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DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF
AN INSTRUMENT TO ASSESS THE TREATMENT FIDELITY OF A
BRIEF OPPORTUNISTIC INTERVENTION TO REDUCE SUBSTANCE USE
AMONG PREGNANT WOMEN

A Dissertation

Submitted to the School of Nursing

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By

Antonia Rae Torrey

August 2011

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Antonia Rae Torrey

2011

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ABSTRACT

DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF AN INSTRUMENT TO ASSESS THE TREATMENT FIDELITY OF A BRIEF OPPORTUNISTIC INTERVENTION TO REDUCE SUBSTANCE USE AMONG PREGNANT WOMEN

By

Antonia Rae Torrey

August 2011

Dissertation supervised by Linda Goodfellow PhD, RN

Although abstinence from alcohol, tobacco, and other drugs (ATOD) among pregnant women is a leading national objective, prenatal use has not decreased. Evidence-based interventions that can be replicated in practice are critically needed and brief interventions have shown promise in reducing prenatal ATOD use. The “I Am Concerned” (IAC) brief opportunistic intervention is currently being implemented by frontline primary prenatal care staff members in several areas of the United States. Evaluation of treatment fidelity, to determine if behavioral interventions are delivered as intended, is essential to controlled research. This study constituted the first step in the development and psychometric evaluation of an instrument designed to measure the treatment fidelity with which the IAC brief opportunistic intervention is implemented. A conceptual framework derived from motivational interviewing and self-determination

theory, both based on the fundamental assumption that individuals are inherently inclined toward positive change, guided operationalization of the IAC behavioral elements that ultimately took shape as the 18-item IAC treatment fidelity instrument.

This methodologic study used a 6-phase protocol to develop and refine the IAC treatment fidelity instrument and evaluate its psychometric properties. Independent raters used the instrument to evaluate audio recordings (N = 49) of experienced frontline staff members implementing the IAC brief opportunistic intervention with standardized patients portraying ATOD-using pregnant women in a simulated clinic setting.

Psychometric analysis provided evidence of content validity. Intra-class correlation coefficients (ICC) calculated for inter-rater reliability were satisfactory for subscales (0.64) and (0.62) and ranged from -0.07 to 0.81 for individual items. Internal consistency alpha coefficients were satisfactory for the total scale (0.72) and lower than acceptable for adherence (0.54) and competence (0.56) subscales. Overall high rater percentage agreement and negatively skewed ratings distribution indicated that reliability results were paradoxically low due to the base rate problem. The study results support revision and ongoing testing of the IAC treatment fidelity instrument.

DEDICATION

This dissertation is dedicated foremost to my husband, Clifford Paul Torrey, whose steadfast support, patient understanding, and unwavering confidence helped me to persevere and made it possible for me to complete this endeavor. I also dedicate this work to my children, Jesse Lynne Torrey, Barbara Gay Torrey Workman, Austin Roy Torrey, and Madalyn Wolf Torrey, whose love and laughter helped me to maintain some perspective and remember that there is more to life than academia. Finally, I dedicate this to my mother, Lynne Henderson, who raised me to believe that I was capable of accomplishing anything.

Looking backward to those who started me on this journey, my heartfelt appreciation to my dear friend and once boss Kathy Borland, who counseled me to learn to type properly and carry on with my nursing education. I followed some of her advice. I also extend my gratitude and respect to four exceptional nurses who, by example, demonstrated the value of a doctoral education: my sister Dr. Dorothy Jo Henderson, who first lit the spark that influenced me to pursue a PhD in nursing, Dr. Ann Grant who has long inspired me with her vision of nursing, Dr. Colleen Love, whose perceptiveness and insight galvanized my desire to become a nurse researcher, and Dr. Helen M. Ference, whose teachings infused the study of nursing with magic.

I also give thanks to a circle of extraordinarily compassionate women whose positive presence and empathy brought me understanding when I most needed it: my sister Sulinda Jane Torrey, sister-in-law Mary Lee Torrey, niece Sara Yost, and dear friends Vicki Carroll and Suzanne Hustedt.

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Chapter I

Introduction

Statement of the Problem

Prenatal substance use is a foremost public health concern that transcends societal boundaries (Chasnoff, Landress, & Barrett, 1990; Vega, Kolody, Hwang, & Noble, 1993), affecting not only the pregnant woman and her fetus, but her family and community as well (Ettliger, 2000; Reis, Mills-Thomas, Robinson, & Anderson, 1992; Sun, 2004). Negative sequelae associated with prenatal use of alcohol, tobacco, or other drugs (ATOD) have been well established (Armstrong et al., 2003; Bennett, 1999; Mahony, 1998; Redding & Selleck, 1993; Shiono et al., 1995). Prenatal ATOD exposure has been linked to significant fetal complications including prematurity (Shiono, Klebanoff, & Rhoads, 1986), brain damage (Riley, McGee, & Sowell, 2004), and intrauterine death (Mahony, 1998). Neurobehavioral teratogenic effects associated with prenatal substance exposure include impaired executive function (Fried, 2002), lifelong learning disabilities, and mental retardation (Streissguth et al., 1991).

Abstinence from alcohol, cigarettes, and illicit drugs among pregnant women are leading maternal and infant health objectives that have been targeted in the agendas set by Healthy People 2000, 2010 (Centers for Disease Control and Prevention, 2000). Despite this national focus, prenatal use of these substances has not decreased (Substance Abuse and Mental Health Services Administration, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010).

Background

Pregnancy has been described as a unique window of opportunity to positively influence the substance-using woman (Daley, Argeriou, & McCarty, 1998). The regular contact afforded by prenatal care allows providers an unparalleled chance to identify pregnant women who are using potentially harmful substances. Current obstetric practice guidelines recommend universal screening of pregnant women for past and present ATOD use to facilitate timely recognition during the critical stages of fetal development (American Academy of Pediatrics, 2002; American College of Obstetricians and Gynecologists, 2008; American Society of Addiction Medicine, 1989). However, prenatal care providers frequently fail to identify and intervene with substance-using patients (Chasnoff, Neuman, Thornton, & Callaghan, 2001). Deficient knowledge regarding treatment, lack of time, personal discomfort, and fear of acquiring a reputation that would deter patients have all been reported as reasons why practitioners fail to screen routinely for substance use by their pregnant patients (Zellman et al., 1999).

Societal attitudes toward pregnant women who drink alcohol, smoke cigarettes or use drugs are negative, influenced by traditional beliefs about femininity and motherhood (Carter, 2002). Society's stigmatic, punitive view of prenatal substance use contributes to the difficulties associated with the identification and treatment of this complex health disorder (Reis et al., 1992). Pregnant women are reluctant to disclose ATOD use, fearing negative responses such as distrust, labeling, disenfranchisement, incarceration, prosecution, and loss of custody (Jessup, Humphreys, Brindis, & Lee, 2003; Selleck & Redding, 1998; Tillett & Osborne, 2001). When prenatal ATOD use is identified, women frequently deny the need for assistance to reduce their use (Howell & Chasnoff, 1999).

Relatively few pregnant women accept referrals to substance use treatment and, among those who do, less than half follow through with the full course of treatment (Brady & Ashley, 2005).

There is a critical need for effective interventions that can be promptly implemented in the primary prenatal care setting when a pregnant woman discloses potentially harmful substance use to a healthcare provider. Brief interventions are time-limited, patient-focused, counseling strategies, implemented with the goal of motivating healthy decision-making, that have shown promise in the treatment of problem behaviors (Clay, 2010). Brief interventions are not only used for patients actively seeking treatment, but can occur opportunistically when health care providers become aware of problem behaviors during encounters that were initiated by patients for another reason (Moyer, Finney, Swearingen, & Vergun, 2002). Brief drinking-focused interventions have been used effectively during clinical encounters between health care providers and patients to motivate change (Bien, Miller, & Tonigan, 1993; Emmen, Schippers, Bleijenberg, & Wollersheim, 2004). Researchers have also reported success using this methodology in decreasing substance use during pregnancy (Armstrong et al., 2003; Chang et al., 2005; Ferreira-Borges, 2005; O'Connor & Whaley, 2007). Despite the reported success of these and similar studies, they lack key methodological ingredients that are critically needed to facilitate effective translation of a promising brief intervention from the research setting to the practice arena.

Before a behavioral therapy can be generalized to clinical practice, it must meet the standards required of an empirically supported therapy by incorporating and reporting methodological aspects that make it reasonable to assume that the positive

effects observed were actually a result of the experimental treatment rather than from other confounding factors (Carroll & Rounsaville, 2007; Chambless & Hollon, 1998). This can be illustrated by comparing behavior therapy research to a controlled clinical trial conducted to investigate the effectiveness of a new drug. In addition to all of the procedural elements required of any randomized, controlled clinical trial, a drug clinical trial must stipulate specifics regarding the drug's pharmacokinetics and the precise dosages used in the study. This same rigor is required of a clinical trial seeking to determine the efficacy of a behavioral intervention. The study must incorporate and provide precise information about the components of the treatment intervention that distinguishes it from other behavioral interventions, and provide methodological assurance that the treatment intervention was actually delivered.

Monitoring and evaluating treatment fidelity, to determine if the intervention was delivered as intended, is an essential requirement of controlled therapeutic intervention research (Bellg et al., 2004). This imperative has become progressively evident as the literature increasingly abounds with reports of efficacious behavioral therapies that fail to be put into practice (Carroll & Rounsaville, 2007).

