blood testing. Although drug testing blood samples is useful quantitatively, it is also a very invasive procedure which requires trained personnel and special handling procedures. Further, it may not be as useful as urine testing because most illicit substances leave the blood within a few hours of use and concentrations fall below threshold levels of detection (Wolff et al., 1999). These drawbacks limit the utility of blood testing as a screening tool in pregnant women.

Saliva testing. Collection of saliva is easy and less invasive than collecting other biological samples. The window of detection for oral fluid ranges from five to 48 hours and is typically shorter than that of urine (Verstraete, 2004). In a study of pregnant opiate-dependent women, saliva testing was a highly sensitive method for detecting opiate and cocaine use (Dams, Choo, Lambert, Jones, & Huestis, 2007). However, the authors acknowledge that rates of detection will vary by cut-off concentrations, type of collection device, and detection method used. Thus, while it is a promising alternative to more invasive methods, additional research is needed to standardize the collection and testing of oral fluid.

Infant specimen testing. Testing newborn's hair, urine and meconium are additional methods to detect prenatal drug use. Drugs and their metabolites are believed to accumulate in meconium at about 18 weeks gestation, when it is first produced, allowing drug use in the second and third trimesters to be detected (Ostrea, et al., 1992). This method provides a longer window of detection over oral fluid and urine testing. In addition, drug and metabolite concentrations may be higher in meconium than urine (Ostrea, Brady, Parks, Asensio, & Naluz, 1989). Hair taken from an infant may offer a more pure calendar of a mother's drug use than her own hair as it has not been subject to the same contaminants (e.g., chemical processing, external exposure to drugs). However, a newborn may not have enough hair to adequately test for exposure to drugs (Eyler et al., 2005). Urine testing may be a useful alternative; however, this method is still limited to only recent drug use by the mother.

Summary of biological methods. A variety of biological specimens have been used to detect prenatal drug use, including urine, hair, blood, oral fluid, and meconium. As elaborated above, each method has strengths and limitations. For detecting prenatal drug use, no biological method has been identified as the "gold standard." Drug testing does help identify women who deny use; however it may not be a cost-effective approach (Eyler et al., 2005). Further, identifying prenatal drug use at delivery (i.e., by testing infant specimens) prevents the possibility of early intervention and reducing harm to the fetus/infant.

Direct screening methods. While many screening tools have been developed to assess at-risk drinking, a lesser number of measures exist to detect illicit drug use and problems. Furthermore, many of the existing screeners for problematic drug were adapted from or patterned after alcohol screening tools (e.g., the word, "drinking," was replaced with "drug use" in the Drug CAGE). To an even lesser extent have measures been developed for or validated on pregnant women. Most screeners are direct or face-valid (i.e., they ask specifically about

substance use and its consequences), rely on individuals' self-report and are administered as paper-and-pencil questionnaires or brief interviews. Examples of specific direct to screen for prenatal drug use are described below.

Drug CAGE. The Drug CAGE is a 4-item, yes/no questionnaire designed to detect problematic drug use by asking: 1) Have you ever felt you should cut down on your drug use?; 2) Have people annoyed you by criticizing your drug use?; 3) Have you ever felt bad or guilty about your drug use?; and 4) Have you ever used drugs first thing in the morning to steady your nerve? The CAGE was originally developed to screen for problem drinking (Ewing, 1984) and has become a widely-used alcohol screening tool for a variety of populations (Bradley, Boyd-Wickizer, Powell, & Burma, 1998; Bradley, Kivlahan, Daniel, Bush, McDonell, Fihn et al., 2001; Satre, Knight, Dickson-Fuhrmann, & Jarvick, 2004; Williams, Horton, Samet, & Saitz, 2007), including pregnant women (Russell, Martier, Sokol, Mudar, Bottoms, Jacobson et al., 1994; Russell, Martier, Sokol, Mudar, Jacobson, and Jacobson, 1996). Additionally, the CAGE was adapted to assess general substance use (i.e., use of alcohol and/or drugs; Brown & Rounds, 1995) and also drug use (Midanik, Zahnd, & Klein, 1998; Kelly et al., 2001). A positive response to at least one of questions signifies at-risk substance use (Bradley, Kivlahan, Bush, McDonell, & Fihn, 2001).

Midanik and colleagues (1998) modified the CAGE for use as a prenatal drug screener in a racially diverse sample of pregnant women (N = 1147) recruited from non-medical settings (e.g., community organizations and social service agencies). They argued that the open timeframe (i.e., have you ever) limits the CAGE's utility in pregnant women and so they restricted questions to the 12 months prior to pregnancy recognition. This adapted version of the Drug CAGE was validated against self-reported drug use, which was broken down into lighter drugs (i.e., uppers, diet pills, stimulants, tranquilizers, sleeping pills, valium, morphine, other

pain killers, sedatives), heavier drugs (i.e., cocaine/crack, methamphetamine, ice, heroin, methadone, speedballs) and marijuana/hashish, during the same time period. Sensitivity or the proportion of self-reported drug users who screened positive on the CAGE and specificity, the proportion of self-reported non-users who screened negative on the CAGE, of this adapted measure were evaluated. Results indicated very low sensitivity for lighter drugs and marijuana and higher sensitivity for harder drugs. Specificity was high no matter the type of drug used. Thus, for lighter drugs and marijuana, the Drug CAGE does not appear to be an effective screening tool for pregnant women. However, an argument can be made to support the measure's utility in identifying women at risk for heavier drug use. According to ROC analysis, a cut-off of 1 was found to be the optimal score to optimize both sensitivity and specificity. However, when sensitivity is valued over specificity, a cut-point of 3 was recommended to identify harder prenatal drug use.

While this research is informative, Midanik and colleagues' (1998) results must be viewed in consideration of a major limitation: the study relied completely on pregnant women's self-reported drug use to validate the modified CAGE. As previously described, underreporting is common among pregnant women. Thus, it is imperative for future research examining the utility of the drug CAGE as a screening tool for prenatal drug use to employ drug use criterions that are less vulnerable to self-report bias (i.e., biological measures).

DAST. The Drug Abuse Screening Test (Skinner, 1982) is another commonly-used screening tool for problematic drug use. The self-administered questionnaire was developed by adapting items from the Michigan Alcoholism Screening Test (MAST; Selzer, 1971) and exists in three versions (10-, 20- and 28-items). The yes/no items measure consequences of drug use and other factors associated with drug use disorders. The measure in varying forms has been widely used in a number of populations, including individuals with known drug problems

(Gavin, Ross, & Skinner, 1989; Bohn, Babor, & Kranzler, 1991; Kush & Sowers, 1996), psychiatric patients (Staley & El-Guebaly, 1990), union members (El-Bassel, Schilling, Schinke, Orlandi, Wei-Huei, & Back, 1997) and female offenders (Salstone, Halliwell, & Hayslip, 1994).

In a review of the DAST's psychometric properties (Yudko, Lozhkina, & Fouts, 2007), the measure showed good internal consistency (α ranged from .74- .94) and test-retest reliability (r ranged from .71- .85). Evidence was also found to support the criterion and construct validity of the DAST. Additionally, the measure's discriminative validity (i.e., its ability to separate individuals with and without drug use disorders) was examined by comparing scores on the DAST against a criterion measure, either a psychiatric diagnosis of substance abuse or dependence or symptoms of the disorders. Overall, sensitivity and specificity was extremely variable and differed based on the population of interest, version, type of criterion (presence of a diagnosis or symptoms) and cutoff score used (Yudko et al., 2007). Interestingly, the DAST has only been compared to measures based on self-report (e.g., other screening instruments or a structured clinical interview).

The DAST is a face-valid measure: if an individual does not want to be identified with drug problems, then he or she can easily provide responses that are not indicative of a problem. It is not surprising then that the DAST has been found to be negatively correlated with both social desirability ($r = -.38, p < .001$) and denial ($r = -.28, p < .001$; Skinner, 1982). In an employment setting, where negative consequences are possible, a stronger relationship was seen between DAST scores and social desirability ($r = -.47$; El-Bassel et al., 1997). Together, these results question the utility of the DAST with individuals who may be motivated to minimize or conceal drug use (e.g., in the workplace, criminal justice settings). Additional research with the DAST is needed in order to determine its usefulness in populations vulnerable to underreporting.

Drawbacks of the Drug CAGE and DAST. While the CAGE and the DAST have been commonly used, their application to pregnant women is still questionable. First, these measures have only been validated against self-reported criteria. In the study by Midanik and colleagues (1998) the criterion was self-disclosed drug use in the 12 months prior to pregnancy recognition. In the case of the DAST, a diagnosis of drug abuse or dependence, which is primarily based on self-report, was frequently used as the criterion for drug problems (Cocco & Carey, 1998; Maisto, Carey, Carey, Gordon, & Gleason, 2000). In these studies, self-report was validated against self-report. This is problematic given that self-report relies on individuals' accuracy in reporting their own behavior and thus may be biased. Furthermore, the screening tools described above may also be inappropriate for pregnant women given that their purpose is to identify *problematic* drug use (i.e., drug use and associated problems that reach a diagnosable level). During pregnancy, any use of illicit drugs can be considered problematic given the possible negative effects on the fetus. Consequently, a woman's drug use does not need to meet a diagnosable level in order for her to be at-risk and so she may be missed on a screening tool designed to detect problematic use (Anthony et al., 2007).

The 4P's Plus. The 4P's Plus is a short, five-question screening tool administered by prenatal care providers to identify pregnant women in need of additional assessment and/or monitoring of their alcohol, tobacco, and/or illicit drug use (Chasnoff, McGourty, Bailey, Hutchins, Lightfoot, Pawson, et al., 2005). Questions ask women about their parents' and partner's problems with alcohol and/or drugs, use of alcohol in the past and use of alcohol and cigarettes in the month prior to becoming pregnant. A woman is considered to have a "positive" screen if she admits use of alcohol or tobacco in the month before she knew she was pregnant. The 4P's Plus is considered an effective and easy to administer tool to identify women at highest risk of prenatal substance use (Chasnoff et al., 2005).

Direct methods and self-report. The direct screening methods discussed above are face-valid techniques that rely on self-report. Self-report is problematic because it is vulnerable to forgetting. Individuals may inaccurately recall the frequency, duration, and quantity of their drug use (Lester et al., 2001). Additionally, individuals can also easily deny or minimize their drug use if they do not want to be identified. Research has shown that individuals tend to underreport or minimize their substance use (Magura & Kang, 1996). As previously mentioned, this is not only true in the general population, but also among pregnant women (Frank et al., 1988, Ostrea et al., 1992, NIDA, 1996), whose disclosure of use carries significant legal and social implications (Derauf, Katz, & Easa, 2003; Markovic, Ness, Cefilli, Grisso, Stahmer, & Shaw, 2000; Harrison, Haaga, & Richards, 1993).

Translational issues with direct screening methods. While direct screening methods may be useful to a certain degree, there are other issues that impact the utility of direct prenatal drug screening. In addition to self-report bias, providers themselves can be a source of bias. Although ACOG recommends universal screening of all pregnant women, regardless of their social status, educational level, race, or ethnicity (ACOG, 2006), this does not necessarily always occur. Providers may selectively screen women based on their own biases (i.e., they may only ask the women who they think are using drugs during pregnancy). For instance, they may decide to screen on the basis of pregnancy complications, poor pregnancy outcomes or correlates of drug use, instead of screening universally (Weir et al., 1998).

Chasnoff, Landress, and Barrett (1990) examined the rate of illicit drug use among all women seeking prenatal care at five public health clinics ($n = 380$) and 12 private obstetrical offices ($n = 335$) in Pinellas County, Florida, where reporting of known prenatal drug use is mandated by law. Prevalence rates of drug use were compared to providers' post-delivery reports to health authorities of women who used drugs prenatally. The study found that providers were

10 times more likely to report African American women than Caucasian women to authorities even though their rates of drug use were similar. In addition, women of lower socio-economic status were more likely to be reported than women of higher SES. Sadly, similar racial and economic biases were also found in a more recent study of provider decisions to test for illicit prenatal drug use (Veda Kunins, Belline, Chazotte, & Du, 2007). Given these biases, it is not surprising that pregnant African American women and women of lower SES are more likely to underreport their drug use, especially under non-anonymous screening conditions (Chasnoff et al., 1990; Alvik, Haldorsen, & Lindemann, 2005).

In addition to provider bias, additional barriers prevent identification of women at-risk for prenatal drug use. Such obstacles include providers' lack of knowledge and skill of how to screen effectively and intervene with positive screens (Chasnoff et al., 2001; Miller, Ornstein, Nietert, & Anton, 2004), time constraints (Yarnall et al., 2003) and lack of familiarity with resources and referral sources (McLellan, Lewis, O'Brien, & Kleber, 2000; Trude & Soddard, 2003). In addition, providers may be deterred from asking women about their substance use because of the possible legal implications of a positive response or because they feel uncomfortable doing so and fear offending their patients (Anthony et al., 2010; Chasnoff et al., 2001; Chavkin, 1990; Morse, Gehshan, & Hutchins, 1997). Regardless of the reason why health care providers are not universally screening prenatal care patients for substance use, the consequence is the same: women who use illicit drugs prenatally are, for the most part, "missed" at a critical time for intervention.

Indirect methods. Given the limitations of current screening tools, efforts have been made to utilize indirect techniques for identifying substance abuse. Such instruments attempt to circumvent the issue of underreporting by avoiding obvious questions about substance use. Subscales on the Minnesota Multiphasic Personality Inventory- 2 (MMPI-2) and the Substance

Abuse Subtle Screening Inventory (SASSI-3; Miller & Lazowski, 1999) are examples of such indirect measures.

MMPI-2 subscales. The MacAndrew Alcoholism Scale-Revised (MAC-R; MacAndrew, 1965) and the Addiction Potential Scale (APS; Weed, Butcher, McKenna, & Ben-Porath, 1992) are two subtle scales designed to distinguish between individuals with substance use disorders and controls. Both scales were developed by identifying items that differentiated individuals with a known SUD (e.g., inpatients at a chemical-dependency program) from individuals with no SUD (e.g., psychiatric inpatients, individuals from the MMPI-2 normative sample). MMPI items included in these scales do not deal directly with substance use but rather reflect personality dimensions and life situations frequently endorsed by individuals with a SUD. For example, factor analysis of the APS revealed six factors: harmful habits, positive treatment attitudes, forthcoming, hypomania, risk taking, and passivity (Weed, Butcher, & Ben-Porath, 1995). Among treatment-seeking individuals, the APS was found to have poor sensitivity (.46-.64; Rouse, Butcher, & Miller, 1999; Stein, Graham, Ben-Porath, & McNulty, 1999). More recent research using a structured clinical interview as the gold standard found no clinical utility for the APS (Clements & Heintz, 2002). Similar to psychometric studies with direct measures, the “gold standard” was a self-report measure, so self-report was again validated against self-report. An additional limitation of MMPI scales is that development was limited to items already part of the MMPI-2; thus, many possible items of potential utility in predicting drug use among pregnant women (e.g., pregnancy-related variables) could not be considered.