Brief intervention implementation is a flexible, dynamic, individualized event, and these factors must be considered when designing fidelity assessment strategies. Measurement of treatment fidelity requires use of a research instrument that indexes the essential elements of an intervention and quantifies interventionist behaviors (Stein, Sargent, & Rafaels, 2007). Development of a treatment fidelity instrument entails operationalization of the treatment concepts and clinical protocol, guided by the theory on which the brief intervention is founded (C. F. Waltz, Strickland, & Lenz, 2005).

There are further considerations to be taken into account in the potential extrapolation of an efficacious intervention to the clinical practice setting. Most brief intervention studies that have been published to date have used specialists, such as physicians or therapists, in the role of interventionist. While such a design undoubtedly optimizes internal validity, it limits applicability to the real world of managed primary care where cost issues are a paramount consideration, and specialist time is a rare and expensive commodity ("Rising Costs Force," 2004; Wallace & Savitz, 2008). Primary care personnel with the earliest and most sustained contact with patients are frontline staff (Grumbach, Osmond, Vranizan, Jaffe, & Bindman, 1998). Frontline caregivers found in primary care offices or clinics are usually registered nurses, licensed vocational nurses, licensed practical nurses, and medical assistants (Chasnoff, McGourty, Wells, & McCurties, 2008; Grumbach & Bodenheimer, 2004). If potentially harmful substance use is disclosed to the caregiver, the apposite response is a brief opportunistic intervention (Chang, 2004). If potentially harmful substance use is disclosed to the caregiver, the apposite response is a brief opportunistic intervention

Prenatal care providers in several areas of the United States (Alabama, Arkansas, California, Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, New Jersey, New Mexico, Nevada, Oklahoma, Oregon, West Virginia, and the Commonwealth of Puerto Rico) use frontline staff to implement a particular brief opportunistic intervention for pregnant women who disclose current ATOD use (Chasnoff et al., 2008; Children's Research Triangle, 2008). This is the "I Am Concerned" (IAC) brief opportunistic intervention, which was specifically developed to address harmful prenatal substance use (Chasnoff & McGourty, 2003).

Awareness of IAC implementation by frontline staff, coupled with a lack of research demonstrating large-scale success with brief interventions in reducing ATOD use in pregnancy stimulated this proposal, which was born out of a desire to determine the efficacy of the IAC brief intervention when implemented by frontline staff. This study is the first step toward realizing this goal. There is a critical need for controlled clinical research that incorporates rigorous assessment of treatment fidelity to foster identification of evidence-based, efficacious interventions that help to reduce prenatal substance use. Such studies are necessary to promote effective translation from the research setting to primary care practice where the treatment can benefit childbearing women, their families, and society.

Purpose of the Study

The specific aims of this study were to: (a) develop an instrument that can be used accurately and reliably to measure the treatment fidelity with which the IAC brief opportunistic intervention is implemented; and (b) establish evidence of validity and reliability associated with the use of this instrument.

The long-term goals of this line of research are to: (a) use this instrument to measure and ascertain the treatment fidelity with which frontline staff implement the IAC brief opportunistic intervention when it is delivered in a clinical setting for pregnant women who disclose ATOD use, (b) determine the efficacy of the IAC brief opportunistic intervention when implemented by frontline staff through randomized controlled study, and (c) disseminate the findings derived from this research to foster use of evidence-based interventions and reduce maternal ATOD use and adverse fetal consequences.

Research Questions

This dissertation project answered the following questions:

1. What is the content validity associated with an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco, and other drugs by pregnant women?
2. What is the inter-rater reliability associated with use of an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco and other drugs by pregnant women?
3. What is the internal consistency reliability associated with use of an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco, and other drugs by pregnant women?

Operational Definitions of Study Terms

Frontline staff members. These are primary health care personnel who interact with patients in advance of physicians or mid-level practitioners. The frontline staff members who work in prenatal offices or clinics are usually registered nurses, licensed vocational nurses, or medical assistants.

Brief opportunistic intervention. A short, structured, behavioral treatment implemented by prenatal care providers when a clinical opportunity is presented to facilitate healthy decision-making on behalf of clients who are not specifically seeking treatment to reduce their ATOD use.

Treatment fidelity. This is the degree to which the IAC brief opportunistic intervention is delivered as intended by the treatment protocol. The components of treatment fidelity are: (a) adherence, the extent to which the essential elements that distinguish the IAC brief opportunistic intervention have been implemented; and (b) competence, the quality of implementation and the skill with which frontline staff deliver the intervention and exhibit behaviors likely to engage and motivate clients.

Prenatal substance use. Denotes any use of alcohol, tobacco, or illicit drugs, or misuse of prescription drugs during pregnancy.

Standardized patient. Individual recruited and trained to act as a real patient to simulate a set of symptoms or problems. In this study, associate degree nursing students were the standardized patients. They portrayed ATOD-using pregnant women in a simulated clinical environment.

Assumptions Underlying the Research

This study rested on the following assumptions:

1. Psychological traits and behaviors can be quantified and measured.
2. It is possible to measure treatment fidelity in a simulated clinical situation.
3. Independent raters listening to audio recordings of treatment sessions will be able to determine quantitative, objective measurements of treatment fidelity.

Significance to Nursing

Despite additional funding designated for the treatment of drug-addicted, childbearing women, little progress has been achieved with the national initiatives that have been implemented to discourage prenatal substance use (Substance Abuse and Mental Health Services Administration, 2008). National objectives regarding prenatal

substance exposure remain unrealized as abstinence rates associated with alcohol and other drugs have declined or remained the same (National Center for Health Statistics, 1999). There is significant need for research to identify interventions that will decrease rates of ATOD use among childbearing women. This research endeavor was an initial step in addressing this need.

Nursing researchers seek to provide evidence that supports the use of particular practices that are effective and efficient (Polit & Hungler, 1999). This study was premised on the staffing mix found in the primary health care environment and the reality of spiraling health care costs. Frontline staff members are cost-effective caregivers and, as such, they interface first and most frequently with patients. Prenatal care providers are using frontline prenatal clinic staff to implement the IAC brief opportunistic intervention for pregnant women who disclose current ATOD use (Chasnoff, Wells, McGourty, & Bailey, 2007). However, the quality of brief intervention implementation by this level of provider has yet to be determined. This study was a necessary first step toward determining the treatment fidelity with which frontline staff members implement brief opportunistic interventions in the primary clinic setting. In addition, the findings of this study will lay the foundation for a future randomized, controlled study measuring the efficacy of the IAC brief opportunistic intervention.

Chapter 2

Review of Literature

The continuing phenomenon of potentially harmful ATOD use during pregnancy has driven the quest for effective treatments (American College of Obstetricians and Gynecologists Committee on Ethics, 2004). Brief interventions using motivational interviewing techniques have shown promise in reducing prenatal substance use (Armstrong et al., 2003; Ferreira-Borges, 2005; Haug, Svikis, & DiClemente, 2004; O'Connor & Whaley, 2007). However, meaningful, replicable findings from randomized clinical trials exploring the efficacy of brief interventions are dependent on faithful delivery of the independent variable. A valid and reliable instrument enabling assessment and quantification of interventionist behaviors is necessary to establish treatment fidelity. The literature review for this research was organized around these elements and includes a summary of the research findings related to the harmful effects of prenatal ATOD exposure, brief intervention study findings and a comprehensive examination of the literature associated with treatment fidelity. I begin by describing the conceptual framework that provided the theoretical context for this study.

Conceptual Framework

This study was guided by concepts derived from motivational interviewing (MI), first described in 1983 when psychologist William R. Miller published an article explicating the innovative process he used to intervene with problem drinking. In the ensuing years, the concepts and approaches fundamental to MI have been further refined, elaborated and articulated (Miller & Rollnick, 1991, 2002), and MI's theoretical framework has evolved through substantial testing (Miller & Rollnick, 2009).

Motivational interviewing. MI grew out of dissatisfaction with the confrontational, aggressive strategies that were widely advocated at the time for the treatment of addictive behaviors (Miller & Rollnick, 1991). Defined as a “client-centered, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence” (Miller & Rollnick, 2002, p. 25), MI draws on constructs from several theoretical frameworks. The emphasis placed by client-centered theory on empathy as a critical condition of a therapeutic atmosphere (C. R. Rogers, 1956) was credited as providing significant inspiration during the development of MI. Maintaining a structured and directive therapeutic interaction within a collaborative environment is a hallmark of cognitive therapy (Beck, Wright, Newman, & Liese, 1993) that also became a central element of MI. Other theories that influenced the development of MI include cognitive dissonance theory (Festinger & Carlsmith, 1959), which posits that people are driven to reduce inner conflict created by discrepancies between their actions and their beliefs, and the theory of self-perception (Bem, 1967), which holds that people tend to develop attitudes by observing their behaviors, rather than the reverse.

Miller and Rollnick (1991) aligned MI with key constructs of the trans-theoretical model of change (Prochaska & DiClemente, 1982). This model includes the hypothesis that individuals who are modifying behaviors move from a state of pre-contemplation, when no change is being considered, into a cyclical, multi-stage process that progresses through contemplation, determination, action, maintenance, and relapse. Prochaska and DiClemente’s inclusion of relapse as a normal, nonpathologic stage in the process of change was significant because it acknowledged that individuals often return to previous behaviors when attempting to change long-standing patterns. The original trans-

theoretical model was conceptualized as a wheel of change, around which individuals typically circled several times before achieving stable behavior change (Prochaska & DiClemente, 1982), later revised to a spiral model, reflecting research findings that relapsing individuals typically reinitiate the process of change in the contemplation or preparation stages instead of regressing all the way back to the pre-contemplation stage (Prochaska, DiClemente, & Norcross, 1992). Initially, MI theory included a hypothesis that motivational approaches should differ in accordance with the location of the client in the change process, and specific therapeutic tasks targeted to each of the trans-theoretical stages were originally recommended to facilitate client progress toward sustained change. (Miller & Rollnick, 1991). However, this hypothesis was not supported by the findings of Project MATCH, a large clinical trial conducted to determine if patient-treatment matching improved outcomes for alcohol dependent individuals (Project MATCH Research Group, 1998).

Principles of motivational interviewing. W. R. Miller and Rollnick (2002) identified four general principles involved in the application of MI. These are: expressing empathy, developing discrepancy, rolling with resistance, and supporting self-efficacy.

Empathy is defined as “the quality or process of entering fully, through imagination, into another’s feelings or motives” (Barnhart & Barnhart, 1984, p. 691). An empathetic counseling approach is not unique to MI, because many forms of Rogerian client-centered psychotherapy involve empathy on the part of the therapist to some degree. However, MI places particular emphasis on empathy, which is described as a “fundamental and defining characteristic” (Miller & Rollnick, 2002, p. 37). Expressing empathy involves perceiving the world from the perspective of the client through

respectful, reflective listening (Miller & Rollnick, 1991, 2002). The therapeutic attitude that frames this principle is one of acceptance, a mind-set that denotes understanding rather than agreement or endorsement. This attitude of respect and acceptance is believed essential to the creation of a therapeutic alliance that will foster change. Observer ratings of therapist empathy were found to be predictive of positive therapeutic outcomes in a study conducted by W. R. Miller, Taylor, and West (1980) with problem drinkers, as well as in a large meta-analysis of empathy research (Bohart, Elliott, Greenberg, & Watson, 2002). Another crucial aspect of this principle is recognition that client ambivalence is a normal component of change, and is to be expected rather than viewed as aberrant.

The second principle of MI is intentional development of discrepancy, predicated on the hypothesis that people are motivated to change when they perceive inconsistencies between their behaviors and their core values (Miller & Rollnick, 1991, 2002). This directive approach is a departure from traditional client-centered counseling, which is non-directive and exploratory (C. R. Rogers, Kirschenbaum, & Henderson, 1989). MI involves facilitating clients' awareness of the discrepancy between the way they want their life to be versus their current behavior through the use of techniques such as open-ended questions, that elicit change talk (self-motivating speech) (Miller & Rollnick, 2002). The therapist attempts to amplify the perception of discrepancy by reflecting, elaborating, and affirming the client's change talk. A significant correlation was established between the frequency and strength of commitment language voiced by drug-using clients during the final moments of MI therapy and their degree of abstinence at a 1-year follow-up (Amrhein, Miller, Yahne, Palmer, & Fulcher, 2003). The therapeutic goal is to help the client develop awareness of discrepancy without feeling pressured or

coerced to do so. In keeping with this goal, a fundamental dynamic involved in developing discrepancy is that it is the client, not the therapist, who articulates the reasons for change. This accords with the finding that motivation tends to be enhanced when people hear themselves presenting arguments in support of change, as opposed to hearing them voiced by another (Bem, 1967). Although the mechanism by which MI triggers behavior change is unclear, the occurrence of increased commitment language may evidence a pivotal decision to engage in the process of change (Miller & Rose, 2009).

Because MI-guided therapists expect clients to be ambivalent regarding the importance of change, it follows that client reluctance to change will also be viewed as a normal, non-pathological part of the change process. This philosophy is manifested in the third general MI principle, rolling with resistance (Miller & Rollnick, 1991, 2002). Client resistance is not only expected, it is conceptualized as a treatment opportunity that can facilitate meaningful movement in the direction of change. Any resistance on the part of the client is met with therapist nonresistance, and argument is assiduously avoided. Clients' feelings are respected and acknowledged through reflective responses, and resistant comments are viewed as an indication to respond differently or alter the approach. MI places clients, rather than therapists, in the role of the expert who must find solutions to the problems they have identified. In keeping with this overriding philosophy, client questions are typically reframed and directed back to the client. A controlled comparison conducted with problem drinkers found a directive-confrontational counseling approach significantly predictive of increased frequency of client resistant

responses during therapy and their reported level of alcohol consumed at the 12-month follow-up (Miller, Benefield, & Tonigan, 1993).

The fourth theoretical premise upon which MI is based is the concept of self-efficacy (Miller & Rollnick, 1991, 2002). Self-efficacy, defined as an appraisal of one's ability to carry out a specific task (Bandura, 2007), is a key predictor of an individual's degree of perseverance (Bandura, 1977). Support of client self-efficacy flows logically from previous MI principles; the assertion that the client has the sole responsibility to direct change implies that the client is perceived as capable of doing so (Miller & Rollnick, 1991, 2002). An intrinsic aspect of this principle is recognition that the therapist's own belief in the client's ability to accomplish meaningful change can work as a "self-fulfilling prophecy" (Miller & Rollnick, 2002, p. 41). The outcomes of individuals receiving treatment for alcoholism were significantly influenced in the direction of therapists' expectancies (Leake & King, 1977; Parker, Winstead, & Willi, 1979). Viewed from an MI perspective, enhancing confidence is an attribute that is elicited, rather than imposed by the therapist, through interviewing techniques that include reframing, affirming previous successes, brainstorming, and providing information when appropriate within the context of the therapeutic interaction (Miller & Rollnick, 2002).

Spirit of motivational interviewing. Miller and Rollnick (2002) emphasized that MI is more of "a way of being with people" (p. 34) than a set of techniques and cautioned that effective application of MI requires thoroughly understanding the spirit of MI. The components of the fundamental spirit of MI are (a) creating a collaborative and supportive atmosphere; (b) evoking motivation for change from within the client; and (c) affirming and respecting the client's autonomy. Collectively, these overarching

characteristics generate the fundamental nature that appropriately occurs within the context of MI-guided therapy.

The FRAMES model. Various modified approaches have been developed that integrate the spirit and principles of MI with non-motivational interviewing techniques (Miller & Rollnick, 2002); these have been termed “adaptations of motivational interviewing” (AMI) (Burke, Arkowitz, & Menchola, 2003). Most studies testing the efficacy of MI have been found to involve AMIs (Burke et al.), rather than the pure clinical style described by Miller and Rollnick (1991, 2002). One such AMI is the FRAMES model, a brief intervention approach that has been widely adopted as a strategy to stimulate and support client behavior change (Miller & Rollnick, 1991). FRAMES provided inspiration to the authors of the IAC brief opportunistic intervention (Chasnoff & McGourty, 2003) that is at the core of this study. The acronym “FRAMES” represents the key elements embodied with this approach:

1. Feedback is provided regarding the interventionist’s appraisal of the client’s current health status.
2. Responsibility of the client for behavior change is explicitly emphasized.
3. Advice is given unambiguously to make a change.
4. Menu of strategies is provided that can assist the client to achieve change.
5. Empathy forms the foundation of the interventionist’s interaction with the client.
6. Self-efficacy is fostered and reinforced by the interventionist.

Numerous clinical trials have investigated the effectiveness of MI techniques in the treatment of addictive behaviors, and several meta-analyses have been carried out to

determine effect sizes across studies (Burke et al., 2003; Carey, Scott-Sheldon, Carey, & DeMartini, 2007; Hettema, Steele, & Miller, 2005; Rubak, Sandbaek, Lauritzen, & Christensen, 2005; Vasilaki, Hosier, & Cox, 2006). While MI counseling strategies were effective in the treatment of alcohol abuse (Burke et al., 2003; Carey et al., 2007; Hettema et al., 2005; Rubak et al., 2005; Vasilaki et al., 2006), and drug use (Burke et al., 2003; Hettema et al., 2005), they did not result in significant reductions in smoking (Burke et al., 2003; Hettema et al., 2005; Rubak et al., 2005). MI was associated with larger effect sizes earlier in the course of addiction counseling in comparison with control or no treatment, which decreased over time as control group effect sizes effectively caught up with MI treatment groups (Hettema et al., 2005; Vasilaki et al., 2006). The positive effects of MI were more enduring when combined with other therapies and when introduced early in the treatment regimen (Hettema et al., 2005). MI was found to be more effective for both treatment-seeking and nontreatment-seeking individuals, although larger effect sizes were noted with treatment-seeking samples (Vasilaki et al., 2006).

Motivational interviewing theory. Although substantial evidence exists to support the efficacy of MI-guided therapy, it has been criticized for lacking a sound theoretical base (Draycott & Dabbs, 1998). Self-determination theory (SDT), a conceptual model of motivation proposed by Deci and Ryan (2002), has been suggested as a useful framework with which to illuminate the basic theoretic assumptions that undergird MI (Foote et al., 1999; Ginsburg, Mann, Rotgers, & Weekes, 2002; Markland, Ryan, Tobin, & Rollnick, 2005; Vansteenkiste & Sheldon, 2006).

Self-determination theory. SDT evolved from the study of intrinsic and extrinsic motivation; and describes the nature of human needs, the motives that drive need

fulfillment, and the environmental characteristics that affect human behavior (Deci & Ryan, 2002; Ryan & Deci, 2006). A basic tenet of SDT is the supposition that human beings have an instinctive inclination to develop an integrated self-image (Deci & Ryan, 2002). This propensity to develop an inner sense of unity fosters the drive to establish constructive links among various facets of one's own psyche as well as establish meaningful connections with other individuals.