Substance Abuse Subtle Screening Inventory. The Substance Abuse Subtle Screening Inventory (SASSI-3; Miller & Lazowski, 1999) is a 93-item proprietary measure comprised of both indirect and direct items designed to screen for substance dependence. One scale is comprised of 67 true/false items that are both indirect (e.g., “I am rarely at a loss for words”) and

direct (e.g., “I have used alcohol or ‘pot’ too much or too often”). The authors recommend administering this scale first, before the second scale, which is composed of 26 Likert-scaled questions that ask directly about substance use and its negative consequences. The SASSI includes four clinical subscales (Face Valid Alcohol, Face Valid Other Drugs, Obvious Attributes, and Subtle Attributes), two defensiveness subscales (Defensiveness and Supplemental Addiction Measure) and either two or three supplementary subscales (Random Answer Pattern, Corrections, and Family Problems). Scores on the SASSI are interpreted according to decision rules and thus individuals are classified as “high probability of having a substance dependence disorder” if their profile meets criteria for one of the conditions (e.g., above the 84th percentile on any two clinical subscales). Empirical evidence supporting the SASSI is weak. One peer-reviewed study comparing scores on the measure to urinalysis data, found that the measure failed to identify 45% of pregnant women who tested positive for drugs (Horrigan & Piazza, 1999). Further, a recent review of the SASSI’s psychometric properties ($N = 36$ articles) “found no independent empirical evidence that the SASSI is more sensitive or accurate or less susceptible to falsification in screening for SUDs than simpler direct scales [e.g., CAGE, Michigan Alcoholism Screening Test, Alcohol Use Disorders Identification Test] available in the public domain” (Feldstein & Miller, 2007, p. 47). The authors of the review also concluded that it is unclear what the indirect scales are measuring: the indirect items purport to assess correlates of SUDs, although the nature of these traits is not clearly specified and have been found to change with treatment.

Summary of indirect methods. Overall, existing measures that rely on subtle or indirect methods of identification (i.e., the subscales on the MMPI-2 and the SASSI, described above) do not appear to be well-suited for use as a screening tool for pregnant women in prenatal care settings. While an indirect methodology may limit socially desirable responding, clearly

additional research is needed to develop a more time- and cost-efficient screening tool to better detect prenatal drug use.

New direction with an indirect method. In a recently completed project, Drs. Ondersma and Svikis examined indirect drug screening involving validation with objective measures of drug use in a sample of post-partum women at an urban, obstetric hospital in Detroit, Michigan. A checklist of indirect factors associated with drug use disorders, the Wayne Indirect Drug Use Screener (WIDUS; Ondersma et al., 2009) was validated against hair and urine analysis. This corroboration using biological testing was a key methodological advantage over previous efforts to identify an indirect measure.

The WIDUS. The WIDUS is a true/false index of items known to tap correlates of drug abuse and dependence. The creation of this measure reflected Newcomb and Feliz-Ortiz's (1992) epidemiological/cumulative stress and resiliency model which conceptualizes risk as multiply-determined, emphasizing both protective and risk factors. In order to identify correlates of drug use, an extensive literature review was conducted by Dr. Ondersma and his colleagues. The domains sampled from correlational research included the following: (1) behavioral correlates, such as tobacco or alcohol use, emergency room use, gambling, fighting, promiscuity, criminal behavior, and less involvement in school, work, or religious activities; (2) medical correlates, such as chronic illness, sexually transmitted diseases, and dental problems; (3) psychological correlates, including depression, anxiety (particularly those associated with PTSD), neurobehavioral disinhibition in childhood (such as oppositional or conduct disorders), risk taking, sensation-seeking, and attitudes/expectancies consistent with drug use; (4) experiential correlates, such as having experienced trauma, childhood abuse, automobile accidents, blackouts, running away as a youth, time in foster care or group homes, interpersonal victimization, violence exposure, and poor parental bonding; and (5) demographic correlates, including being

younger, unemployed, unmarried, or a recipient of some form of public assistance. For a more complete list of correlates and their references, please see Appendix A. Protective factors in all of these areas, such as law abidance, religious involvement, self-acceptance, and positive relationships with parents (Newcomb & Felix-Ortiz, 1992), were also included along with risk factors in order to provide a more complete picture of overall risk.

Items reflecting each drug use correlate and protective factor were generated and combined to form an initial item pool. A panel of experts, Dr. David Streiner, a statistician and psychometrician, Dr. Ralph Tarter, creator of the Drug Use Screening Inventory (DUSI) and Dr. Charles R. Schuster, a senior drug abuse researcher, reviewed the items. Following expert review, a small sample of post-partum women ($N = 10$), who had recently delivered at Hutzel Women's Hospital in Detroit, Michigan, rated the initial item pool on the clarity, interpretation, and acceptability of each item. After incorporating this feedback into a finalized version, the 127-item measure was administered via an audio-enhanced computer-assisted self-interview (A-CASI) software program to a sample of 400 post-partum women recruited from their post-delivery hospital rooms. The software relied on a three-dimensional cartoon character, Peedy the parrot, to provide instructions and guide the participant through the questionnaire. Following completion of the WIDUS, hair and urine samples were collected. Data analysis identified a subsample of seven items that best predicted drug use (i.e., positive by urine and/or hair testing). These items are presented in Table 1.

Table 1

<i>WIDUS Items</i>	
#	Item
1	I am currently married
2	In the past year, I have been bothered by pain in my teeth or mouth
3	I have smoked 100 cigarettes in my entire life
4	There have been times in my life, for at least two weeks straight, where I felt like everything was an effort
5	Most of my friends smoke cigarettes
6	I get mad easily and feel a need to off some steam
7	I often have trouble sleeping

Dr. Ondersma’s study also involved an additional component that addresses what to do when women screen positive on the WIDUS. Women who screen positive on an indirect screener cannot be viewed as known drug users. Consequently, traditional methods of intervention would not apply. Dr. Ondersma and his colleagues developed an indirect, brief intervention software program designed to promote self-change or treatment-seeking among women who screen positive. The intervention is a single, 20-minute session that addresses substance use indirectly within topics of emotional health, healthy lifestyle and safety in and around the home. Therefore, the intervention is still relevant to women who are falsely identified as drug users by the WIDUS (i.e., false positives).

Overall, the development and validation of the WIDUS represents a significant effort to improve the identification prenatal drug use. Most importantly, this screening tool was developed and validated against non-self-report measures of drug use (i.e., urine and hair assays), unlike other commonly-used screeners which were validated against self-report. This measure was also developed within the context of anonymity and using ACASI technology, both of which have been shown to reduce underreporting (Durant, Carey, & Schroder, 2002; Newman et al., 2002). Finally, the WIDUS is an innocuous, indirect measure of drug use and thus likely to minimize the amount of underreporting present with direct screening tools.

Current Study

The purpose of the current study was to develop and validate an indirect measure of drug use that can identify pregnant women who have a history of recent drug use, regardless of their willingness to disclose such use. The study built upon the work of Drs. Ondersma and Svikis in order to examine what indirect items best predicted drug use in this sample of pregnant women. Specifically, four questions were asked to guide this research:

- 1) Are women in this population underreporting the incidence of prenatal drug use? If so, what is the extent of the discrepancy between self-report and UDS?
- 2) Do pregnancy-related variables contribute additional predictive validity to an existing indirect drug screening tool developed with postpartum women (i.e., the WIDUS)?
- 3) Considering both prenatal and general drug use correlates, which items best predict recent drug use in this sample of pregnant women?
- 4) How well do direct measures of drug use predict prenatal drug use (i.e., positive UDS) compared to indirect measures?

Based on past research, the following hypotheses were made: Hypothesis 1) pregnant women will underreport recent drug use (i.e., prevalence rates of drug use will be higher according to urinalysis than direct self-report); Hypothesis 2) indirect screening tools will be a better predictor of recent drug use according to urine toxicology results than direct screening methods.

Method

Participants

Participants were 231 pregnant women attending a return prenatal appointment at the VCUHS Women's Health Clinic. Demographic characteristics for the sample are summarized in Table 2. Specifically, the sample was primarily African American (66%), single (75%) and 25

years of age or younger (61%; ages 18-25). The mean estimated gestational age (EGA) for the fetus, at time of assessment was 26.4 weeks (SD = 9.0), which is the beginning of the third trimester. Additional pregnancy-related statistics are presented in Table 3.

Table 2

Demographic characteristics N = 231

Variable	n	%
Age (years)		
18 - 21	73	32
22 - 25	67	29
26 - 29	43	19
30 - 33	32	14
34 - 37	12	5
≥ 38	4	2
Race/Ethnicity		
Black or African American	152	66
White	55	24
More than one race	12	5
American Indian or Alaska Native	8	3
Hispanic or Latino	4	2
Marital status		
Married	59	25
Education		
Completed high school or received GED	181	78
Employment		
Working 20 hours or more per week	83	36
Insurance/Support		
Have health insurance through an employer	80	35
Receive some form of public assistance	162	70
Relationship status		
None	42	18
Yes, with the FoB	183	80
Yes, but not with the FoB	5	2
Contact with FoB		
Yes, current	215	94
In the past only	15	6
Do not know FoB well	0	0

Note. FoB = Father of my baby.

Table 3

Pregnancy characteristics N = 231

Variables	Mean (SD) or <i>n</i>	Range or %
EGA (weeks)	26.35 (9.0)	2, 40
EGA at pregnancy recognition ^a	6.48 (4.2)	1, 31
EGA at first OB appointment	9.42 (4.8)	1, 27
Parity		
Primigravida	67	29
Total pregnancies (including current)	2.73 (1.9)	1, 8
Live births	1.56 (1.5)	0, 8
Pregnancy intention		
Wanted to be pregnant sooner	33	14
Wanted to be pregnant then	52	23
Wanted to be pregnant later	83	36
Did not want to be pregnant then or in future	37	16
Do not know	25	11

Note. EGA = Estimated gestational age.

^aHow many weeks pregnant were you when you first thought you might be pregnant?

Inclusion Criteria: To be eligible for the study, women had to be: at least 18 year of age, pregnant, and able to understand spoken English. In addition, women had to have completed at least one prenatal visit in the VCUHS OB clinic prior to study enrollment in order to exclude women who used drugs without knowledge of their pregnancy.

Exclusion Criteria: Women who were unable to provide informed consent due to cognitive impairment or a major psychiatric illness were ineligible for the study.

Sampling Procedures

Participants were recruited from the VCUHS Women's Health Clinic, which provides a wide variety of obstetric and gynecological services for women in the greater Richmond, Virginia area. Approximately 90 new obstetric patients are seen in the prenatal care clinics each month. Women were approached while waiting for their OB appointment in the clinic waiting room and screened for eligibility (please see Appendix B for Recruitment Script). If a woman was eligible, she was given a brief explanation of the two-phase project and potential to earn \$40

in gift cards. Study procedures were approved by the VCU Institutional Review Board (protocol number HM12365) and the NIH NIDA Ethics Committee.

Materials

All study questionnaires, including the WIDUS-P development version, were administered via computer as opposed to paper-and-pencil or face-to-face interview methods. Women used headphones to hear each item and the various response options were read aloud as they appeared on the computer screen. The computerized test battery measures are described below in the order that they were administered. Order of administration was important for the generalizability of results and thus the indirect items of drug use had to be completed prior to the more direct measures of prenatal drug use risk.

Wayne Indirect Drug Use Screener- Pregnancy (WIDUS-P). The WIDUS-P development version (please see Appendix C), consists of 86 items and contains 64 of the 127 items from the development version of the WIDUS. Items from the WIDUS were selected for one of two reasons. Forty of the items were chosen because of their superior performance on selection criteria (e.g., endorsement rates, reading level, association with drug use, participant and expert ratings) in Dr. Ondersma's analyses of 400 postpartum women. The item, "I smoked at least one cigarette during the last month of my pregnancy," which was a top 40 item, was changed to "I smoked at least one cigarette the week before I learned I was pregnant" in order to make it applicable to a pregnant sample. Due to the difference in the nature of the samples (i.e., the WIDUS was developed using a sample of post-partum women whereas the current study will recruit pregnant women), additional items (i.e., 24 from the development version of the WIDUS) were added to capture domains potentially relevant to a sample of pregnant women. In addition, based on a review of the literature focused on correlates of drug use during pregnancy (see section above), additional items were generated to include correlates not already addressed in the

top 40 WIDUS items or the additional 24 items retained from the WIDUS development version. Additional items included general pregnancy-related questions, such as estimated gestational age at first prenatal visit, pregnancy intention (i.e., intended, unwanted, mistimed, or ambivalent; Mohllajee, Curtis, Morrow, & Marchbanks, 2007), and types of maternal loss experienced (i.e., died during birth/stillborn, abortion, death during the first 4 months of pregnancy, death after the first 4 months of pregnancy).

Drs. Ondersma and Svikis subsequently evaluated each item for its clarity and usefulness in identifying drug-using pregnant women within the VCUHS OB/Gyn clinic. Considerations were also made to ensure that items appropriately sampled relevant domains (e.g., exposure to violence was assessed using several items, rather than a single item), yet did not contribute unnecessarily to the length of the measure.

Drug CAGE. The drug CAGE is a 4-item measure that asks questions about four problem domains: annoyance, cutting down, guilt, and eye-opener use. A “yes” response to one or more items was used to categorize participants as drug-positive according to this measure (Bradley et al., 2001).

Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST; WHO ASSIST Working Group, 2002). The ASSIST was developed to detect substance use in primary and general medical settings. In Dr. Ondersma’s original WIDUS development study, the first two items of the ASSIST were included in the measure to screen for drug use in the most direct and parsimonious way possible. These same items were also included in the present study, as they ask whether participants have ever used marijuana, cocaine, opiates, or amphetamines in their lifetime as well as during three months prior to pregnancy recognition. The present study also added a third question which asked specifically about recent (last month) drug use via self-report.

Drug Abuse Screening Test (DAST-10; Bohn et al., 1991). The DAST is a widely-used, self-report questionnaire that measures consequences of drug use and other factors associated with drug use disorders. The cut-off score for the 10-item version is 3 (Skinner, 1982). The psychometric properties of the DAST have been supported in a number of studies (Yudko et al., 2007); however, as previously mentioned, the DAST's utility as a screening tool in populations vulnerable to social desirability and denial (Skinner, 1982; El-Bassel et al., 1997) is of concern. Dr. Harvey Skinner provided his permission for use of the DAST in the present research study.