According to SDT, individuals have fundamental needs that must be satisfied to achieve psychological health (Deci & Ryan, 2000, 2002; Ryan & Deci, 2000). Needs are conceptualized as "innate psychological nutriment that are essential for ongoing psychological growth, integrity, and well-being" (Deci & Ryan, 2000, p. 229). The drive to meet these needs causes individuals to consciously or unconsciously seek situations that will allow them to be fulfilled (Deci & Ryan, 2002). Three universal needs are identified, the needs for autonomy, competence, and relatedness.

1. Autonomous individuals perceive that their behavior is self-determined, rather than controlled by external forces.
2. Individuals who have fulfilled their need for competence have a sense of confidence and effectiveness in relation to their interactions with their social environment and the expression of their capabilities.
3. Satisfying the need for relatedness instills feelings of connectedness, belonging and genuine caring with others.

Another fundamental concept of SDT is the distinction between causal variables that motivate an individual's behaviors. SDT differentiates between behavior that is motivated autonomously and behavior motivated by a controlled orientation (Deci &

Ryan, 2002; Ryan & Connell, 1989). Behavior motivated by autonomous orientation occurs with volition from an internal impetus and is based one's own interests.

Conversely, controlled orientation refers to behavior that involves external regulation, such as through coercion from others, or self-edicts about how one should behave. These motivations are conceptualized as ordered along a "gradient of autonomy" (Ryan & Connell, 1989, p. 759) from internal to external causality. SDT theory includes the hypothesis that individuals will tend to gravitate toward autonomously motivated behaviors when their innate needs for competence, relatedness, and autonomy have been met (Deci & Ryan, 2002; Ryan & Connell, 1989).

According to SDT, individuals are intrinsically motivated to self-regulate and become increasingly autonomous through a process called internalization. (Deci & Ryan, 2002; Ryan & Connell, 1989). Internalization involves the assimilation of externally regulated values into internally regulated values. Two forms of internalization are recognized by SDT, introjection and integration. Introjection is a suboptimal type of internalization that occurs when an externally regulated value is partially taken in without full acceptance as one's own. Integration involves more extensive internalization that takes place when individuals fully assimilate an externally regulated value, synthesizing the behavior with their core sense of self and accepting it as their own.

Motivational interviewing and self-determination theory. The basic premises of SDT mesh conceptually with the elements that shape MI and provide a theoretical basis for interpreting the efficacy of MI (Foote et al., 1999; Ginsburg et al., 2002; Markland et al., 2005; Vansteenkiste & Sheldon, 2006). Both frameworks are based on the fundamental assumption that individuals are inherently inclined toward positive

change (Markland et al.; Vansteenkiste & Sheldon). Described by Deci and Ryan (2002) as “natural, innate, and constructive tendencies to develop an ever more elaborated and unified sense of self” (p. 5), this concept was characterized by Miller and Rollnick (2002) as “a natural process of change” (p. 4). These beliefs support the approach to counseling that is endorsed by both SDT and MI, that the therapist’s role is to elicit the client’s inherent motivation, rather than attempt to establish a process of change. SDT defines this concept as assisting “autonomous motivation for specific health care or educational behaviors” (p. 239).

Markland and colleagues (2005) aligned the construct of universal needs specified within the SDT framework to MI principles and techniques, and, although not explicitly stated, the FRAMES strategies of giving advice and providing feedback. The MI-guided interventionist supports clients in meeting each of the SDT basic needs as follows:

1. Competence: present clear and neutral information about behavior and outcomes, help the client develop appropriate goals, provide positive feedback, and support self-efficacy.
2. Autonomy: avoid coercion, roll with resistance, explore options, encourage change talk, and let the client make decisions about what and how to change.
3. Relatedness: express empathy, explore client’s concerns, demonstrate understanding of the client's position, and avoid judgment or blame (p. 821).

Seen through the conceptual lens of SDT, MI therapeutic outcomes can be construed as associated with fulfillment of basic needs (Markland et al., 2005; Vansteenkiste & Sheldon, 2006). Placing key MI elements within the conceptual

boundaries of SDT creates a theoretic bridge between MI and behavior change and affords researchers a means of gaining deeper insight into the way that MI works.

Summary. The focus of this study was development of a research instrument capable of valid and reliable measurement of the fidelity with which the IAC brief opportunistic intervention is implemented. This process required operationalization of complex variables, reducing them from abstract concepts to observable indicators. The likelihood that the resulting tool reflected the phenomenon of interest was enhanced through the use of a guiding conceptual framework (C. F. Waltz et al., 2005). MI principles and techniques, instrumental in the development of the IAC, are theoretically strengthened when bolstered by SDT constructs. The union of these two models provided a core ideology that was used to guide the conceptual translation of key principles involved in IAC implementation.

Prenatal Substance Exposure

Alcohol, tobacco, marijuana, cocaine, opioids, and amphetamines are the drugs most commonly used by pregnant women (Shiono, 1996; Suellentrop, Morrow, Williams, & D'Angelo, 2006; Vega et al., 1993) and poly-drug use patterns are pervasive (Chasnoff et al., 2008; Lester, Andreozzi, & Appiah, 2004; Lester et al., 2001; Wolfe, Davis, Guydish, & Delucchi, 2005). Although public concern has been primarily focused on illicit substances, use of legally obtained alcohol and tobacco is far more prevalent during pregnancy. Researchers conducting a landmark prenatal substance exposure study in 1992, analyzed data obtained through urine toxicology screening and self-reported tobacco use from 29,494 pregnant women presenting for delivery in California hospitals (Vega et al.). Specific drug prevalence rates were: tobacco, 8.82%; alcohol, 6.72%;

marijuana, 1.88%; opioids, 1.47%; cocaine, 1.11%; amphetamines, 0.66%. Overall, 5.16% of the women screens were positive for one or more illicit drugs. The predominance of alcohol and tobacco use is corroborated by national prevalence data from the *National Household Survey on Drug Abuse* (Substance Abuse and Mental Health Services Administration, 2010). Estimated rates of use from the 2009 survey (the most recent year available for study) of pregnant women aged 15 to 44 years were: tobacco, 15.3%; alcohol, 10.0%; and illicit drug use, 4.5% (individual illicit drug prevalence rates were not provided).

Prenatal alcohol use. Alcohol is a widely recognized human teratogen and the negative effect on fetuses of mothers who consume alcohol has been well established. Fetal alcohol exposure is a principal cause of birth defects, mental retardation, and neurodevelopmental disorders, sequelae that are entirely preventable (Barr & Streissguth, 2001; Goodlett, Horn, & Zhou, 2005; Lester, Tronick et al., 2004; Meschke, Holl, & Messelt, 2003). During pregnancy, there is no amount of alcohol that can be safely consumed, nor any period of time that is considered safe to drink (Barr & Streissguth, 2001). Alcohol crosses the placental barrier and enters fetal circulation rapidly after maternal ingestion (Streissguth & Finnegan, 1996). Analysis of the placental transfer properties of alcohol reveals that it diffuses freely across the placental membrane, resulting in fetal serum concentrations that equal or exceed maternal serum levels (Little & VanBeveren, 1996). Alcohol is eliminated more slowly from amniotic fluid than from maternal circulation, remaining in fetal circulation when it is no longer present in maternal serum (Tranmer, 1985).

Prenatal tobacco use. There is considerable evidence regarding the fetal harm caused by prenatal exposure to tobacco, adverse impacts that extend into the postnatal period. Although there has been a concerted effort to increase awareness regarding the risks associated with smoking during pregnancy, prenatal tobacco use remains a significant public health concern (Centers for Disease Control and Prevention, 2000). Cigarette smoke is a complex substance composed of more than 4,000 compounds; some originate in the tobacco itself and others are created when the tobacco is burned (Lester, Andreozzi et al., 2004; Talbot, 2008). Harmful effects associated with intrauterine tobacco exposure are thought to be primarily due to chemically mediated interference with reproductive organ function and the teratogenic aspects of nicotine (Greene & Goodman, 2003; Lester, Andreozzi et al.; Medoff-Cooper & Verklan, 1992; Miles, Lanni, Jansson, & Svikis, 2006)

Prenatal opioid use. *Opioid* describes any drug that attaches to opiate receptors in the central nervous system (Deglin & Vallerand, 2009). This class of drugs includes morphine (a naturally occurring opioid), heroin (semi-synthetic), and methadone (synthetic); all of these produce nearly identical effects (U.S. Drug Enforcement Administration, 2009). A rapid rate of opioid placental transfer has been demonstrated directly using animal models (Ruckebusch, Gaujoux, & Eghbali, 1976) and indirectly by acute signs of withdrawal exhibited by opioid-exposed neonates following delivery (Greene & Goodman, 2003). Neonatal abstinence syndrome is marked by behavioral and physiologic indicators that include irritability, hypertonia, diarrhea, vomiting, and poor feeding (Curet & Hsi, 2002; Johnson, 2001; Kenner, Dreyer, & Amlung, 2000; Oei & Lui, 2007).