Urine drug screening (UDS). Urine samples were obtained from all participants who agreed to participate in Phase 2 of data collection. Cups with embedded test strips on the cap (i.e., Reditest[®] RediCup[®] drug screen, 10 panel), were purchased from Redwood Toxicology Laboratory, a federally-certified supplier. Screens were performed by the main investigator and trained research assistants and provided only qualitative data (i.e., positive or negative) on methamphetamine, cocaine, marijuana, benzodiazepines, methadone, barbiturates, MDMA (ecstasy), opiates, PCP, and oxycodone use. With the exception of marijuana, urinalysis provides a window of detection between 24 and 48 hours. Detection of marijuana varies according to the extent of use; however detection can range from two to 14 days. For the gold standard criterion of drug use (i.e., urinalysis drug assay), a participant's drug status was considered "drug positive" if she screened positive for methamphetamines, cocaine, marijuana, barbiturates, MDMA and/or PCP. While evidence of benzodiazepine, methadone, opiate and/or oxycodone use via urinalysis drug testing might also demonstrate prenatal drug use, these categories of drug were not considered in the construction of the primary drug use variable because the positive screen could be the result of prescription (i.e., licit) use of these substances.

Design and Procedures

The primary goal of the study was measurement development and validation. A critical design component of this research, intended to protect the validity of findings, was that participation was completely anonymous. Participants were not required to provide their name or other identifying information to participate in the study (i.e., they were not required to sign a consent form). Such anonymity was important as it may have minimized the fear of negative consequences and stigma associated with self-reporting drug use or providing a positive urine sample. Consequently, anonymity may have encouraged greater rates of participation and more accurate responses on both indirect items and direct measures of drug use.

Another important design consideration involved the use of sequential informed consent to protect the generalizability of the WIDUS-P. Generalizability depends on how closely future clinical applications of the WIDUS for pregnant women can be replicated. This meant that participants must not have initially known that they would be asked for permission to drug test their urine. If women were aware of the possibility of drug screening while answering questions, they may have responded differently than if they had no knowledge of the potential to be tested. In this situation, altered responding would have limited the use of the WIDUS in settings where drug does not routinely occur (e.g., prenatal care clinics). Therefore, a two phase consent procedure allowed for initial withholding of information necessary for valid measure development. Participants completed Phase 1, which involved completion of the computerized battery, before they learned about the existence of Phase 2 (collection of a urine sample). This procedure was critical to preserve the external validity of the WIDUS-P.

Phase 1 procedures. Phase 1 concerned the administration of the computerized battery. Due to issues of validity previously mentioned, information about urine drug testing was withheld until after the participant completed the computerized battery. When a woman

expressed interest in the study, she was asked to come to the research space adjacent to the 6th floor Women's Health clinic after her prenatal appointment. Once she arrived there, a research staff member informed her of study details (please see Appendix D, "Information Sheet #1"), including what kinds of questions will be asked, her rights as a participant, the anonymous and voluntary nature of the project (i.e., she will not be asked to give her name), her compensation for completing phase 1 of a \$20 gift card, and that phase 2 will be described to her after she has completed phase 1. Participants were assured that their information would not be shared with clinic staff. After the woman provided verbal consent to participate, the researcher introduced her to the tablet PC, instructed her to put on headphones, and begin the computer program. Headphones were used in order to protect participants' privacy and to circumvent issues of literacy. The computer program, via an animated character (i.e., Peedy the parrot), instructed the participant how to use the computer and answer questions, and then introduced the questionnaire. Previous research utilizing this software and animated character has shown that women (N = +1000) found it easy to use and likeable (e.g., Ondersma, Chase, Svikis, & Schuster, 2005). Once the participant answered all computer questions, the program prompted the participant to tell the researcher she was finished. The researcher then entered an identification number for the participant so that the data could be linked to her urinalysis results. After the computerized assessment was complete, the research assistant gave the participant a \$20 gift card. Total administration time for phase 1 was 20-25 minutes.

Phase 2 procedures. After providing compensation for phase 1, the researcher described phase 2 to the participant (please see Appendix E "Information Sheet #2"). She was told that the second phase involved unsupervised collection of a urine sample and that she would be compensated with a second \$20 gift card. If the woman agreed to participate, the researcher took the participant to the public restroom located in the adjacent hallway, informed her that a urine

cup was located in the metal cabinet behind the door and instructed her to place the cup back in the cabinet once she provided the sample. After the participant left the restroom, the researcher gave her another \$20 gift card and an information sheet (see Appendix F “Information Sheet #3”) that debriefed her on why Phase 1 and 2 were conducted separately and thanked her for participating. Once she left, the staff member entered the research office adjacent to the bathroom, retrieved the urine sample from the cabinet and assayed the sample for drugs using the test cup. Test results were recorded, along with the participant’s identification number, and then the test strip was wrapped in paper towel and disposed of in a waste basket.

Data Analysis Plan

In order to maintain consistency with procedures used to develop the original WIDUS and to allow for comparison, the present study used data analytic procedures similar to those employed in Dr. Ondersma’s R21 NIDA grant. Specifically, this included randomly dividing the sample into a training sample ($n = 131$) and a validation sample ($n = 100$) in order to develop and validate indirect measures. In addition, a similar multi-step strategy (described below) was used to reduce the initial item pool and evaluate the predictive validity of these indirect measures.

Research question 1. The first research question asked whether women in this sample minimized or denied prenatal drug use and if so, to what extent did self-report differ from UDS results. Hypothesis 1 predicted that rates of drug use by urinalysis drug assay would be greater than rates by self-report. To test this hypothesis, rates of self-reported past month drug use and positive drug status were compared.

Research question 2. The second research question asked whether pregnancy variables contributed additional predictive validity to the WIDUS. Forty-five pregnancy items were evaluated. The item, “how many weeks pregnant are you” was used as demographic data. To address this question, we reduced the number of variables predictive of positive drug status using

a three-step process with the training sample ($n=131$). This process included removing items based on:

- 1) ***Exclusionary criteria.*** Frequencies of positive endorsement and Flesch-Kincaid ratings of reading grade level were determined for each item. Items were removed based on poor endorsement (i.e., endorsement less than 10%) and high reading levels (i.e., Flesch-Kincaid rating higher than a 9th grade reading level).
- 2) ***Univariate relationship with drug status.*** Each remaining variable's univariate association with urine toxicology results was then examined by performing a chi-square test for independence. A total of 13 variables (12 items with the largest chi-square value plus the plus the total score for the original WIDUS) were chosen for inclusion in the next step based on the recommended 10:1 events per variable ratio in logistic regression analysis (Peduzzi, Concato, Kemper, Holfond, & Feinstein, 1996) and given the training sample size of 131.
- 3) ***Multivariate relationship with drug status.*** In this step, hierarchical logistical regression was used to examine the multivariate relationship between these 12 variables and drug status, above and beyond the WIDUS. Participants' drug status was entered as the criterion variable, the WIDUS was entered at block 1 and the 12 pregnancy variables were entered at block 2. Subsequent hierarchical logistical regressions were performed to determine the final item(s) to be included.

Following this process, ROC curve analyses were conducted to determine the predictive validity of adding the pregnancy item(s) identified in step three to the WIDUS. A ROC curve plots the rate of true positives (sensitivity) against the false positive rate (1- specificity) for different possible cutoff scores of a test. The more closely the curve follows the left-hand and top borders, the more accurate the measure. Area under the curve (AUC) is the likelihood that any given

positive case will score higher than a given negative case on the screening tool and is commonly used as a summary measure of classification accuracy. An AUC of .50 signifies that the screening tool is accurately classifying positive cases at a rate equivalent to chance (Swets, 1988). Sensitivity (the percentage of women with a positive urine screen who are also identified as at-risk by the screener) and specificity (the percentage of women with a negative urine screen who are also identified as not at-risk by the screener) for this new measure were calculated. Given the primary goal of this measure was to identify women who used drugs during pregnancy, sensitivity was valued over specificity in determining a cut-off score. Sensitivity was also prioritized because of the small consequences of false positives; it is be more desirable for a non-drug using woman to screen positive and receive intervention than for a drug-using woman to screen negatively and miss intervention. Positive predictive value (i.e., the percentage of women who are positive on the screener who also have a positive toxicology screen), negative predictive value (i.e., the percentage of women who are negative on the screener who also have a negative toxicology screen) and percent correctly classified were also calculated for the measure at the optimal cut-off score.

Cross-validation. The addition of the pregnancy item(s) to the WIDUS was cross-validated in the validation sample ($n=100$) using hierarchical logistic regression, ROC curve analysis, and other statistics (positive predictive value, negative predictive value, and classification accuracy).

Research question 3. The third research question asked which indirect items, including both general and pregnancy variables, best predicted recent drug use. Three demographic items (i.e., age, ethnic background and EGA) were not included, reducing the total number of indirect items evaluated to 83. To determine which items should be included in the pregnancy screener (i.e., the Wayne Indirect Drug Use Screener- Pregnancy; WIDUS-P), the same three-step

procedure used in question 2 was applied to data from the training sample and used to reduce the number of items to a 4-7 item measure. This process included removing items based on:

- 1) ***Exclusionary criteria.*** Frequencies of positive endorsement and Flesch-Kincaid ratings of reading grade level were calculated for each item. Items were removed based on poor endorsement (i.e., endorsement less than 10%), high reading levels (i.e., Flesch-Kincaid rating higher than a 9th grade reading level), highly stigmatizing content (e.g., abuse, violence, involvement with police) and direct alcohol and illicit drug content (e.g., family history of drug or alcohol problems, marijuana use by friends or partner).
- 2) ***Univariate relationship with drug status.*** Chi-square tests of independence were calculated for all remaining variables to evaluate their univariate association with urine toxicology results. Thirteen variables were chosen for inclusion in the next step based on previously mentioned N:k ratio recommendation.
- 3) ***Multivariate relationship with drug status.*** In Step 3, we performed a series of logistic regression analyses to assess each of the 13 variables' multivariate association with drug status in order to further reduce the item count. In the first logistic regression, items with a *p*-value greater than .5 were eliminated. Additional logistic regression analyses were performed to remove items with lower odds ratios and higher levels of significance. The primary consideration in retaining items was the size of their association with drug status, rather than significance. The remaining items were combined to form the WIDUS-P.

ROC curve analysis was conducted to determine the predictive validity of the WIDUS-P and an optimal cut-off score. PPV, NPV and percent correctly classified were also calculated for the determined cut-off score.

Cross validation. The WIDUS-P was then cross-validated on the validation sample ($n=100$) using logistic regression and ROC curve analyses. Other statistics of predictive validity (PVV, NPV and classification accuracy) were also calculated. To supplement these cross-validation analyses, we selected five random samples of 100 participants (among the total sample, $N=231$) and calculated AUC, sensitivity, specificity, PPV, NPV and classification accuracy to further examine the validity of the WIDUS-P.

Finally, we performed two hierarchical logistic regression analyses in order to compare the WIDUS-P to the WIDUS. For both analyses, participants' drug status was entered as the criterion variable. For the first analysis, the WIDUS was entered at block 1 and the WIDUS-P was entered at block 2. The reverse was entered for the second logistic regression analysis.

Research question 4. Given the frequent use of direct screening tools to identify at-risk drug use, the fourth research question examined the predictive validity of these methods compared to that of indirect methods (i.e., the WIDUS, WIDUS-P and the additional indirect measure adapted in questions two). The second hypothesis predicted that indirect screening tools would be a better predictor of recent drug use than direct screening methods. To evaluate this hypothesis, sensitivity for each direct screening method (i.e., the DAST, Drug CAGE, and single questions of lifetime, pre-pregnancy and past month drug use) was calculated and compared to the sensitivity of indirect methods. Specificity, PPV, NPV and classification accuracy were also determined for all methods to provide additional comparison.

Results

Recruitment

Study recruitment took place between May 28, 2010 and May 31, 2011. While it is likely that women were screened eligible on multiple occasions (due to attending multiple OB visits during the recruitment period) and thus this number is likely an overestimation, 1571 women

were eligible for study participation. Of these women, $N=245$ (16%) pregnant women provided informed consent and completed Phase 1 (computerized assessment). Of these, $N=231$ (94%) also completed Phase 2 (provided urine sample for drug assay). For the $n=14$ women who began phase 1, reasons given for not continuing study participation included: not having enough time ($n = 6$), not being able to urinate ($n = 4$) and being too tired ($n = 1$). An additional three women did not provide an explanation for their decision. One woman provided consent but did not provide any data, thus only 13 women completed phase 1. Descriptive data from these non-completers (i.e., completed phase 1 only) are presented in Table 4 as a comparison to data from participants who completed both phases of the study (i.e., participants who also provided a urine sample). None of the non-completers self-reported recent (i.e., past month) drug use, compared to 5% of study completers (11 of 231 women).

Recoding of Variables

Several variables were re-coded or computed prior to data analysis to adjust for their association with drug status. A value of “1” was assigned to the response consistent with the variable’s predicted direction of association with drug use. For the item concerning pregnancy intention, responses of “I wanted to be pregnant later,” “I didn’t want to be pregnant then or at any time in the future,” and “I don’t know” (i.e., unintended pregnancy) were coded as “1” and responses of “I wanted to be pregnant sooner” and “I wanted to be pregnant then” (i.e., intended pregnancy) were coded as “0”. Relationship status was re-coded so that “I am not in a relationship” signified “1.” Although the item regarding amount of contact with the father of the baby was originally categorical, with three response options, one response (“I don’t know the father of this baby that well”) was never endorsed. Instead, the variable was re-coded into current contact (coded “0”) and past contact only (coded “1”). In addition, continuous variables concerning prenatal characteristics were dichotomized according to cut-offs identified by quartile

frequencies and the variable's hypothesized relationship with drug status. For instance, the item, "how many weeks pregnant were you when you first thought you might be pregnant," was coded positive if the participant responded 4 or more weeks (82% of the sample). The items concerning number of weeks pregnant at first OB appointment (6 weeks or more coded as "1"; 83% of sample endorsed this response) and number of pregnancies (multigravida coded as "1"; 71% of the sample endorsed this response) were also dichotomized. Finally, several variables were reverse-coded to account for their direction of association with drug status. For example, being unmarried has been shown to be significantly associated with prenatal drug use (El Marroun et al., 2008) so the item, "I am currently married," was reverse-scored. Other recoded items were "I graduated from high school or completed my GED," "I am currently working 20 hours or more per week," "I currently have health insurance through an employer," "I almost always use condoms during sex," and "I am currently in a relationship."

Item Endorsement

Rates of positive endorsement for indirect items ranged from 2% to 72%. Table 3 presents the rate of positive endorsement for each dichotomous item in the full sample ($N = 231$) in order from most to least commonly endorsed. Frequencies for the reverse-coded items (symbolized with an asterisk in Table 4), rather than for the original item, are presented in this table (e.g., 65% of participants do not currently have health insurance through an employer). Categorical and continuous pregnancy variables were previously described in Tables 2 and 3, respectively.

Table 4

WIDUS-P Item Responses

#	Type	Item	% Yes	
			N= 231	n =13 ^a
11	G	I often eat fast food and/or junk food	72	70
7	P	I currently receive some form of public assistance, such as food stamps, WIC, Medicaid, SSI or TANF	70	62
6	G	*I currently have health insurance through an employer, either mine or a family member's	65	62
10	P	*I almost always use condoms during sex	65	62
5	G	*I am currently working less than 20 hrs per week	64	54
12	G	I have been treated at an emergency room in the past year	63	54
54	G	I get bored easily	63	54
21	G	Most of my friends think marijuana is no big deal	62	54
58	G	At least one person in my immediate family (parent, brother, or sister) has had problems with depression	59	62
22	P	I have at least one caffeinate beverage (for example, caffeinated soda, coffee, or energy drink) every day	58	69
34	G	There have been times in my life, for at least two weeks straight, where it felt like everything was an effort	57	69
61	G	I am easily upset about things	52	23
8	P	At least once in my life, I have been diagnosed with a STD, such as gonorrhea, Chlamydia, Herpes, syphilis, HIV, or any other STI	51	70
19	G	Most of my friends smoke cigarettes	49	46
33	P	There have been times in my life, for at least two weeks straight, where I felt so down or depressed that nothing could cheer me up	49	39
46	P	It's hard to get places because of transportation	48	39
47	P	In the past 12 months, I've worried about my housing situation	48	15
64	P	Over the past month, I have felt down, depressed, or helpless	48	23
16	G	I was a daily smoker during the year before I learned I was pregnant	47	39
20	G	At least two of my closest friends use marijuana	47	39
37	P	One or more of my biological parents have had a problem with drugs or alcohol	47	54
41	P	In my lifetime, I have been hit, slapped, kicked or otherwise physically hurt by someone	47	23
85	P	The father of this baby currently smokes cigarettes	47	39
15	G	I have smoked at least 100 cigarettes in my entire life	46	46
18	G	I'm often around second hand cigarette smoke	46	31
32	G	There have been times in my life, for at least two weeks straight, where I felt completely hopeless about things	45	46
14	G	In the past year, I have been bothered by pain in my teeth or mouth	44	31
51	G	I get mad easily and feel a need to blow off some steam	44	23
17	G	I smoked at least one cigarette the week before I learned I was pregnant	43	46
65	G	Drugs are everywhere in my neighborhood	43	31

31	G	There have been times in my life, for at least two weeks straight, where I felt completely worthless	39	31
53	G	I feel overwhelmed by my life and my problems	38	15
57	G	I experience “flashbacks” of bad things that have happened to me	38	31
86	P	The father of this baby thinks marijuana is no big deal	36	39
36	G	As an adult, I have seen somebody get stabbed, shot, or seriously beaten	35	23
66	G	I often have trouble sleeping (not counting during pregnancy)	34	31
67	P	I feel very overwhelmed when thinking about taking care of a new baby	34	31
68	P	I have repeated and disturbing memories of a stressful thing that happened to me	33	31
69	G	I lose my temper very easily	33	23
63	G	I have seen or experienced worse things than most other people have	31	15
24	P	When I was a child, I saw someone get stabbed, shot, or seriously beaten	30	15
23	P	When I was a child, I saw adults in my home physically hurting each other	28	23
42	P	There have been times in my life I have not felt safe around my current partner or past partner	28	8
50	G	Things have usually gone against me in life	28	8
38	G	One or more of my brothers or sisters has had a problem with drugs or alcohol	27	31
60	G	In elementary school, I often got into trouble with teachers or the principal because of my behavior (fighting, talking in class, or coming to class late)	27	8
39	G	I have been abandoned by someone I love more than most people have	26	15
3	G	*I am currently married	25	8
25	P	When I was a child, an adult hit me hard enough to cause bleeding, bruises, or welts	25	8
40	G	I have been in trouble with the police	25	8
26	P	When I was a child, an adult touched my private parts in a sexual manner, or got me to touch their private parts in a sexual manner	24	8
48	P	I often move from place to place	23	0
80	P	Have you ever had a pregnancy that ended during the first 4 months (not including an abortion)?	23	15
4	G	*I graduated from high school or completed my GED	22	15
13	G	I have missing teeth	22	23
45	P	In the past year, I’ve gone hungry because I didn’t have enough money to buy food	22	0
82	P	Have you ever had an abortion?	22	23
30	P	Since my sixteenth birthday, I have been injured in an assault or fight (not counting during sports)	21	15
71	G	I often feel empty inside	21	0
49	P	In the past year, the police have been called to my home because of	20	0

		a fight or argument		
27	P	When I was a child, I saw people using drugs in my home	19	8
43	P	Within the last year, I have been hit, slapped, kicked or otherwise physically hurt by someone	19	8
52	P	Some of my immediate family members are pretty violent	17	0
72	P	In the past, I have attempted to hurt myself	17	23
70	P	In the past, I have told someone I was going to hurt myself	16	31
55	G	I live life on the edge	14	8
28	P	Since my sixteenth birthday, I have had fractures or dislocations to my bones or joints	12	8
35	G	As an adult, I have been badly beaten up at least once	12	8
62	G	When I was younger than 13 years old, I often stayed out past midnight	11	0
56	P	I have conflict with people in authority, like teachers, supervisors, and the police	10	0
44	P	During my current pregnancy, I have been hit, slapped, kicked or otherwise physically hurt by someone	8	8
81	P	Have you ever had a pregnancy that ended after 4 months but before birth?	8	8
79	P	Have you ever had a baby that died during birth or was stillborn?	7	8
84	P	Current contact with father of this baby	7	0
59	P	I sometimes do really harmful things to myself	5	0
29	P	Since my sixteenth birthday, I have injured my head	4	0
9	P	I have been diagnosed with Hepatitis C	2	0

Note. * = Item was changed from original item to reflect reverse-coding; G = general item. P = pregnancy item. Item responses were true/false or yes/no.

^a13 women consented for study participation but did not complete phase 2.

Prenatal Drug Use

Prevalence of drug use. Rates of drug use varied by type of report (i.e., self-report versus urine drug screening) and time frame. Urinalysis documented higher rates of recent drug use than self-report. Forty-three participants (19%) tested positive for at least one drug. When drugs that could have been consumed with a prescription (i.e., benzodiazepines, methadone, opiates and oxycodone) were excluded from analyses, the rate decreased to 16% ($n = 36$). Note, this prevalence rate and not the abovementioned rate is used to describe recent drug use by UDS for the remainder of the study. Among self-reported drug use, prevalence of lifetime drug use was the highest (39%, $n = 90$), followed by use during the 3 months prior to pregnancy (20%, $n = 46$) and lastly, past month drug use (5%, $n = 11$). Interestingly, in response to question #1 on

the DAST, only 19% ($n = 43$) of participants reported using drugs “other than those required for medical reasons” in the past 12 months. This difference highlights the inconsistency in self-reported drug use: 20% reported using in the three months prior to pregnancy, but only 19% reported using in the past year.

Type of drug use. The most commonly used drug, according to urinalysis, was marijuana. Among the total sample, 15% ($n = 34$) of participants tested positive for marijuana. A much smaller percentage tested positive for methadone (1.7%, $n = 4$), opiates (1.7%, $n = 4$), oxycodone (1.3%, $n = 3$), cocaine (0.9%, $n = 2$), methamphetamines (0.4%; $n = 1$), and barbiturates (0.4%, $n = 1$). Benzodiazepines, MDMA, and PCP were not recently used by pregnant women in this sample. Table 5 describes the type of drug use by participants coded as “drug positive.” Most drug-using women tested positive for marijuana only (89%).

Table 5

Type of Drug Use among “Drug Positive” Participants, $n = 36$

Type	<i>n</i>
Marijuana	32
Marijuana and cocaine	1
Marijuana and methamphetamine	1
Cocaine	1
Barbiturates	1

Research question 1: Self-reported drug use versus UDS.

In support of Hypothesis 1, the rate of drug use by urinalysis (16%, $n = 36$) was three times higher than the rate by self-report (5%, $n = 11$). Two-thirds of the women who tested positive (67%, $n = 15$) denied using in the past month.

Research Question 2: Predictive Validity of Pregnancy Variables

Step 1: Exclusionary criteria. Fifteen items were removed for under endorsement (i.e., < 10%) and high reading levels (i.e., if they required a 9th grade reading level or higher according to Flesch-Kincaid ratings), reducing the item count to 30. In addition, the item, “How many of

these pregnancies ended in the birth of a live baby” was removed because it was dependent on a previous item and could be not evaluated independently.

Step 2: Univariate relationship with drug status. The twelve items with the largest chi-square value were retained (values ranged from 2.93 to 10.27).

Step 3: Multivariate relationship with drug status. Of the 12 variables entered into the hierarchical logistic regression in block 2 (block 1 = WIDUS), three items with the lowest p-value ($p < .35$) and highest odds ratio ($\text{Exp}(B) > 2$) were retained: abortion ($\text{Exp}(B) = 3.38, p = .046$), assistance ($\text{Exp}(B) = 2.939, p = .23$) and housing ($\text{Exp}(B) = 2.08, p = .31$). Hierarchical logistic regression was repeated with only the abortion, assistance and housing items entered at block 2. Table 6 presents the odds ratios and significance of each predictor in this model and shows that the abortion variable was the only one to retain significance. The addition of these variables at block 2 was statistically significant, $\chi^2(3) = 10.61, p = .014$, and increased the rate of correction classification from 77% to 83%.

Table 6

Summary of Hierarchical Logistic Regression Analysis for WIDUS + Pregnancy Variables Block 2 (N = 131)

Variable	Sig.	OR	95% CI
WIDUS	.02	1.55	[1.06, 2.28]
Abortion	.02	3.40	[1.17, 9.84]
Housing	.14	2.44	[.75, 7.99]
Assistance	.17	3.11	[.62, 15.67]

Note. Sig. = p-value; OR = odds ratio; CI = confidence interval; Abortion = Have you ever had an abortion; Assistance = I currently receive some form of public assistance, such as food stamps, WIC, Medicaid, SSI, or TANF; Housing = In the past 12 months, I’ve worried about my housing situation.

Next, we examined the addition of the abortion item to the WIDUS. In a hierarchical logistic regression analysis, the WIDUS was entered at block 1 and the abortion item was entered at block 2. Odds ratios for the WIDUS and abortion item are reported in Table 7. The abortion item added significant additional variance to the WIDUS, $\chi^2(3) = 6.06, p = .01$. The effect size of

adding abortion to the WIDUS was small, with Cox and Snell R-square = .15 and Nagelkerke R-square = .24.

Table 7

Summary of Hierarchical Logistic Regression Analysis for WIDUS + Abortion Block 2 (N = 131)

Variable	Sig.	OR	95% CI
WIDUS	<.001	1.91	[1.35, 2.69]
Abortion	.014	3.75	[1.31, 10.71]

Note. Sig. = p-value; OR = odds ratio; CI = confidence interval; Abortion = Have you ever had an abortion.

The ROC curve for the WIDUS+abortion showed an AUC of .77 (standard error = .045, $p < .001$, 95% CI = .68, .85), indicating that there is a 77% likelihood that a randomly selected woman with a positive UDS will have a higher WIDUS+abortion score than a randomly selected woman with a negative UDS. This is a slight improvement in classification accuracy from the WIDUS (AUC = .74, standard error = .05, $p < .001$, 95% CI = .65, .84). ROC curve analysis indicated that a cut-off score of 4 optimized sensitivity (.81). Specificity was .57. At this cutoff score, the measure's positive predictive value (i.e., the percentage of women who are positive on the WIDUS+abortion who also have a positive toxicology screen) was .32 and negative predictive value (i.e., the percentage of women who are negative on the WIDUS+abortion who also have a negative toxicology screen) was .92. Overall, the WIDUS+abortion, with a cutoff score of 4, correctly classified 71% of cases.

Cross-validation. When the hierarchical logistic regression (block 1 = WIDUS, block 2 = abortion) was repeated, the abortion item did not significantly predict drug status above and beyond the WIDUS, $\chi^2(1) = 2.22$, $p = .14$; however the effect of the variable still maintained its magnitude (OR = 3.0, $p = .13$, 95% CI = .724, 12.41). Using a cut-off score of four, sensitivity was high (.80) with moderate specificity (.66). The positive predictive value was .21, while the

negative predictive value was .97. Overall, the WIDUS plus the abortion item correctly classified 76% of participants.

Research Question 3: Predictive Validity of Indirect Items within a Pregnant Sample

Step 1: Exclusionary criteria. Nineteen items were removed for under endorsement (i.e., < 10%), high reading levels (i.e., Flesch-Kincaid 9th grade reading level rating or higher), highly stigmatizing content (e.g., abuse, violence, involvement with police) and direct alcohol and illicit drug content (e.g., family history of drug or alcohol problems, marijuana use by friends or partner) were eliminated. This step removed 19 items, reducing the item count to 64.

Step 2: Univariate relationship with drug status. The 13 items with the largest chi-square value were retained (values ranged from 4.82 to 15.99) and included in step three.

Step 3: Multivariate relationship with drug status. In the first logistic regression, items with a *p*-value greater than .5 were eliminated, removing five of the 13 items. Table 8 shows the subsequent two logistic regression analyses. In the eight predictor model, the upset and friends cigarettes items were removed because of their lower odds ratio and higher level of significance in comparison to the other six items. This resulted in the six predictor model. As seen in Table 8, these six items were strongly associated with drug status (odds ratios range from 2.82 to 16.85) and therefore were retained. As previously mentioned, the primary consideration for retaining these items was the size of their association with drug status, rather than significance.

Table 8

Summary of Logistic Regression Analyses in the Training Sample

Variable	Sig.	OR	95% CI
Eight Predictors ^a			
Midnight	.002	15.58	[2.65, 91.68]
Abortion	.008	6.18	[1.61, 23.77]
100 cigarettes	.012	6.86	[1.53, 30.80]
Pain	.015	5.34	[1.39, 20.52]
Seen worse	.086	2.74	[.87, 8.69]
Hours	.139	2.98	[.70, 12.67]
Upset	.270	2.08	[.57, 7.59]
Friends cigarettes	.691	0.76	[.19, 2.98]
Six Predictors ^b			
Midnight	.001	16.85	[3.06, 92.76]
Abortion	.011	5.45	[1.47, 20.13]
100 cigarettes	.008	6.37	[1.61, 25.19]
Pain	.016	5.06	[1.36, 18.87]
Seen worse	.079	2.82	[.89, 8.96]
Hours	.120	3.03	[.75, 12.22]

Note. Sig. = p-value; OR = odds ratio; CI = confidence interval; 100 cigarettes = I have smoked at least 100 cigarettes in my entire lifetime; Abortion = Have you ever had an abortion; Friends cigarettes = Most of my friends smoke cigarettes; Hours = I currently work less than 20 hours per week; Midnight = When I was younger than 13 years old, I often stayed out past midnight; Pain = In the past year, I have been bothered by pain in my teeth or mouth; Seen worse = I have seen or experienced worse things than most other people have; Upset = I am easily upset about things.

^aLogistic regression model with eight predictors.