Prenatal cocaine use. Cocaine's vasoconstrictive properties have been suggested as the mechanism underlying the damage associated with prenatal use (Holzman & Paneth, 1994; Plessinger & Woods, 1993, 1998). Uterine arterial vasoconstriction induced by maternal cocaine use is associated with impaired placental perfusion and subsequent fetal hypoxemia (Woods, Plessinger, & Clark, 1987). An in vitro placental perfusion study found that cocaine interfered with amino acid transport across the placenta, a phenomenon that may further contribute to the fetal harm associated with prenatal use of cocaine (Pastrakuljic, Derewlany, Knie, & Koren, 2000).

Prenatal amphetamine use. Amphetamine mixtures comprise a group of central nervous stimulants, including amphetamine, methamphetamine, and dextroamphetamine, with very similar properties and actions (National Institute on Drug Abuse, 2009). These drugs induce synaptic release of catecholamines, producing numerous pharmacological effects that include vasoconstriction, insomnia, and anorexia (Deglin & Vallerand, 2009). The maternal and fetal effects of amphetamine, while similar to those produced by cocaine, are not identical (Plessinger, 1998). Animal research has demonstrated the facility with which amphetamine compounds cross into the fetal compartment, resulting in peak fetal concentrations that ultimately exceed maternal serum levels due to the slower rate of fetal elimination (Burchfield, Lucas, Abrams, Miller, & DeVane, 1991). Fetal damage associated with prenatal amphetamine exposure may occur directly through placental transfer or indirectly as a result of vasoconstrictive and sympathomimetic effects on the mother (Wouldes, LaGasse, Sheridan, & Lester, 2004). Neonatal abstinence syndrome that has been observed by some researchers studying amphetamine-

exposed newborns (Oei & Lui, 2007; Smith et al., 2003) has not been observed in others (Ludlow, Evans, & Hulse, 2004).

Brief Interventions

Brief intervention has been characterized as a short, dynamic form of psychotherapy (Borden, 1999) delivered by trained individuals with the goal of assisting clients with problems of living (Gurman & Messer, 2005). Brief intervention is a type of treatment modality that refers to multiple therapeutic techniques of varying lengths, used with diverse groups, in assorted settings (Bien et al., 1993; Miller & Wilbourne, 2001; Moyer et al., 2002; Tevyaw & Monti, 2004). Therapeutic components of brief interventions may include: motivational interviewing, advice, education, counseling, feedback, behavior contracting, or self-control training (Miller & Wilbourne, 2001). Although brief interventions are, by definition, shorter in duration than more extensive traditional behavioral therapy, there is wide variation in the length of treatments given this designation. Brief interventions can be delivered opportunistically in a primary care setting as a single 5- to 10-minute event for nontreatment-seeking individuals, or conducted by a therapist over three to four sessions for individuals seeking treatment for specific problem behaviors (Moyer et al., 2002). Despite this wide variation, brief interventions have been found effective in reducing the incidence of harmful alcohol use with a variety of populations across a wide range of settings (Bien et al., 1993; Kaner et al., 2007; Miller & Wilbourne, 2001; Moyer et al., 2002; Perl, 2001; Vasilaki et al., 2006; Wilk, Jensen, & Havighurst, 1997).

Brief intervention efficacy in the general population. Researchers have measured the impact of brief interventions on alcohol consumption among the general populations. Meta-analyses of findings of similar studies showed a significant benefit associated with brief interventions; all reported small to medium aggregate effect sizes in support of brief intervention groups as compared to control groups (Kaner et al., 2007; Moyer et al., 2002; Vasilaki et al., 2006; Wilk et al., 1997). Brief interventions were more effective with heavier drinkers (Kaner et al., 2007; Vasilaki et al., 2006; Wilk et al., 1997), a finding not supported in the study by Moyer and colleagues (2002), who found larger effect sizes when heavy drinkers were removed from the analysis. Treatment-seeking patients received greater benefit from brief intervention (Moyer et al., 2002) or no significant difference in effect (Vasilaki et al., 2006) compared to nontreatment-seekers. One study found greater effect sizes among men as compared to women (Kaner et al., 2007), a finding that was not corroborated in other reviews (Moyer et al., 2002; Vasilaki et al., 2006; Wilk et al., 1997). Aspects of time were considered in some of the analyses. While Wilk et al., (1997) found that effect size increased with more than one session, no significant difference in effect size was associated with the length of the brief intervention (Kaner et al., 2007; Moyer et al., 2002; Wilk et al., 1997). Effect sizes were largest at earlier follow-ups and tended to degrade over time and (Moyer et al., 2002; Vasilaki et al., 2006).

These studies provide support for the role of brief interventions in reducing harmful drinking among heavy drinkers in the general population. They also highlight the value that a preponderance of controlled studies plays in demonstrating relationships and causality.

Brief interventions with pregnant women. Brief interventions have been reported to benefit pregnant, substance-using women (Armstrong et al., 2003; G. Chang et al., 2005; Ferreira-Borges, 2005; O'Connor & Whaley, 2007). The American College of Obstetricians and Gynecologists (2008) recommends universal ATOD screening followed by brief interventions and appropriate referrals for ATOD-positive pregnant women.

Four randomized controlled studies analyzed the impact of brief interventions on prenatal alcohol consumption. Pregnant women identified at risk for prenatal alcohol intake were randomized to experimental groups receiving brief educational interventions (Chang et al., 2005; Chang, Wilkins-Haug, Berman, & Goetz, 1999; O'Connor & Whaley, 2007) or motivational interviews (Handmaker, Miller, & Manicke, 1999). O'Connor and Whaley (2007) reported a 5-fold increase in days of abstinence among women in the brief intervention group ($F[1.241] = 4.33, p < .04$). G. Chang and colleagues (2005) found that an already significant reduction in prenatal alcohol consumption in the treatment group ($b = -0.163, SE [b] = 0.063, p < .01$) was magnified when the woman's partner was present for the intervention ($b = -0.932, SE [b] = 0.468, p < .05$). In the other two studies, the difference in alcohol intake between control and intervention groups did not reach statistical significance (Chang et al., 1999; Handmaker et al., 1999).

Neonatal measures have been analyzed to assess the effect of brief interventions given to substance-using pregnant women (Armstrong et al., 2003; O'Connor & Whaley, 2007). Researchers compared the fetal mortality rate of two groups of pregnant women participating in the Supplemental Nutrition Program for Women, Infants, and Children

(WIC) who had alcohol-positive screening results (O'Connor & Whaley, 2007). Infants born to women who had received a 15-minute brief intervention from WIC nutritionists were heavier ($F [1.194] = 3.59, p < .06$), and longer ($F [1.194] = 4.48, p < .03$) at birth in comparison to the infants born to the women in the control group who received assessment and advice to stop drinking. Other investigators compared neonatal outcomes of infants born to ATOD-positive pregnant women who (a) received a screening only, (b) received a screening and an assessment, or (c) received screening, assessment, and a brief intervention, with a control group of women who had screened negative for ATOD use (Armstrong et al.). Chi-square analysis revealed no significant difference in the incidence of preterm delivery, birth weight, or assisted ventilation rate between the brief intervention and control groups (all p values > 0.17). Conversely, significant differences were noted on all three outcomes for the other two groups of ATOD-using women in comparison to the control (all p values < 0.0024).

The effectiveness of brief interventions among pregnant tobacco smokers has been studied. Ferreira-Borges (2005) found that women in the brief intervention experimental group had significantly higher levels of tobacco abstinence at a 2-month follow-up assessment compared to the women in the control group ($\chi^2 = 4.93, p = 0.02$). In another randomized controlled trial with methadone-maintained, nicotine-dependent pregnant women, no significant difference in reduction of tobacco use between the brief intervention and control groups was observed (Haug et al., 2004). The complex psychosocial issues associated with opioid-dependent pregnant women limit the generalizability of these findings.

Although there have been relatively few studies conducted with pregnant women, brief interventions have demonstrated some effectiveness in reducing prenatal substance use and exerting a beneficial impact on neonatal outcomes. Further controlled research incorporating assessment of treatment fidelity is needed to determine the effectiveness of specific brief interventions and to facilitate replication in the primary care prenatal setting.

Non-specialist brief intervention implementation. Another promising avenue of study is determining the relative effectiveness of brief intervention by non-specialists. Although most brief intervention research has used physicians or research staff to implement the interventions, there are a few studies that have examined this treatment modality with non-specialists.

Investigators compared the provider-specific frequency of brief intervention implementation for patients who screened positive for harmful levels of alcohol use by two levels of providers in a multi-site study (Babor, Higgins-Biddle, Dauser, Higgins, & Burleson, 2005). Under one study condition, medical providers (physicians, physician assistants or nurse practitioners) delivered the brief interventions. In the other condition, brief interventions were implemented by mid-level professionals (nurses or health educators). Researchers found that mid-level professionals screened a higher percentage of patients than medical providers (24% and 19% respectively) and, among those patients screening positive, more patients in the mid-level condition received a brief intervention (73.1% versus 57.1%). This study focused solely on the frequency of implementation and did not measure comparative alcohol intake reduction.

Gamma-glutamyl transferase (GGT), a liver function test capable of detecting chronic alcohol intake (Pagana & Pagana, 2009), was the pre-treatment and post-treatment measurement used to determine the effectiveness of a brief intervention delivered by a nurse to patients identified as heavy drinkers (Tomson, Romelsjo, & Aberg, 1998). The mean GGT values (measured in microkatal per liter) in the nurse-interventionist treatment group had decreased significantly from 1.52 at baseline to 1.21 at the 2-year follow-up ($p = 0.02$), while the GGT values of the control group receiving traditional physician advice increased from 1.74 to 2.16 ($p = 0.34$).