^bLogistic regression model with six predictors.

The six indirect items listed in Table 8 were combined to form the WIDUS-Pregnancy (WIDUS-P). The ROC curve for the WIDUS-P is presented in Figure 1 and shows an AUC of .87 (standard error = .036, $p < .001$, 95% CI = .80, .94), indicating that there is an 87% likelihood that a randomly selected woman with a positive UDS will have a higher WIDUS-P score than a randomly selected woman with a negative UDS. Said another way, the WIDUS-P demonstrated good accuracy in classifying women who tested positive for recent drug use.

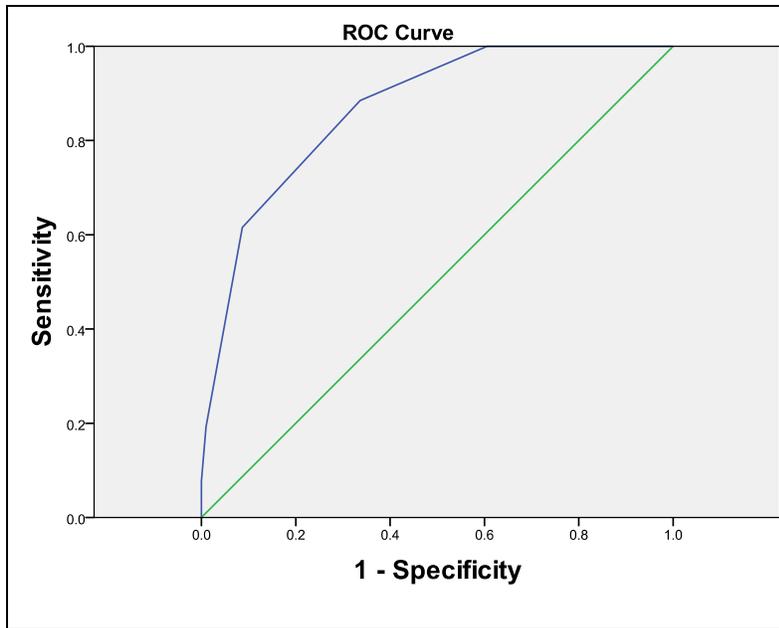


Figure 1. ROC curve for the six-item WIDUS-P measure predicting prenatal drug use in the training sample. Diagonal line represents chance prediction. AUC = .87.

Table 9 lists the sensitivity and specificity for each possible cut-off score and also displays the dramatic changes in sensitivity and specificity associated with a change in cut-off score. Given the primary consideration of sensitivity, the optimal cut-off score was three (sensitivity = .89). At this cutoff score, the measure's positive predictive value (i.e., the percentage of women who are positive on the WIDUS-P who also have a positive toxicology screen) was .40 and negative predictive value (i.e., the percentage of women who are negative on the WIDUS-P who also have a negative toxicology screen) was .96. Overall, the WIDUS-P, with a cutoff score of 3, correctly classified 70.8% of cases.

Table 9

WIDUS-P Cutoff Score Sensitivity and Specificity N= 131

WIDUS-P score positive if greater than or equal to:	Sensitivity	Specificity	% Positive
1	1.00	.14	89
2	1.00	.39	68
3	.89	.66	45
4	.62	.91	19
5	.19	.99	4.6
6	.08	1.00	1.5

Note. WIDUS-P score = sum of 6 items rated from 0 to 1.

Cross-validation procedures and analyses. The 6-item WIDUS-P was then cross-validated on the validation sample (N = 100). Scores on the WIDUS-P were reasonably well-distributed (mean = 2.28, SD = 1.39, skewness = .21, kurtosis = -.41) and yielded an AUC of .85 (standard error = .05, $p < .001$; see Figure 2), only a slight decrease from an AUC of .87 in the training sample. The 95% confidence interval for the AUC was .76 to .94. Although scores on the WIDUS-P were generally well-distributed, positive cases were more common with higher scores (with the exception of a score of 6; see Table 10), resulting in an irregularly shaped curve. As shown in Table 11, there was an improvement in sensitivity and specificity for a cut-off score of 3 in the validation sample (.90 and .74, respectively). Similar to the ROC curve for the training sample, the ROC curve for the validation sample showed dramatic changes in sensitivity and specificity associated with changes in cut-off score steps. The positive predictive value of the WIDUS-P decreased to .28, which meant that 28% of participants who had a positive WIDUS-P score tested positive for drug use. The negative predictive value was .99. Classification accuracy improved from 70.8% in the training sample to 76% in the validation sample.

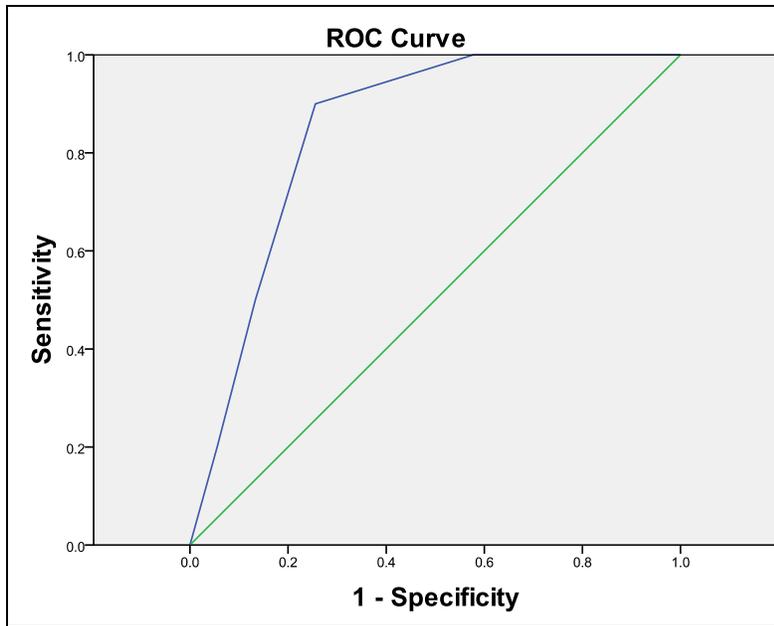


Figure 2. ROC curve for the six-item WIDUS-P measure predicting prenatal drug use in the validation sample. Diagonal line represents chance prediction. AUC = .85.

Table 10

Percent of Drug Positive Participants as a Function of WIDUS-P score

WIDUS-P score	% testing positive	N
0	0%	13
1	0%	25
2	3.3%	30
3	27%	15
4	30%	10
5	29%	7
6	-	0

Note. $n = 100$.

Table 11

WIDUS Cutoff Score Sensitivity and Specificity $n = 100$

WIDUS-P score positive if greater than or equal to:	Sensitivity	Specificity
1	1.00	.14
2	1.00	.42
3	.90	.74
4	.50	.87
5	.20	.94
6	.00	1.00

Note. WIDUS-P score = sum of 6 items rated from 0 to 1.

A logistic regression was performed to determine how strongly the six items that comprised the WIDUS-P predicted drug status. Results are shown in Table 12. All items, with the exception of the hours item, performed in the predicted direction (i.e., increased the odds of testing positive for recent prenatal drug use).

Table 12

Summary of Logistic Regression Analyses in the Validation Sample

Variable	Sig.	OR	95% CI
Midnight	.09	5.43	[0.79, 37.52]
Abortion	.02	10.37	[1.50, 71.83]
100 cigarettes	.26	2.67	[0.49, 14.58]
Pain	.23	0.32	[0.05, 2.02]
Seen worse	.02	11.05	[1.56, 78.52]
Hours	.71	1.50	[0.18, 12.11]

Note. Sig. = *p*-value; OR = odds ratio; CI = confidence interval; 100 cigarettes = I have smoked at least 100 cigarettes in my entire lifetime; Abortion = Have you ever had an abortion; Friends cigarettes = Most of my friends smoke cigarettes; Hours = I currently work less than 20 hours per week; Midnight = When I was younger than 13 years old, I often stayed out past midnight; Pain = In the past year, I have been bothered by pain in my teeth or mouth; Seen worse = I have seen or experienced worse things than most other people have; Upset = I am easily upset about things.

Additional cross-validation procedures. Table 13 presents data from ROC curve analyses of five random samples (from the full sample) of 100 participants: the WIDUS-P (cut-off score = 3), on average, maintained good classification accuracy (AUC = .86), sensitivity (.88) and specificity (.69).

Table 13

Cross-validation of the WIDUS-P (cutoff score = 3) in Five Randomly Selected Samples

Sample	AUC (SE)*	Sensitivity	Specificity	PPV	NPV	Classification Accuracy
1	.88 (.04)	.95	.64	.38	.98	70%
2	.90 (.04)	.94	.74	.41	.98	77%
3	.84 (.05)	.87	.67	.32	.97	70%
4	.89 (.04)	.93	.73	.38	.98	76%
5	.79 (.06)	.73	.66	.28	.93	67%
Average	.86	.88	.69	.35	.97	72%

Note. *N* = 100; AUC = area under the curve; SE = standard error.

* *p* < .001.

WIDUS-P versus WIDUS. Table 14 describes the results of a hierarchical logistic regression examining the effect of WIDUS-P on drug status, after controlling for the WIDUS. As shown, the WIDUS-P was a significant predictor of drug status after controlling for the effect of the WIDUS ($\chi^2(1) = 6.05, p < .05$). Table 15 shows the reverse: the effect of WIDUS on drug status after controlling for the WIDUS-P. Unlike the results of previous analysis, the WIDUS was not a significant predictor of drug status above and beyond the WIDUS-P ($\chi^2(1) = .003, p > .05$). Although both measures were significant predictors of drug status when compared alone to the constant-only model (as shown in Block 1 of Table 14 and 15), only the WIDUS-P offered significant additional predictive validity.

Table 14

Effect of the WIDUS-P on Drug Status, Controlling for the WIDUS

Variable	Sig.	OR	95% CI
		Block 1 ^a	
WIDUS	.01	1.82	[1.13, 2.93]
		Block 2 ^b	
WIDUS	.96	1.02	[.52, 2.00]
WIDUS-P	.02	2.54	[1.16, 5.14]

Note. N = 100. Sig. = p-value; OR = odds ratio; CI = confidence interval.

^a $\chi^2(1) = 7.30, p < .01$.

^b $\chi^2(1) = 6.05, p < .05$.

Table 15

Effect of the WIDUS on Drug Status, Controlling for the WIDUS-P

Variable	Sig.	OR	95% CI
		Block 1 ^a	
WIDUS-P	.001	2.48	[1.44, 4.28]
		Block 2 ^b	
WIDUS-P	.02	2.45	[1.16, 5.14]
WIDUS	.96	1.02	[.52, 2.00]

Note. N = 100. Sig. = p-value; OR = odds ratio; CI = confidence interval.

^a $\chi^2(1) = 13.35, p < .001$.

^b $\chi^2(1) = .003, p > .05$.

Research Question 4: Direct versus Indirect Measures of Prenatal Drug Use

Sensitivity, specificity, PPV, NPV and classification accuracy for the standardized measures, the DAST and Drug CAGE, single questions of lifetime, pre-pregnancy and past month drug use, and the indirect methods (WIDUS, WIDUS+abortion, WIDUS-P) are presented in Table X. As predicted in Hypothesis 2, the indirect measures outperformed all direct measures of prenatal drug use with regard to sensitivity. The WIDUS and the WIDUS-P identified almost 90% of all drug users; however, the WIDUS-P was a more specific measure. The WIDUS+abortion was less sensitive, but still identified more drug-users than direct methods. Among the direct methods, the DAST, with a cutoff score of one, identified the highest percentage of prenatal drug users (72%) and also demonstrated good specificity (.76). Using a higher cutoff score for both the DAST and Drug CAGE resulted in higher specificity, but it reduced sensitivity by almost half. Sensitivity of the direct questions increased as the time period in question became more remote; the inverse relationship was observed for specificity. Asking participants if they used drugs in the past month correctly identified the greatest number of participants (91%); however, this question only identified 34% of drug users.

In addition, Table 16 reports the percentage of participants who screened positive on a measure (based on the cut-off score reported in parentheses) or positively endorsed a question. Based on comparison of self-reported last month drug use to the DAST and Drug CAGE scores, women appear more willing to disclose drug use consequences (32% for both measures) than admit to recent drug use (5%).

Table 16

Accuracy of indirect and direct screening tools in identifying prenatal drug use, N = 231

Screening Method	Sensitivity	Specificity	PPV	NPV	Classification Accuracy	% Positive
WIDUS-P (3) ^a	.90	.74	.28	.99	76.%	32
WIDUS (3)	.89	.44	.23	.96	51%	61
WIDUS+abortion (4) ^a	.80	.66	.21	.97	76%	39
DAST (1)	.72	.76	.36	.94	75%	32
Lifetime ^b	.69	.66	.28	.92	67%	39
CAGE (1)	.64	.75	.32	.92	73%	32
Three months ^c	.58	.87	.46	.92	83%	20
DAST (2)	.39	.90	.42	.89	82%	14
CAGE (2)	.39	.87	.36	.88	79%	17
Last month ^d	.34	.99	.91	.91	91%	5

Note. Cutoff scores for the WIDUS, DAST, and CAGE are in parentheses.

^aStatistics are from the validation sample (N = 100).

^bDrug use endorsed in lifetime.

^cDrug use endorsed during the three months prior to pregnancy recognition.

^dDrug use endorsed in the last month.

Discussion

The purpose of this study was to develop an indirect screening tool to detect prenatal drug use. The research built upon the work of Dr. Steven Ondersma and colleagues, during the development of the Wayne Indirect Drug Use Screener (WIDUS). The current study was an extension of this research, with a focus on detecting drug use in pregnant women. Four main research questions: (1) Are women in this population underreporting prenatal drug use? If so, what is the extent of the discrepancy between self- and biological-report?, (2) Do pregnancy-related variables offer additional predictive validity to an existing indirect drug screening tool developed with postpartum women (i.e., the WIDUS)?, (3) Considering both prenatal and general drug use correlates, what items best predict recent drug use in this sample of pregnant women?, and (4) How well do direct (e.g., standardized screening questions) and indirect measures of prenatal drug use predict objective evidence of such use (i.e., positive UDS)? It was hypothesized that women will underreport their prenatal drug use (Hypothesis 1) and that

indirect screening tools will better identify recent drug use than direct screening measures (Hypothesis 2).

The subsequent discussion will answer these questions by summarizing results of data analysis. The implications of these findings, as well as directions for future research, will then be presented. Lastly, limitations of the study will be addressed.

Research Question 1: Self-reported Drug Use versus UDS

When self-report and objective (USD) measures of prenatal drug use were compared, prevalence rates varied, evidencing underreporting in this study. As hypothesized, participants tested positive for recent drug use at a rate higher than they self-reported. This was true even after certain drugs that could have been used legally (i.e., with a prescription) were excluded, lowering the prevalence rate by biological report from 19% to 16%. Thus, even when using a conservative rate, only one-third of participants who tested positive self-reported drug use in the past month. It is likely that the “true” rate of prenatal drug use (i.e., use of any illicit drug during pregnancy) is even higher and would reflect higher rates of underreporting. Nonetheless, rates of underreporting are consistent with results from other urban, prenatal samples (Markovic et al., 2000; Ostrea et al., 1992) and the the parent study (Grekin et al., 2010).

Research Question 2: Predictive Validity of Pregnancy Variables

The second research question- do pregnancy-related variables contribute additional predictive validity to the original WIDUS screener- was evaluated using N = 46 pregnancy-related items. Surprisingly, only one item retained statistical significance at the end of the item reduction process. The abortion item added significant predictive validity above and beyond the WIDUS. While this item added significant predictive validity, above and beyond the WIDUS, the item focused on the controversial issue of abortion.

While it may be surprising that *only* the abortion item was significantly associated with prenatal drug status within the context of other risk factors, it is not unexpected that this item retained significance during multivariate analyses. Several studies have documented an association between abortion and mental health problems. However, there is discrepancy within the literature as to how this relationship is best conceptualized. Some researchers view abortion as a traumatic experience with negative psychological consequences (Coleman, Coyle, Shuping, & Rue, 2009), others attribute the association between abortion and mental health problems to common risk factors (i.e., SES, violence history, prior mental health, described in Steinberg & Finer, 2011). In an investigation of the common-risk-factors model with a nationally representative sample (i.e., women who responded to the abortion question as part of the National Comorbidity Survey Part II; N = 2065), Steinberg & Finer (2011) examined the relationship between history of abortion (0, 1, and multiple abortions) and having a substance use disorder (according to DSM III-R criteria). After controlling for socio-demographic (e.g., race, income, marital status) and other risk factors (e.g., intimate partner violence, age at first abortion or pregnancy), abortion (having multiple versus zero abortions) was significantly associated with having a current substance use disorder diagnosis (OR = 3.7, 95% CI = 1.2, 11.7). Although the strength of this association was reduced when common risk factors were controlled for (i.e., the OR decreased from 5.2, 95% CI = 2.2, 12.2), these findings still lend support to the current results concerning the predictive validity of the abortion item.

Research Question 3: Predictive Validity of Indirect Items within a Pregnant Sample

Research question 3 concerns which indirect items, among both prenatal and general drug use correlates, best predict recent drug use. Utilizing the full item pool, six indirect items were retained during the item reduction process as a result of their univariate and multivariate relationships with drug status. Together, these six items formed the WIDUS-Pregnancy

(WIDUS-P). Two items, the 100 cigarettes and pain (in teeth or mouth) items, overlapped with the WIDUS. The abortion item, retained in question 2, was also included. Overall, the measure performed well in cross-validation analyses. The WIDUS-P showed good accuracy in distinguishing recent drug users from non-drug users (i.e., women with no evidence of recent prenatal drug use). Within the validation sample, it identified 90% of women who tested positive for recent drug use and almost three-quarters of women who did not test positive. With a cut-off score of three, the WIDUS-P correctly classified 76% of all women in the validation sample. In addition, it accounted for significant unique variance, not captured by the WIDUS, in predicting prenatal drug use. Data from randomly selected validation samples also support the classification accuracy and high sensitivity of this measure.

Research Question 4: Direct versus Indirect Measures of Prenatal Drug Use

Research question 4 focused on how well the direct self-report measures of drug use predicted prenatal drug use (i.e., positive UDS) in this sample of pregnant women. The indirect measures, the WIDUS, WIDUS+abortion and WIDUS-P, were superior to all direct measures and questions in terms of sensitivity. The WIDUS-P emerged as the most sensitive indirect measure as well as the most specific. The DAST and the Drug CAGE, using the lowest possible cut-off scores, were moderately sensitive screening tools; although, the DAST outperformed the CAGE (.72 versus .64). Overall, the direct methods (i.e., the question about last month use, the DAST with a cut-off score of 2, and the question about use during the 3 months prior to pregnancy recognition) accurately classified the most participants; however they had only poor to moderate sensitivity. For example, asking women if they used drugs in the past month correctly identified almost 91% of participants, but missed two-thirds of drug users. Given the study's priority on identifying prenatal drug use, indirect measures were more successful at identifying UDS positive cases of prenatal drug use than direct methods.

Although, indirect methods clearly offer a predictive advantage, the utility of direct measures may be sample dependent. Results from Grekin and colleagues (2010), utilizing data from the parent study at Wayne State University, support a different perspective of the DAST's sensitivity and disclosure of drug use. In their sample of 300 women who had recently delivered at an urban obstetric hospital in Detroit, the DAST was less accurate than in the current study in identifying prenatal drug use. For identifying any drug use (i.e., cocaine, amphetamines, opiates and/or marijuana), the DAST, with a cut-off of one, was less sensitive (.47 versus .72 in current study). Rates of self-reported past year drug use, according to the DAST-10, question #1, also differed between samples, with participants in the current sample endorsing higher rates (13% versus 19%).

Overall, women in the present study self-reported drug use and its consequences more freely than women in the Detroit sample. Women in this study might have felt more comfortable disclosing for several reasons. One, they were in an outpatient setting versus a controlled environment, where they were only interacting with staff for a specified amount of time and could leave voluntarily. In addition, because women were still pregnant, the possible consequences of prenatal drug use (e.g., loss of custody) were less immediate and thus women might not have felt as vulnerable (Harris & Paltrow, 2003). Lastly, some participants were recruited from "high-risk" clinics which included women with known medical conditions and substance problems that complicated pregnancy. For some participants, they may have felt more comfortable disclosing prenatal drug use because their medical providers were already aware of this information and/or they were openly seeking treatment for drug use. Together, differences between samples suggest that self-disclosure, and consequently, the utility of the DAST as a screening tool for prenatal drug use, may be sample dependent.

Implications and Future Directions

Implications of the present study's results are discussed below within the context of 1) the sample's severity of biopsychosocial risk factors, 2) advances in methodological issues related to screening for prenatal drug use and estimating rates of underreporting, and 3) indirect measures as a promising screening approach. Directions for future research are also described.

Severity of psychosocial risk factors. While the primary focus of the present study was measure development, study findings also point out the nature and types of psychosocial risk factors that impact the target group of pregnant women. Self-report data confirm that many witnessed or experienced various negative life events, including childhood physical and sexual abuse, physical abuse as an adult, and unsafe partner relationships. For many women, drugs were present in their childhood environments as well as during their current pregnancy. About half the sample reported smoking cigarettes prior to becoming pregnant and a similar percentage reported that the father of their fetus was a current smoker. Many women also had close friends who used marijuana. These data affirm the need for better screening and intervention programs focused not only on substance use but also other areas of risk.

As a whole, current study participants were predominantly young, low-income, minority women and many noted this was not their first pregnancy. Health disparities research has found infant mortality and morbidity rate differences continue to be an area of much concern. Specifically, NCHS found the death rate for African American infants (13.3/1,000 live births) was two times higher than the national average of 5.6/1,000 live births (NCHS, 2011). Central to the problem of infant mortality is preterm birth (MacDorman, Callaghan, Mathews, Hoyert, & Kochanek, 2007), with African Americans accounting for the highest percentage of cases (17.8% versus 11.5% for Whites; Behrman & Stith-Butler, 2006). One important risk factor for such

outcomes is prenatal substance use. Clearly, the present sample of women is at increased risk for having a preterm birth or other maternal or infant complications.

It is important to recognize that the risks for adverse pregnancy-related outcomes are not limited to those women who screened positive for prenatal drug use by UDS or self-report. Many of the larger pool of women (84%) did not screen positive for prenatal drug use, but nonetheless remain at increased risk for poorer outcomes due to a variety of factors. First, it is likely that some women were still missed with the more intensive screening procedures used in the present study. Urine drug assays have a limited window of detection (i.e., up to 2-3 weeks for regular marijuana use) and thus can only identify more recent use so the prevalence of any drug during pregnancy is likely to be higher. Other women used pre-pregnancy but then stopped. Many will return to use post-partum (Ebrahim & Gfroerer, 2003). A significant proportion of study participants reported current symptoms of depression or anxiety (about half reported “feeling down, depressed or hopeless,” and being “easily upset”). Difficulty controlling anger was another common problem, with 52% of women noting they “get easily and [feel] a need to blow off some steam.” Current health and economic stressors (e.g., ER visits, poor nutrition, transportation issues, housing instability) were also quite common. Collectively, this information suggests that in addition to interventions for prenatal drug use, there is a need for multi-faceted prevention and intervention efforts to promote general health and well-being in this at risk population of women and their children.

Advances in methodological practices. During development and validation of an indirect drug use screener in the target population of low-income, minority women, several methodological considerations were given careful thought and consideration. First, specific steps were taken to create an environment that assured patients of anonymity and confidentiality. For example, self-report surveys were administered using ACASI technology. Such practices

tend to promote disclosure of sensitive behaviors (Durant et al., 2002; Newman et al., 2002). Second, the present project was one of the few that compared self-report screeners to a biological measure of drug use (i.e., urinalysis). While urine drug screening is not without limitations, particularly for substances with a short half-life, it nonetheless provides a more objective measure of recent substance use, thereby minimizing effect of underreporting on rates of prenatal drug use. Consequently, study findings offer new information about the sensitivity and specificity of two commonly-used screening tools for predicting prenatal drug use (DAST and Drug CAGE). Results yielded only moderate sensitivity for both screeners, suggesting many at-risk women would have fallen through the cracks if screening was limited to such tools.

Despite practices to facilitate self-reported drug use, pregnant women in this sample still underreported their drug use (69% tested positive by UDS, but denied past month use). Results suggest that under the best of circumstances, every two out of three women who screened positive by UDS would not, in clinical practice, come to attention of their healthcare providers via current screening practices (i.e., direct self-report). This finding is consistent with the results of Grekin and colleagues (2010), who found that 80% of the sample who had a positive urine and/or hair screen denied drug use. In comparing these two studies, there is also evidence to support some differences in the degree of disclosure of drug use and related consequences between these two samples (i.e., differences in endorsement rates of DAST items, greater legal consequences associated with testing positive postpartum versus testing positive prenatally in an outpatient setting). Regardless, screening efforts that rely solely on self-report to identify prenatal drug use are likely to miss a significant proportion of drug users even when ideal conditions for disclosure are present. Not surprisingly given underreporting, indirect screening measures emerged as the best approach to identify recent prenatal drug use.

The merit of indirect screening. The WIDUS, WIDUS+abortion and WIDUS-P were the most sensitive screening tools, identifying the greatest proportion of drug users. While additional research is needed to further examine the predictive validity of these different screeners, collectively, these findings provide a promising start to better identification of prenatal drug use. Interestingly, the WIDUS, which was developed and validated on postpartum women in Detroit, performed well in identifying pregnant drug users in this sample. This supports generalizability of the WIDUS from postpartum women to other samples of urban pregnant women. Additionally, the results of this study suggest that adding the abortion item may increase the predictive validity of the WIDUS. Although this improvement may be small, it may lead to better identification of prenatal drug use across time. An important consideration to adding this item is that women may feel uncomfortable answering this question. While the item is indirect (i.e., it does not reference drugs) and may add unique variance, it may threaten the innocuous intention of an indirect measure. Conversely, pregnant women may not view this question as offensive because it is asked within an OB setting where questions about their reproductive health are appropriate and expected. Future studies are needed to support the incremental validity of the abortion item to the WIDUS and also to determine OB patients' acceptability of including the abortion item in a brief measure.

The WIDUS-P, developed and validated on this sample was the most sensitive measure of prenatal drug use. While the WIDUS-P performed well as a prenatal drug use screener in this sample, it is important to take into consideration the generalizability of this measure given the shape of its ROC curve. For the ROC curves of both the training and validation samples, changes in cut-off scores at certain levels were associated with dramatic changes in sensitivity and specificity. For example, within the validation sample, sensitivity decreased from .90 to .50 when the cut-off score was increased from three to four. In this sample, the optimal cut-off score was

three. A higher cut-off score results in a significant compromise in sensitivity. However, given that cut-off scores are very sample dependent, these drastic changes in sensitivity and specificity could be problematic when the WIDUS-P is used in different samples. The WIDUS-P may not be as useful for identifying prenatal drug use when applied to different samples of pregnant women (e.g., private practice settings, rural OB clinics).

Clearly, further research is needed to evaluate the predictive validity of each of these three measures. At present, there is too much variability to make definitive statements across studies and measures. Next steps include evaluating these measures in different samples of pregnant women (e.g., women who have recently delivered at VCU, other urban OB clinics), extending the window of drug detection by including hair analysis, and utilizing different statistical techniques in both the development (i.e., item reduction process) and validation phase of measure development. In this study, we chose to develop the WIDUS-P on a sample of 131 participants and then validate it on the remaining 100 participants. An alternative approach would have been to use CART or LOO (leave one out) cross-validation. Different statistical processes may identify additional items that contribute unique variance not captured in the WIDUS-P items. Similarly, they may also confirm the predictive validity of the WIDUS-P items.

Further investigation of indirect screening, based on the present findings, could also be extended to examine the combination of direct and indirect screening. Asking participants directly about their drug use in the past month had high specificity, but low sensitivity. On the other hand, the WIDUS-P had high sensitivity and lower specificity. Combining these approaches could lead to an ideal combination of sensitivity and specificity. Concurrent screening (i.e., in a single measure, asking the WIDUS-P items first and then question about past month use) is preferable to sequential screening (i.e., administering the WIDUS-P only if past month drug use is denied) because women could become defensive when asked directly about

recent drug use and consequently, minimize subsequent report of any behaviors or life experiences.

Indirect screening is a stark contrast to current screening approaches which are either non-existent or involve direct mention of drug use and its consequences. Compared to these methods, an indirect approach offers more effective screening. As supported by the present findings, indirect tools are more sensitive measures of prenatal drug use than direct methods: they identify a greater proportion of recent drug users. This is of paramount importance because in order for prenatal interventions to be effective, screening tools must first accurately identify at-risk women. From a public health perspective, if a significant proportion of women who use drugs prenatally are missed, the intervention has less of an impact at the population level. Interventions are also less effective when they are not easily applied to real world settings (Smeeth & Ebrahim, 2000). The innocuous nature of indirect screening enables this approach to be easily implemented into regular clinic practice. OB clinic staff will likely be more receptive to using a screener which does not directly address drug use than using a face-valid screener such as the DAST or Drug CAGE. Additionally, a computerized screening tool offers both time and cost savings for providers, as well as greater translational value, as it can be easily integrated into standard care in a variety of health settings. Taken together, an indirect, computerized screener, such as the ones reported in this study, can allow practitioners to screen more pregnant women and better identify those at risk for drug use.