In the study conducted by O'Connor and Whaley (2006), WIC nutritionists implemented brief interventions for pregnant women. This is the only prenatal study that has used nonmedically trained health professionals as interventionists. To date, no studies have been published measuring the effectiveness of brief interventions conducted by frontline staff in reducing ATOD use during pregnancy.

Brief intervention cost-effectiveness. Fleming and colleagues (2002) estimated economic costs and benefits associated with physician-conducted brief interventions for the treatment of problem drinking. A randomized, controlled clinical trial was performed to evaluate the long-term effectiveness of a brief intervention delivered to patients who screened positive for at-risk drinking. The trial found sustained reductions in alcohol use in the treatment group over the 48-month follow-up period. These researchers also performed a complex benefit cost analysis that estimated a net benefit of \$7,780 per patient receiving the brief intervention. The calculated differential in cost savings between the two groups was derived from medical care savings (emergency department visits and hospitalizations), avoidance of legal events (e.g., arrests for assault, abuse,

theft, disorderly conduct, property damage), and motor vehicle events (driving under the influence, crashes, and fatalities). The results of this study provide compelling evidence in support of using brief interventions to treat problem drinking in terms of cost as well as efficacy.

Treatment Fidelity

In the 1950s, as new schools of psychoanalytic thought arose and the incidence of comparative behavioral therapy outcome research increased, the scientific community began to voice concerns regarding the reported effectiveness of psychotherapeutic interventions (Luborsky, Singer, & Luborsky, 1975). This literature review section presents a chronology of the development of treatment fidelity, which emerged as a methodological strategy to address these concerns. Significant procedural aspects associated with the assessment of treatment fidelity will also be explored.

History of treatment fidelity. Eysenck (1952) challenged hypotheses that psychotherapy facilitated recovery from neuroses. He summarized the results of descriptive studies that reported improvement of neurotic patients after psychotherapy and compared these findings using statistics derived from hospital records and disability claims to estimate percentages of similar patients who recovered without benefit of psychotherapy. He deduced an aggregate recovery rate of 72% for patients receiving no psychotherapy (under the care of a general practitioner or in custodial treatment), while only 66% of patients receiving psychotherapeutic treatment recovered. Eysenck acknowledged the shortcomings of his actuarial comparison but nevertheless concluded that his findings raised serious concerns regarding the results of studies reporting favorable effects of psychotherapy. His recommendation for further “carefully planned

and methodologically more adequate” (p. 323) experimental research to provide reliable evidence regarding the efficacy of psychotherapy was an early harbinger of the scientific community’s recognition of the importance of identifying research strategies assuring accurate, faithful treatment delivery.

A comprehensive evaluation of controlled comparative treatment research, a field of study that began in the middle 1950s, reported that the studies reviewed rarely offered evidence that the delivered treatment actually corresponded to the intended treatment (Luborsky et al., 1975). Insignificant differences were noted between psychotherapeutic models in terms of their demonstrated effectiveness, leading investigators to conclude that patients tend to benefit from any therapy that involves a helping relationship with a therapist.

The concept of fidelity, introduced in 1981, was defined as the faithfulness with which researchers and clinicians implemented behavioral treatments (Yeaton & Sechrest, 1981). The authors coined the terms “treatment strength” to refer to the “a priori likelihood that the treatment could have its intended outcome” (p. 156) and “treatment integrity” as “the degree to which treatment is delivered as intended,” (p. 160) and argued that any determination regarding the appropriateness of a treatment should only be made after attending closely to both strength and integrity.

A review of applied behavioral research literature published between 1968 and 1980, reported that, although articles consistently contained reliability estimates of the dependent variable, 80% failed to report adequate efforts to ensure integrity of the independent variable (Peterson, Homer, & Wonderlich, 1982). The lack of methodological rigor created doubt about the quality of data and conclusions resulting

from these studies, and recommendations included intensive interventionist training and incorporation of a method to measure the accuracy of treatment delivery to ensure accurate application of the independent variable.

A “technology model” of research design and implementation proposed using the same precision and rigorous methodology applied to pharmacology trials when carrying out behavioral therapy research (Carroll & Rounsaville, 1990). To protect the independent variable and enhance internal validity, this approach specified manual-guided treatment, thorough operationalization of treatment delivery, interventionist training, and ongoing supervision of treatment implementation.

The term “treatment fidelity” was first introduced in a survey of psychosocial therapy outcome literature culled from major journals published between 1980 and 1988 (Moncher & Prinz, 1991) Among the 359 treatment outcome studies evaluated, over half made no mention of design methods to address treatment fidelity.

A review of prevention program outcome evaluation literature was conducted to determine the degree to which the programs were implemented as planned (Dane & Schneider, 1998). When behavioral intervention studies published between 1980 and 1994 were examined, investigators found that only 24% of the programs incorporated procedures to verify program integrity. In addition, they noted that, although the major journals containing most of the studies included in the sample stipulated inclusion of program integrity strategies as a prerequisite of publication acceptance, these requirements appeared to have been loosely enforced.

Rounsaville, Carroll, and Onken (2001) discussed the evolution of treatment efficacy research and the mandate placed on investigators to develop treatment manuals

and valid methods of evaluating treatment fidelity in order to qualify for government-funded research support. They reported that, due to the considerable effort involved in addressing treatment fidelity in advance of conducting randomized clinical trials, the National Institute on Drug Abuse had developed the “Stage Model of Behavioral Therapies Research.” The model demarcates three distinct stages of research and advocates research-funding support at each level to encourage development and testing of innovative therapies. Appropriate stage-one research activities include the development of programs, manuals, training, fidelity measures, and pilot testing.

A meta-analysis of the treatment fidelity practices reported in health behavior change outcome literature between 1990 and 2000 reported no significant increase in the frequency with which researchers addressed the issue of treatment fidelity (Borrelli et al., 2005). Of the articles analyzed, 54% failed to identify inclusion of strategies necessary to monitor the reliability and validity of behavioral interventions.

A review of randomized controlled trials testing the efficacy of psychotherapeutic interventions was published between 2000 and 2004 (Perepletchikova, Treat, & Kazdin, 2007). Investigators found that, although the evaluative measures used to determine adequacy were consistent with those recommended in the literature, only 3.5% of the studies reported implementation of adequate treatment fidelity procedures. They also noted that researchers consistently devoted greater attention to reliability and operational definitions of behaviors serving as outcome measures, than to those associated with the independent variable, echoing an observation made 25 years earlier (Peterson et al., 1982).

Rationale for assessing treatment fidelity. Strategies allowing assessment of treatment fidelity are requisite components of submissions for government grant funds and referred journal publications. Nevertheless, most of the investigators who have conducted comparative psychotherapy research have failed to address treatment fidelity despite the increasing emphasis placed upon this by the scientific community. Rationale articulated in the literature regarding the importance of incorporating treatment fidelity processes in psychotherapy research include considerations involving external validity, internal validity, statistical analyses, interventionist training, and feasibility of treatment.

External validity. Research is generally not conducted solely to discover relationships among variables for the individuals participating in the study, but also to reach conclusions that can benefit populations extending beyond the study sample (Polit & Hungler, 1999). External validity refers to generalizability, or the degree to which the results of the study would hold with other populations, in other places, and with alternative measurement instruments (Campbell & Stanley, 1966). Research results that can be generalized to other settings and samples are said to have a high degree of external validity (Campbell & Stanley, 1966).

A relevant aspect of external validity in relation to treatment fidelity pertains to the focus on translation of research findings into practice settings. There are advantages in a study that provides unambiguous treatment guidelines and clear documentation of the procedures used to assess the quality of implementation. When a study incorporating these procedures reports that an effective treatment was implemented with high fidelity, the opportunity for dissemination of effective treatments across the research-practice gap is increased (Bellg et al., 2004; Dumas, Lynch, Laughlin, Smith, & Prinz, 2001; Spillane

et al., 2007).

Treatment fidelity is critical to the maintenance of external validity in controlled psychotherapy research. The processes involved in treatment fidelity assessment require clear identification of treatment content; this is also necessary for replication of results (Moncher & Prinz, 1991). Use of a treatment manual has been identified as essential to the conduct of behavioral treatments in clinical trials to standardize interventionist training, and to reduce implementation variance (Rounsaville et al., 2001). A review of health behavior change outcome studies published between 1990 and 2000 noted that 35% reported use of a treatment manual (Borrelli et al., 2005); a similar review of studies published between 2000 and 2004 found that 65% reported use of a specific treatment protocol (Perepletchikova et al., 2007). This change in the frequency of use of treatment manuals is significant and may herald a trend.

Use of a treatment manual alone is insufficient to protect against threats to external validity. While a detailed description of proper implementation is necessary, it is also necessary to assess, verify, and document the quality of treatment implementation (Dumas et al., 2001; Peterson et al., 1982). These activities comprise the core of treatment fidelity and must be built into study methodology before a legitimate evaluation of treatment efficacy can occur.

Internal validity. When the goal of research is to establish a causal relationship, internal validity is a primary consideration (Trochim & Donnelly, 2007). Internal validity refers to the degree that it is possible to infer that the effect on the dependent variable was actually produced by the independent variable rather than resulting from extraneous variables (Campbell & Stanley, 1966). Faithful delivery of the independent variable is a

hallmark of controlled research. When the independent variable takes the form of a drug in a randomized controlled trial, it may be sufficient to simply report the dosage and route of administration. However, when a randomized controlled trial is conducted to compare the efficacy of psychotherapeutic treatment with an alternative control treatment, it is insufficient to simply state in the method section that a given treatment was implemented (Peterson et al., 1982). The implementation of a complex behavioral treatment by an interventionist is much less straightforward, and a fair comparison to the control depends on methodological assurances that the intended treatment was actually delivered as designed (Luborsky et al., 1975; Moncher & Prinz, 1991; Peterson et al., 1982).

Compromises to internal validity may result from inaccurate interventionist implementation such as the omission of prescribed treatment components or the addition of proscribed components (Borrelli et al., 2005; Moncher & Prinz, 1991; Perepletchikova et al., 2007). Thus, significant results could actually be due to an effective treatment or a Type I error that occurred because unintended ingredients were added to the intervention. Conversely, insignificant results could be the result of a weak treatment or a Type II error due to inadequate administration of the intervention (Borrelli et al., 2005; Moncher & Prinz, 1991; Perepletchikova et al., 2007; Polit & Hungler, 1999). Regardless of whether research findings note a large treatment effect or lack of effect, failure to address treatment fidelity issues erodes confidence in the study outcomes (Bellg et al., 2004; Borrelli et al., 2005; Luborsky et al., 1975; Moncher & Prinz, 1991; Perepletchikova et al., 2007; Peterson et al., 1982).

Statistical analysis. Attention to treatment fidelity improves statistical power by reducing unintended variability in treatment effect due to uneven delivery by

interventionists (Dumas et al., 2001; Yeaton & Sechrest, 1981). Because sample size is another invariant factor in the calculation of statistical power, attention to treatment fidelity may reduce study costs. As power increases, a proportionately smaller sample size can be used in a test of statistical significance (Bellg et al., 2004; J. Cohen, 1977; Resnick et al., 2005).

Rather than an all-or-none occurrence, treatment fidelity is a phenomenon that can be conceptualized as falling along a continuum measuring the extent of intervention exposure (Moncher & Prinz, 1991). This operationalization allows treatment fidelity to be used as a direct factor in statistical analyses. If fidelity assessment involves measuring the degree of intervention actually received, this “intervention dosage” can be inserted as an independent variable into a regression analysis (Sidani, 1998).

Treatment fidelity measures can be quantified and used in data analyses to determine degrees to which results are due to study intervention. In a longitudinal, multi-site study measuring the effectiveness of a cognitive-behavioral approach to substance abuse prevention, researchers identified a direct relationship between the extent of program implementation and outcomes (Botvin, Baker, Dusenbury, & Tortu, 1990). They found that participants receiving a higher intervention dose had correspondingly lower levels of substance use than individuals receiving a lower dose.

Interventionist training and performance. Results of fidelity assessment can be used as a feedback mechanism to enhance interventionist training and performance (J. Waltz, Addis, Koerner, & Jacobson, 1993). Evaluation of treatment fidelity illuminates lapses in implementation and facilitates identification of interventionists in need of training augmentation (Carroll, Nich, & Rounsaville, 1998; Resnick et al., 2005; J. Waltz

et al., 1993). Additionally, treatment fidelity assessment tends to encourage optimal adherence to the treatment protocol by interventionists (Borrelli et al., 2005).

Treatment feasibility. Assessment of treatment fidelity provides information about the feasibility of implementing a treatment protocol in practice (Dusenbury, Brannigan, Falco, & Hansen, 2003). If treatment interventions were difficult to implement with adequate fidelity, steps can be taken to redesign the protocol to enhance outcomes.

Components of treatment fidelity. Also referred to as treatment integrity (Dane & Schneider, 1998; J. Waltz et al., 1993; Yeaton & Sechrest, 1981), fidelity of implementation (Dusenbury et al., 2003), and intervention fidelity (Santacroce, Maccarelli, & Grey, 2004), Treatment fidelity is a relatively nascent concept described in the literature (Dusenbury et al., 2003). There is general agreement that adherence and competence are the key elements of treatment fidelity.

Adherence. Adherence is a component of treatment fidelity that describes the degree to which the essential processes associated with the treatment protocol are implemented and prohibited elements are avoided (Dane & Schneider, 1998; Dusenbury et al., 2003; Moncher & Prinz, 1991; Santacroce et al., 2004; Stein et al., 2007). Measurement of adherence requires operationalization of the unique elements that distinguish a particular treatment protocol to determine the extent to which the guidelines are followed during implementation (Carroll et al., 2000; Mowbray, Holter, Teague, & Bybee, 2003).

Competence. The second major aspect of treatment fidelity is competence, which is the level of interventionist skill during implementation or quality of treatment (Barber,

Liese, & Abrams, 2003; Hogue, Liddle, & Rowe, 1996; J. Waltz et al., 1993).

Measurement of competence involves operationalization of treatment elements that distinguish the manner in which the interventionist delivers the treatment and may include contextual behaviors such as communication of empathy, collaboration, responsiveness, and sensitivity (Hogue et al., 1996; J. Waltz et al., 1993). Indicators of competence should be theoretically derived from the specific treatment protocol rather than from general concepts of therapeutic behaviors (J. Waltz et al., 1993). As the meaning underlying an interventionist behavior varies, depending on the client context in which it occurs, measurement of treatment competence is a more subtle and complex process than measurement of adherence (Hogue et al., 1996; J. Waltz et al., 1993).

High fidelity implementation requires both adherence and competence (Hogue et al., 1996). Competent implementation is impossible without adherence to treatment guidelines; yet adherence alone is insufficient to assure competent delivery (Barber et al., 2003; Perepletchikova et al., 2007; J. Waltz et al., 1993).

Treatment fidelity measurement. The measurement of treatment fidelity involves identifying theoretically distinctive intervention elements to ensure reliable differentiation among treatments when conducting comparative research (Dane & Schneider, 1998; Hogue, Liddle, Singer, & Leckrone, 2005; Moncher & Prinz, 1991; Santacroce et al., 2004; Stein et al., 2007). The extent to which treatments differ from each other can be sufficiently determined through the development of detailed, precise, protocol-derived measures that include proscribed as well as prescribed behaviors (Mowbray et al., 2003; J. Waltz et al., 1993).

Treatment manuals. A detailed manual that describes the treatment protocol is an essential precondition of treatment fidelity assessment (Rounsaville et al., 2001; J. Waltz et al., 1993). Although the existence of a treatment manual cannot ensure purity of implementation, it does increase the likelihood of consistent, standardized delivery (Bellg et al., 2004). Treatment manuals should clearly specify appropriate interventions and desired therapeutic behaviors to guide training, implementation, and identification of fidelity assessment criteria (Rounsaville et al., 2001; Santacroce et al., 2004). In addition, theoretical foundation and therapeutic objectives are appropriately explicated in the treatment manual (Bellg et al., 2004; Mowbray et al., 2003; Santacroce et al., 2004).

Although manual-guided treatment protocols are the recognized standard, treatment fidelity studies inconsistently use manuals (Bellg et al., 2004; W. R. Miller & Wilbourne, 2001; Mowbray et al., 2003; Perepletchikova et al., 2007). In addition, when manuals have been developed to guide psychotherapeutic treatments, they seldom provide adequate detail regarding competence criteria (J. Waltz et al., 1993).

Instrument design. The design of treatment fidelity instruments differs significantly in accordance with the treatments they have been developed to measure. Complex treatment protocols require tools of correspondingly greater complexity to assess interventionist adherence and competence (Ogrodniczuk & Piper, 1999; Orwin, 2000; Perepletchikova et al., 2007; Stein et al., 2007; J. Waltz et al., 1993). However, lengthy, complicated measures can become unwieldy and impractical to use (Ogrodniczuk & Piper, 1999). Congruence with the theoretical assumptions underlying the interventions is a primary consideration when developing a fidelity measurement tool (J. Waltz et al., 1993).

Scale design. The construction of scale items also varies widely. A simple and economical design involves a checklist format, rating the incidence and frequency of prescribed or proscribed interventions (J. Waltz et al., 1993). This method can obscure subtle differences in interventionist behaviors and may hamper assessment of inter-rater reliability resulting from difficulty detecting differences between coding scores (Stein et al., 2007). Advantages of dichotomous measures include their economy, simplicity, and elimination of outliers (Stein et al., 2007; J. Waltz et al., 1993). A Likert format is an alternative item design allowing ratings of frequency or intensity of a given behavior (DeVellis, 2003). Likert scaling is more complex than dichotomous scaling, requiring more intensive rater training to achieve satisfactory inter-rater reliability (J. Waltz et al., 1993).

Treatment fidelity data collection. Measurement of treatment fidelity requires collection of implementation data. A variety of strategies can be used to accomplish this. Direct methods include audiotapes, video recordings, and in vivo observation of implementation, while indirect methods rely on evidence obtained from sources such as therapist self-reports, process note review, and checklists (Perepletchikova et al., 2007; J. Waltz et al., 1993). Although direct measures are more complex and costly than indirect methods, they are considered the gold standard for collection of fidelity evidence for research (Bellg et al., 2004; Santacroce et al., 2004; Stein et al., 2007). Studies have found that therapists tend to over-report implementation of psychotherapeutic interventions in comparison to the assessment of independent raters (Carroll et al., 1998; Chevron & Rounsaville, 1983). While indirect methods can play a valuable role in the

training and maintenance of treatment fidelity, they cannot substitute for measures involving direct observation (J. Waltz et al., 1993).