Limitations

One of the main limitations of this study was the way in which participants' drug status was defined. Pregnant women were considered "drug positive" if their urine drug screen was positive for methamphetamines, cocaine, marijuana, barbiturates, MDMA and/or PCP. Thus, biological report was based solely on UDS and not both hair and urine testing, as was collected

in Dr. Ondersma's research. This method of biological testing was chosen for several reasons. Urine samples are relatively easy to collect as OB clinic patients are accustomed to providing them as part of their routine prenatal care and this method is less invasive than collecting hair or blood samples. In addition, urinalysis costs less than other methods (e.g., hair analysis costs around \$75/sample). Furthermore, despite urinalysis' short window of detection for most drugs, this method is appropriate because one of the most common drugs of abuse among this population is marijuana (Saitz, Svikis, et al., 2006), which has a much longer window of detection than other drugs (Wolff et al., 1999). Finally, given that the prenatal clinic does not ever screen for illicit drugs and that all study information was collected anonymously, contamination of urine samples by participants was considered unlikely because there was no specific motivation for women to reduce or eliminate use prior to their prenatal visit. Although both urine and hair assay were utilized in Dr. Ondersma's study with postpartum women, for the aforementioned reasons, urinalysis was selected for use in the current study.

As a result of using only urinalysis as the gold standard criterion, the window of detection in this study was shorter than if both methods had been utilized (i.e., the full period of pregnancy was not captured by toxicology screens). Consequently, women who used drugs during pregnancy but outside of the window of detection for urinalysis were "missed." For example, a participant in her third trimester could have used marijuana during her first trimester but not have tested positive on the UDS. Additionally, because it was unknown whether women were using benzodiazepines, methadone, opiates and/or oxycodone legally (i.e., with a prescription), this data was omitted from their drug status. Participants' medical records could not be accessed to rule-out prenatal prescription drug use because the study was anonymous. In this manner, anonymity was both a strength and limitation of the study. Given these limitations, it is likely that the "true" rate of prenatal drug use is even higher than the rate documented (15.6%). It is

possible that this underestimation of drug use affected which indirect items were selected and the predictive validity of the various direct and indirect screening methods examined.

Another limitation concerns the issue of generalizability. The study was conducted with pregnant women who were predominately African American, low-income, and young. From a health disparities perspective, this is an important at-risk group to study; however, results may not generalize well to other populations. In addition, the primary drug used by women who tested positive was marijuana. Thus, it is unknown how well the predictive validity of indirect screeners developed in this study will apply to other classes of drugs.

Final Thoughts

Current prenatal drug use screening practices are insufficient. Indirect screening is a promising approach to better identify drug use in pregnant women, regardless of their willingness to disclose such use. Although changes to prenatal drug use screening addresses only one part of a complex problem, it is an important foundation upon which to impact greater numbers of at-risk women and build more effective interventions.

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Appendix 1

Preliminary Literature Review of Correlates of Current Drug Use: Behavioral, Medical,
Psychological, Experiential, and Demographic
Borrowed from Dr. Steven Ondersma

CORRELATES	REFERENCES
<i>Behavioral Correlates</i>	
Suicide attempt	(Allgulander, Allebeck, Przybeck, & Rice, 1992; Glavak, Kuterovac-Jagodic, & Sakoman, 2003; Schaar & Ojehagan, 2001)
Associating with drug-using peers	Lehman, Barrett, & Simpson, 1990; McCuller, Sussman, Dent, & Teran, 2001; Newcomb, 1997; Newcomb & Felix-Ortiz, 1992)
Gambling, lotto, etc.	(Lesieur, Blume, & Zoppa, 1986; Ramirez, McCormick, Russo, & Taber, 1983)
Involvement in faith	(Adlaf & Smart, 1985; Newcomb & Felix-Ortiz, 1992; Reisinger et al., CPDD, 2005)
Smoking	(Richter, Ahluwalia, Mosier, Nazir, & Ahluwalia, 2002; Newcomb, Galaif, & Locke, 2001; Substance Abuse and Mental Health Services Administration, 2001; Svikis, Henningfield, Gazaway, Huggins, Sosnow, Hranicka, Harrow, & Pickens, 1997)
Problem alcohol use	(Carlson, Falck, Wang, Siegal, & Rahman, 1999; Sanz Aliaga, Sabater Pons, Alfonso Sanchez, Carbajal de Lara, & Sancho Izquierdo, 2000; Schubiner, et al., 2000; Substance Abuse and Mental Health Services Administration, 2001)
Criminality	(Corty & Ball, 1987; Kane & DiBartolo, 2002; Kosten, Gawin, Rounsaville, & Kleber, 1986; Substance Abuse and Mental Health Services Administration, 2001; Villalobos, Cropsey, Weaver, & Stitzer, CPDD, 2005)
Emergency room use	(Hoffman & Goldfrank, 1990)
Lifetime drug use	(Schifano, DiFuria, Forza, Minicuci, & Bricolo, 1998)
Impaired occupational functioning	(Kirisci, Vanyukov, Dunn, & Tarter, 2002; McCusker, Bigelow, Frost, Garfield, Hindin, Vickers-Lahti, & Lewis, 1997; Newcomb, 1997)
Impaired academic functioning	(Ong, 1987; Kirisci, Vanyukov, Dunn, & Tarter, 2002; Newcomb, 1997; Schubiner, Tzelepis, Milberger, Lockhart, Kruger, Kelley, & Schoener, 2000)
Impaired social functioning	(Kirisci, Vanyukov, Dunn, & Tarter, 2002; Lende & Smith,

	2002; Mowbray, Ribisl, Solomon, Luke, & Kewson, 1997)
Age at first cigarette, drink	(McGue, Iacono, Legrand, Malone & Elkins, 2001; Schubiner, Tzelepis, Milberger, Lockhart, Kruger, Kelley, & Schoener, 2000; Word & Bowser, 1997; Young, 1992)
Prenatal care	(Eriksson, Larsson, & Zetterstrom, 1979)
Caffeine intake	(Fillmore, 2003)
<i>Medical Correlates</i>	
Chronic illness	(Cardoso & Jankovic, 1993; Rosenblum, Joseph, Fong, Kipnis, Cleland, & Portenoy, 2003)
Chronic pain	(Longo, Parran, Johnson, & Kinsey, 2001; Rosenblum, Joseph, Fong, Kipnis, Cleland, & Portenoy, 2003)
Any sexually trans. dis.	(French, Mauskopf, Teague, & Roland, 1996; Hwang, Ross, Zack, Bull, Rickman, & Holleman, 2000; Kreek, 1996; Word & Bowser, 1997)
Pneumonia	(French, Mauskopf, Teague, & Roland, 1996; de Gaetano, Bertagnolio, Tumbarello, Tacconelli, Cataldo, Longo, & Cauda, 2000; Gotway, Marder, Hanks, Leung, Dawn, Gean, Reddy, Araoz, & Webb, 2002)
Liver disease	(Novick, Reagan Croxson, Gelb, Stenger, & Kreek, 1997; Tong & el-Farra, 1996)
Hepatitis	(Brown, Hickson, Ajuluchukwu, & Bailey, 1993; French, Mauskopf, Teague, & Roland, 1996; Hwang, Ross, Zack, Bull, Rickman, & Holleman, 2000; Kreek, 1996; Schafer, Boetsch, & Laakmann, 2000)
HIV / HIV risk	(Carlson, Falck, Wang, Siegal, & Rahman, 1999; Hoffman & Goldfrank, 1990; Hwang, Ross, Zack, Bull, Rickman, & Holleman, 2000; Kreek, 1996; Nnadi, Better, Tate, Herning, & Cadet, 2002; Singh, Prasad, & Mohanty, 1999; Specter, 1994; Svikis, Gorenstein, Paluzzi, & Fingerhood, 1998; Word & Bowser, 1997)
Tuberculosis	(Bernado, 1991; Curtis, Friedman, Neaigus, Jose, Goldstein, & Des Jarlais, 1994; Foley, Ehr, Raza, & Devlin, 1995; French, Mauskopf, Teague, & Roland, 1996; Taubes, Galanter, Dernatis, & Westreich, 1998)
Vascular problems	(Perlman & Thordarson, 1999; Roszler, McCarroll, Donovan, Rashid, & Kling, 1989)
<i>Psychological Correlates</i>	
Depression	(Biederman, Faraone, Wozniak, & Monuteaux, 2000; Coelho, Rangel, Ramos, Martins, Prata, & Barros, 2000; Goldberg, Singer, & Garno, 2001; Majewska, 1996; McCuller, Sussman, Dent, & Teran, 2001; Roberts, 2000; Schaar & Ojehagan, 2001; Sussman, Dent, & Galaif, 1997)
Anxiety	(McCuller, Sussman, Dent, & Teran, 2001; Nnadi, Better,

	Tate, Herning, & Cadet, 2002; Word & Bowser, 1997)
PTSD	(Clark, Masson, Delucci, Hall, & Sees, 2001; Majewska, 1996)
Antisocial PD	(Henderson & Galen, 2003; Kosten, Gawin, Rounsaville, & Kleber, 1986; Newcomb, 1997)
Conduct disorder in childhood/ neurobehavioral disinhibition	(Biederman, Faraone, Wozniak, & Monuteaux, 2000; Majewska, 1996; Schubiner, Tzelepis, Milberger, Lockhart, Kruger, Kelley, & Schoener, 2000; Tarter, Kirisci, Mezzich, Cornelius, Pajer, Vanyukov, Garner, Blackson, & Clark, 2003)
Mental disorders in general	(Batki, 1990; Kirisci, Vanyukov, Dunn, & Tarter, 2002; Mason, Kocsis, Melia, Khuri, Sweeney, Wells, Borg, Millman, & Kreek, 1998; Newcomb, 1997; Schaar & Ojehagan, 2001; Schubiner, Tzelepis, Milberger, Lockhart, Kruger, Kelley, & Schoener, 2000; Tidey, Mehl-Madrona, Higgins, & Badger, 1998)
Perceived stress	(Gordon, 2002; Hoffmann & Cerbone, 2002; Kreek, 1996; McMahon, 2001; Sinha, 2001)
Perceived social support	(McMahon, 2001; Schafer, Schnack, & Soyka, 2000; Word & Bowser, 1997)
Feelings of persecution	(Nnadi, Better, Tate, Herning, & Cadet, 2002)
Negative affectivity	(Henderson & Galen, 2003; Stacy, Newcomb, & Bentler, 1993)
Liberal beliefs regarding drugs	(Newcomb, 1997)
Expectancies	(Boyd, 1998; Henderson & Galen, 2003; Newcomb, 1997)
Regret / guilt	(Gerra, Fertonani, Zaimovic, Rota-Graziosi, Avanzini, Caccavari, Delsignore, & Lucchini, 1995; Goldstein, Powers, McCusker, Mundt, Lewis, & Bigelow, 1996)
Boredom	(Binion, Miller, Beauvais, & Oetting, 1988; Mintz, O'Brien, & Pomerantz, 1979; O'Connor, Berry, Morrison, & Brown, 1995; Stacy, Newcomb, & Bentler, 1993; Yeh, Chen, & Sim, 1995)
Impulsivity	(Allen, Moeller, Rhoades, & Cherek, 1998; Coffey, Gudleski, & Saladin, 2003; Goldberg, Singer, & Garno, 2001; Jentsch & Taylor, 1999; Sarramon, Verdoux, Schmitt, & Bourgeois, 1999)
Promiscuity	(Carlson & Seigal, 1991; Roberts, Wechsberg, Zule, & Burroughs, 2003)
Risk-taking	(Hwang, Ross, Zack, Bull, Rickman, & Holleman, 2000; Sawrie, Kabat, Dietz, Greene, Arredondo, & Mann, 1996)
Sensation-seeking	Jaffe & Archer, 1987; Newcomb, 1997; Sarramon, Verdoux, Schmitt, & Bourgeois, 1999; Stacy, Newcomb, & Bentler, 1993; Zuckerman & Neeb, 1979)
Perceived use by others	(Newcomb & Felix-Ortiz, 1992)
Demographic Correlates	

Age	(Newcomb, 1997; Substance Abuse and Mental Health Services Administration, 2001)
Marital status	(Horowitz & White, 1991; Reisinger et al., CPDD, 2005; Schaar & Ojehagan, 2001)
Employment status	(Ong, 1987; Substance Abuse and Mental Health Services Administration, 2001) (Schaar & Ojehagan, 2001; Reisinger, Dowling, Ensminger, & Chilcoat, 2005)
Educational attainment	(Newcomb, 1997; Ong, 1987; Substance Abuse and Mental Health Services Administration, 2001)
Financial status	(Schaar & Ojehagan, 2001)
Family history of addiction	(Compton, Cottler, Ridenour, Ben-Abdallah, & Spitznagal, 2002; Glavak, Kuterovac-Jagodic, & Sakoman, 2003; Hoffmann & Cerbone, 2002; Lehman, Barrett, & Simpson, 1990; Rounsaville, Kosten, Weisman, Prusoff, Pauls, Anton, & Merikangas, 1991)
Receipt of public assistance	(NIDA National Pregnancy and Health Survey, 1996)
Culture, race	(Bowser & Bilal, 2001; Boyd, 1998; Glavak, Kuterovac-Jagodic, & Sakoman, 2003; McCuller, Sussman, Dent, & Teran, 2001; NIDA National Pregnancy and Health Survey, 1996; Kosten, Gawin, Rounsaville, & Kleber, 1986; Smith, Buxton, Bilal, & Seymour, 1993)
<i>Experiential Correlates</i>	
Child sexual abuse	(Cohen & Densen-Gerber, 1982; Hoffman & Goldfrank, 1990; Kane & DiBartolo, 2002; Schafer, Schnack, & Soyka, 2000)
Child physical abuse	(Cohen & Densen-Gerber, 1982; Dube, Felitti, Dong, Chapman, Giles, & Anda, 2003; Kane & DiBartolo, 2002; Schafer, Schnack, & Soyka, 2000)
Child neglect	(Cohen & Densen-Gerber, 1982; Hoffman & Goldfrank, 1990)
Domestic violence	(Cohen & Densen-Gerber, 1982; Goldstein et al., 1996)
Injury	(Rothstein, Levy, Fecher, Gordon, & Bauman, 1992)
Other interpersonal victimization	(Boyd, 1998; Schafer, Schnack, & Soyka, 2000)
Other trauma	(Dube, Felitti, Dong, Chapman, Giles, & Anda, 2003)
Blackouts	(Buelow & Buelow, 1995)
Home shifts	(Larsson, Eriksson, Zetterstrom, 1979; Stein, Newcomb, & Bentler, 1987)
Conflict within family	(Dube, Felitti, Dong, Chapman, Giles, & Anda, 2003; Glavak, Kuterovac-Jagodic, & Sakoman, 2003; McCuller et al., 2001; Newcomb, 1997; Yeh, Chen, & Sim, 1995)
Poor/limited/ inconsistent consequences for misbehavior	(Newcomb, 1997; Yeh, Chen, & Sim, 1995)
Violence exposure in general	(Inciardi & Surratt, 1998)
Running away in adolescence	(Goldstein, Powers, McCusker, Mundt, Lewis, & Bigelow,

	1996; Morey & Friedman, 1993)
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Appendix B

Recruitment Script

Part A.

“Hello, my name is _____ and I am part of the AWHARE Women’s Health Research team here at VCU. We are conducting a project with pregnant women at Nelson Clinic. May I talk to you for a few minutes?”

“First, can I ask if you are at least 18 years old?”

IF “NO”: “Thank you for your time. At this point, you do not qualify for this study.”

“And, may I ask if you are here today for a RETURN prenatal appointment?”

IF “NO”: “Thank you for your time. At this point, you do not qualify for this study.”

“I am working on a research project that focuses on developing a questionnaire that will help identify women who may need help. The project is ANONYMOUS- it will not require you to tell me your name. It involves a questionnaire that will ask you about your health, activities and habits, childhood and teenage experiences, life experiences, thoughts, and feelings. It will take about 30 minutes to complete after your OB appointment today and you will be given up to \$40 in gift cards for your time.”

“Are you interested in participating today?”

IF “YES”: “Ok, well I will wait for you in the waiting room until you finish your appointment. Afterwards, we can go to our research offices across from Ultrasound and I can tell you more about the project and then you can complete the study if you are interested. Here is a reminder card for the study.”

RA will give the woman a reminder card.

After patient’s appointment, RA will take her to office space, *collect the reminder card*, and read Information Sheet #1 to the patient.

Complete Phase 1.

Part B.

RA will give participant her gift card and then read Information Sheet #2.

“Are you interested in participating in Phase 2?”

IF “YES”: “Ok, I will show you where the restroom is. Once you are inside the restroom, you’ll see a metal cabinet. Inside the cabinet is a urine sample cup. Please fill the cup about 1.5 inches full of urine and then place it back in the cabinet when you are done. I’ll be waiting out here after you have finished.”

Complete Phase 2: RA shows the patient to the restroom. After the patient has provided a sample and left the restroom, the RA will give her Information Sheet #3, give her a gift card, and thank her for her participation.

Appendix C

WIDUS-P Development Version

“Basic Information About Me.”		
Here are some questions about you...your living, and work situation right now...Okay, here we go...		
1. How old are you?		a) 18-21
		b) 22-25
		c) 26-29
		d) 30-33
		e) 34-37
		f) ≥ 38
2. What is your ethnic background?		a) American Indian or Alaska Native b) Black or African American c) Hispanic or Latino d) Native Hawaiian or other Pacific Islander e) Asian f) White g) Middle Eastern American (Assyrian, Lebanese, Kurdish, Arab, Aramaic, etc) h) More than one race i) Unknown
3. I am currently married. (5)	True	False
4. I graduated from high school or completed my GED. (6)	True	False
5. I am currently working 20 hours or more per week. (7-edited)	True	False
6. I currently have health insurance through an employer, either mine	True	False

or a family member's (do not include Virginia Premier). (8 edited)		
7. I currently receive some form of public assistance, such as food stamps, WIC, Medicaid, SSI, or TANF. (9)	True	False
“My Health.” Here are some True and False questions about your health...		
8. At least once in my life, I have been diagnosed with a sexually transmitted disease, such as gonorrhea, Chlamydia, Herpes, syphilis, HIV, or any other sexually transmitted infection. (12)	True	False
9. I have been diagnosed with Hepatitis C. (13)	True	False
10. I almost always use condoms during sex. (14)	True	False
11. I often eat fast food and/or junk food. (15)	True	False
12. I have been treated at an emergency room in the past year. (16)	True	False
13. I have missing teeth. (17)	True	False
14. In the past year, I have been bothered by pain in my teeth or mouth. (18)	True	False
“My Activities and Habits.” We'd like to know just a little about what you do, and some of your habits... We ask everybody the same questions...you may or may not do these things... Remember, no one will know your answer...		
15. I have smoked at least 100 cigarettes in my entire life. (19)	True	False
16. I was a daily smoker during the year before I became pregnant. (20)	True	False
17. I smoked at least one cigarette the week before I learned I was pregnant. (21-revised)	True	False
18. I'm often around second hand cigarette smoke. (25)	True	False
19. Most of my friends smoke cigarettes. (26)	True	False
20. At least two of my closest friends use marijuana. (27)	True	False
21. Most of my friends think marijuana is no big deal. (29)	True	False
22. I have at least one caffeinated beverage (for example, caffeinated soda, coffee, or energy drink) every day. (31-revised)	True	False

“My Childhood and Teenage Experiences.” We'd like to ask you about some things that you, may or may not have experienced in your childhood and teenage years...you may or may not have seen similar questions before, but they are different because we are asking about your childhood or teenage years... Please answer True or False on each statement...let's go...		
23. When I was a child, I saw adults in my home physically hurting each other. (34)	True	False
24. When I was a child, I saw someone get stabbed, shot, or seriously beaten. (35)	True	False

25. When I was a child, an adult hit me hard enough to cause bleeding, bruises, or welts. (36)	True	False
26. When I was a child, an adult touched my private parts in a sexual manner, or got me to touch their private parts in a sexual manner. (37)	True	False
27. When I was a child, I saw people using drugs in my home. (40)	True	False
28. Since my sixteenth birthday, I have had fractures or dislocations to my bones or joints. (42)	True	False
29. Since my sixteenth birthday, I have injured my head. (44)	True	False
30. Since my sixteenth birthday, I have been injured in an assault or fight (not counting injuries during sports). (45)	True	False

“My Lifetime Experiences.” We'd like to ask you about some things that you may or may not have experienced in your lifetime...you may or may not have seen similar questions before, but they are different because we are asking about your whole life. Please answer True or False on each statement...		
31. There have been times in my life, for at least two weeks straight, where I felt completely worthless. (47)	True	False
32. There have been times in my life, for at least two weeks straight, where I felt completely hopeless about things. (48)	True	False
33. There have been times in my life, for at least two weeks straight, where I felt so down or depressed that nothing could cheer me up. (49)	True	False
34. There have been times in my life, for at least two weeks straight, where it felt like everything was an effort. (50)	True	False
35. As an adult, I have been badly beaten up at least once. (53)	True	False
36. As an adult, I have seen somebody get stabbed, shot, or seriously beaten. (54)	True	False
37. One or more of my biological parents have had a problem with drugs or alcohol. (56)	True	False
38. One or more of brothers or sisters has had a problem with drugs or alcohol. (57)	True	False
39. I have been abandoned by someone I love more than most people have. (60)	True	False
40. I have been in trouble with the police. (61)	True	False
41. In my lifetime, I have been hit, slapped, kicked or otherwise physically hurt by someone.	True	False
42. There have been times in my life I have not felt safe around my current partner or past partner.	True	False

<p>“My Recent Experiences.”</p> <p>We'd like to ask you about some things that you may or may not have experienced recently...you may or may not have seen similar questions before, but they are different because we are asking ONLY about recent experiences. Please answer True or False on each statement...</p>		
43. Within the last year, I have been hit, slapped, kicked or otherwise physically hurt by someone.	True	False
44. During my current pregnancy, I have been hit, slapped, kicked, or otherwise physically hurt by someone	True	False
45. In the past year, I've gone hungry because I didn't have enough money to buy food.	True	False
46. It's hard to get places because of transportation.	True	False
47. In the past 12 months, I've worried about my housing situation.	True	False
48. I often move from place to place.	True	False

<p>“My Personality, Attitudes, and Feelings.”</p> <p>We would like to ask you some True or False questions about you, your personality, attitudes, and feelings...everybody's answers are different... Some questions may or may not make you feel uncomfortable...so, do your best to answer the questions... Remember that nobody will know your answers... This section is the longest one, it should take about 5 minutes.</p>		
49. In the past year, the police have been called to my home because of a fight or argument. (67)	True	False
50. Things have usually gone against me in life. (69)	True	False
51. I get mad easily and feel a need to blow off some steam. (70)	True	False
52. Some of my immediate family members are pretty violent. (71)	True	False
53. I feel overwhelmed by my life and my problems. (75)	True	False
54. I get bored easily. (79)	True	False
55. I live life on the edge. (80)	True	False
56. I have conflict with people in authority, like teachers, supervisors, and the police. (81)	True	False
57. I experience “flashbacks” of bad things that have happened to me. (82)	True	False
58. At least one person in my immediate family (parent, brother, or sister) has had problems with depression. (83)	True	False
59. I sometimes do really harmful things to myself. (84)	True	False
60. In elementary school, I often got into trouble with teachers or the principal because of my behavior (fighting, talking in class, or coming to class late). (85)	True	False

61. I am easily upset about things. (86)	True	False
62. When I was younger than 13 years old, I often stayed out past midnight. (87)	True	False
63. I have seen or experienced worse things than most other people have. (90)	True	False
64. Over the past month, I have felt down, depressed, or hopeless. (91)	True	False
65. Drugs are everywhere in my neighborhood. (94)	True	False
66. I often have trouble sleeping (not counting during pregnancy). (95)	True	False
67. I feel very overwhelmed when thinking about taking care of a new baby. (96)	True	False
68. I have repeated and disturbing memories of a stressful thing that happened to me. (99)	True	False
69. I lose my temper very easily. (100)	True	False
70. In the past, I have told someone that I was going to hurt myself. (105)	True	False
71. I often feel empty inside. (108)	True	False
72. In the past, I have attempted to hurt myself. (114)	True	False
“My current pregnancy” So, now we’d like to ask you some questions related to your pregnancy.		
73. How many weeks pregnant are you?	1-42	
74. How many weeks pregnant were you when you first thought you might be pregnant?	1-42	
75. How many weeks pregnant were you when attended your 1 st OB appointment.	1-42	
76. Thinking back to just before you got pregnant, how did you feel about becoming pregnant?	a) I wanted to be pregnant sooner. b) I wanted to be pregnant then. c) I wanted to be pregnant later. d) I didn’t want to be pregnant then or at any time in the future. e) I don’t know.	
77. How many times have you been pregnant, including the current pregnancy?	This is my first pregnancy, 1,2,3,4,5, 6, 7, 8 or more	
78. How many of these pregnancies ended in the birth of a live baby?	None, 1,2,3,4,5, 6, 7, 8 or more	
79. Have you ever had a baby that died during birth or was stillborn?	Yes	No

80. Have you ever had a pregnancy that ended during the first 4 months (not including an abortion)?	Yes	No
81. Have you ever had a pregnancy that ended after 4 months but before birth?	Yes	No
82. Have you ever had an abortion?	Yes	No
83. Are you currently in a relationship?	a) Yes, with the father of my baby. b) Yes, with someone other than the father of my baby. c) No, I am not in a relationship.	
“The father of this baby” We’d like to know just a little about your relationship with the father of your baby and some of his habits... We ask everybody the same questions...you may or may not do these things... Remember, no one will know your answer...		
84. Thinking about the amount of contact you’ve had with the father of this baby, which statement best fits you?	a) I’ve had contact with the father of this baby in the past and right now. b) I’ve had contact with the father of this baby in the past but not right now. c) I don’t know the father of this baby that well.	
85. The father of this baby currently smokes cigarettes.	True	False
86. The father of my baby thinks marijuana is no big deal.	True	False

Appendix D

Information Sheet #1

ANONYMOUS SURVEY **Consent Information Sheet**

Are you pregnant?

Part One

- We would like your help in developing a questionnaire that will help identify women who may need help. This survey is for pregnant women who are 18 years of age and older and who are coming to Nelson Clinic for prenatal care.
- If you choose to participate, we'll ask you to complete a questionnaire on the computer while you wait to be called back for your appointment. This survey will take about 20 minutes and will ask you about many different things about yourself, including your background information, health, activities and habits, childhood and teenage experiences, lifetime experiences, personality, attitudes, thoughts, and feelings.
- There are very few risks to you for participating. You may find some questions easy to answer and others may be harder to answer. Please be as honest as possible. If you get uncomfortable and don't want to answer a question, that is ok. If you start the survey and don't want to finish that is ok too.
- This questionnaire is ANONYMOUS, meaning we are not asking you for your name so we won't be connecting your name with your answers.
- Your participation is VOLUNTARY and whether you choose to participate or not will not affect your care at Nelson Clinic.
- For completing the survey, we will give you a \$20 gift certificate.

Part Two: We'll tell you more about part two after you have completed Part One.

This project is a VCU-sponsored research project. If you have any questions about the project, please call Courtney Smith at (804)-628-2553 or Dr. Svikis at (804)-827-1184. Thank you for your help! We appreciate your input and feedback.

If you have any questions about your rights as a participant in this study, you may contact: Office for Research, Virginia Commonwealth University, 800 E. Leigh Street, Suite 113, P.O. Box 980568, Richmond, VA, 23298. Telephone: 804-827-2157.

*****OPTIONAL:** You can sign this consent form if you want to do so. Your signature is not required to participate in the study.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study.

Participant name print	Participant signature	Date
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Witness name printed	Witness signature	Date
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Name of person conducting Informed Consent printed	Signature	Date
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Investigator signature (if different from above)
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Appendix E

Information Sheet #2

Thank you for participating in Part One! Now, we'll tell you about Part Two.

Part Two: The second part of this project asks for your verbal permission to drug test your urine. If you agree to participate, the staff member will perform the test after you provide a sample for the study. They will test your urine in the bathroom without any clinic staff, doctors, or nurses present. After the testing is complete, they will immediately discard the results. Your results will not have your name on it and will NOT be shared with any staff, doctors, or nurses at Nelson Clinic. For your participation, you will be given a \$20 gift card. Just like Part One, your participation is voluntary and will not affect your care at VCUHS.

This project is a VCU-sponsored research project. If you have any questions about the project, please call Courtney Smith at (804)-628-2553 or Dr. Svikis at (804)-827-1184. Thank you for your help! We appreciate your input and feedback.

*****OPTIONAL:** You can sign this consent form if you want to do so. Your signature is not required to participate in the study.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study.

Participant name print	Participant signature	Date
Witness name printed	Witness signature	Date
Name of person conducting Informed Consent printed	Signature	Date
Investigator signature (if different from above)		

Information Sheet #2

Appendix F

Information Sheet #3

Thank you for participating in both Part One and Two of this project. Your help is greatly appreciated. We asked you about Part Two after you completed Part One because we wanted you to answer the questions as any pregnant woman attending prenatal care would do. That is, we did not want to influence your responses to Part 1. If you have any questions about the project, please call Courtney Smith at (804)-628-2553 or Dr. Svikis at (804)-827-1184. Again, thank you for your time!

Vita

Courtney Elizabeth Smith was born on July 16, 1984 in Milwaukee, Wisconsin, and is an American citizen. She graduated from Brookfield Central High School, Brookfield, Wisconsin in 2002. She received her Bachelor of Arts in Psychology and Spanish from Denison University, Granville, Ohio in 2006. She received a Master of Science Degree from Virginia Commonwealth University in 2009.