Another important aspect of treatment fidelity measurement is identifying the appropriate unit of treatment to be used in the fidelity analysis. Approaches that have been used in treatment fidelity research include event-by-event coding, in which each therapist utterance is identified as a scoring unit (Wills, Faltler, & Snyder, 1987), scoring randomly selected session segments (Luborsky, McLellan, Woody, O'Brien, & Auerbach, 1985), and coding entire sessions (Carroll et al., 2000).

Concrete, observable therapist behaviors are specific aspects of the codeable unit that need to be considered when assessing treatment fidelity (J. Waltz et al., 1993). Focusing on actions of the interventionist helps to distinguish implementation from client response behaviors and facilitates measurement of treatment fidelity (Santacroce et al., 2004).

Interventionist training. Adequate interventionist training is essential to establish and maintain treatment fidelity (Bellg et al., 2004; Moncher & Prinz, 1991; Resnick et al., 2005). The purpose of training is to teach new skills, expand and refine existing abilities, preserve implementation quality, and minimize drift from the original protocol (Bellg et al., 2004; Hogue et al., 1996; Santacroce et al., 2004). Standardized training is important to optimize consistency of implementation by interventionists (Bellg et al., 2004; Rounsaville et al., 2001). Use of treatment protocol training manuals facilitates training standardization (Bellg et al., 2004; Resnick et al., 2005; Santacroce et al., 2004). Training variance can be further minimized by having the same instructors conduct workshops when multiple sessions are planned (Bellg et al., 2004).

No single training approach has demonstrated superiority; however interactive teaching strategies that use peer performance feedback have been effective (Grol & Grimshaw, 2003). A manual-based curriculum disseminated through didactic instruction integrated with experiential teaching strategies such as intervention role-playing has been recommended (Bellg et al., 2004; Moncher & Prinz, 1991; Resnick et al., 2005; Santacroce et al., 2004).

Rater selection and training. The selection of raters who will make judgments regarding the quality of implementation is a critical aspect of treatment fidelity research. Raters selected to assess and code treatment fidelity should possess expertise comparable to that of the interventionist (Moras & Hill, 1991; Stein et al., 2007; J. Waltz et al., 1993). The complexity of the fidelity instrument and the degree of difficulty involved in measurement should also be considered when determining rater qualifications. Instruments with specific rating systems based on clearly identifiable interventionist behaviors may be used successfully by individuals with less expertise, while tools requiring consideration of more subtle contextual variables will benefit from raters with more experience (J. Waltz et al., 1993). Raters should not be directly involved in the research project; recruitment of unaffiliated individuals will reduce rating bias and enhance study reliability and validity (Dumas et al., 2001; Hogue et al., 1996; J. Waltz et al., 1993).

Rater training should include teaching components similar to those used to train interventionists (Carroll, Kadden, Donovan, & Zweben, 1994; Hogue et al., 1996; Stein et al., 2007; J. Waltz et al., 1993). Detailed, manual-based treatment protocol instruction is recommended to ensure that raters comprehend intervention strategies and goals

(Carroll et al., 2000; Hogue et al., 1996; Stein et al., 2007; J. Waltz et al., 1993). Rater instruction should include opportunities to code practice audio recordings or videotapes of pilot cases (Carroll et al., 2000; Dumas et al., 2001; Moncher & Prinz, 1991; Stein et al., 2007). Subsequent comparison of trainee results with expert consensus ratings of the same tapes will allow determination of inter-rater reliability (Carroll et al., 2000; Stein et al., 2007). Another teaching strategy to facilitate measurement calibration and enhance inter-rater reliability is to foster regular discussion among raters regarding their mutual interpretation of interventionist behaviors and comparison of ratings (Carroll et al., 2000; Dumas et al., 2001; Moras & Hill, 1991).

Treatment fidelity assessment in brief intervention research. Assessment and measurement of treatment fidelity is a fundamental component of empirical testing conducted to determine whether a psychosocial intervention, found to be effective in a controlled trial, is generalizable and replicable. An extensive review of the prenatal substance use brief intervention research found only two studies reporting incorporation of treatment fidelity procedures.

Researchers conducted a randomized clinical trial to measure change in maternal alcohol use when partners as well as pregnant women participated in a single-session brief intervention (Chang et al., 2005). There is no mention of a manual; the authors describe the intervention as structured, incorporating knowledge assessment, goal setting, and behavioral modification. Implementation was conducted by the primary investigator (a psychiatrist) or master's-degree-prepared nurse practitioners; all were described as clinicians experienced in delivery of the brief intervention. The method used to assess treatment fidelity was evaluation of interventionist summary notes. Interventions were

not audiotaped and there was no report of use of a fidelity measurement tool or the degree of treatment fidelity attained during implementation. As described earlier, G. Chang (2005) and colleagues reported significant declines in alcohol consumption in the brief intervention group. However, replicability of this study was jeopardized by limitations in several of the reported treatment fidelity procedures including (a) lack of a specific treatment protocol or quality control methods to assure fidelity in treatment delivery, (b) subjective assessment of implementation, and (c) failure to develop and implement methods to measure treatment fidelity.

In another controlled trial, O'Connor and Whaley (2007) studied the effectiveness of a brief intervention designed to encourage pregnant women to abstain from alcohol. This manual-guided brief intervention is described as incorporating education, cognitive-behavioral procedures, and goal setting. Interventionists were nutritionists who had received training. A fidelity checklist was used to assess inclusion of brief intervention content. Before participating in the study, interventionists were required to demonstrate 100% reliability in conduct of the brief intervention when assessed by means of the fidelity checklist. A random sample of interview sessions were audiotaped during the study and scored using the fidelity checklist to ensure continued adherence to the protocol. Higher rates of abstinence and improved infant outcomes were reported among women receiving the brief intervention. The treatment fidelity methods described in this study encompass many criteria essential for intervention replication, including (a) provision of a manual detailing a specific treatment protocol, (b) intensive training measures taken to ensure quality of implementation, (c) objective assessment of implementation, and (d) use of a fidelity checklist to assess adherence to intervention

content. Treatment integrity would have been further strengthened if methodological procedures had been incorporated to facilitate assessment of interventionist competence and evaluation of audiotapes by unaffiliated raters.

Gaps in the Literature

Brief intervention studies carried out with the general population and with pregnant women have reported significant reductions in harmful substance use, yet few of these efficacious interventions have been successfully translated from the research setting. It is clear that conducting a rigorous, randomized controlled clinical trial is not enough to ensure that an intervention will be used in practice. Most brief intervention studies have not sufficiently incorporated research strategies that are needed to assure faithful delivery of behavioral treatments, determine their effectiveness, and facilitate adoption.

The dearth of brief intervention studies using non-specialists or frontline staff in the role of interventionist draws attention to another area that warrants study. The increasingly costly nature of healthcare mandates investigation of cost-effective intervention protocols that reflect the reality of standard staffing in primary health care.

This literature review, by presenting what is known about prenatal substance use, brief intervention research, and treatment fidelity, has revealed topics that merit further examination. These areas frame the contribution that this study will make to the current knowledge.

Summary

This chapter presented a review of the literature relevant to this study. MI and SDT concepts were aligned to provide a sturdy conceptual framework that guided

development of the treatment fidelity instrument. An overview of deleterious effects associated with prenatal consumption of alcohol, tobacco, marijuana, opioids, cocaine, and amphetamines was presented. A chronology of historic events in the scientific community provided rationale for the emergence of treatment fidelity. The importance of assessing treatment fidelity in the controlled study of experimental behavioral interventions was illuminated. There is convincing evidence in support of brief interventions in terms of efficacy, efficiency, and cost-effectiveness. Although the literature has contributed positive information regarding the promise of brief interventions in reducing substance use during pregnancy, there is a need for a controlled brief intervention research study with this population that incorporates rigorous treatment fidelity strategies sufficient to assure delivery of the independent variable. It is this gap in the literature that I sought to address in this study.

Chapter 3

Methods

This chapter presents a description of the IAC brief opportunistic intervention followed by a detailed outline of the methods and procedures that were used in the study. The research design, sample, setting, institutional approval of methods for protection of human participants, data collection procedure, instrumentation, and data analyses are addressed.

IAC Brief Opportunistic Intervention

The IAC is a structured, substance-specific protocol developed to facilitate timely provider response to the disclosure of ATOD use during pregnancy. The steps of the IAC are outlined in a manual (Chasnoff & McGourty, 2003) that includes scripted options and suggested language for the interventionist to use depending on the woman's response. The manual contains photographs of substance-exposed children manifesting clinical effects of prenatal alcohol, tobacco, or illicit drugs. The photographs are accompanied by text that describes the potential consequences of use. Per IAC protocol, the interventionist displays photographs depicting negative outcomes associated with the specific substances that the woman has reported using and discusses their potential consequences during pregnancy.

Remarks are prefaced with the words "I am concerned..." when discussing negative sequelae associated with prenatal substance use to avoid conveying an intimidating or threatening attitude. Women are unambiguously advised to discontinue, rather than decrease, ATOD use. The interventionist continuously assesses the woman's demeanor and responsiveness throughout the intervention to determine her reaction, and

modify the approach accordingly. If the woman becomes distressed, the interventionist is advised to yield in the interest of maintaining a therapeutic relationship, and defer further treatment until a future opportunity presents itself. Referrals to drug, alcohol, or smoking cessation will be offered as indicated. If the woman is open to referral, the provider will facilitate an appointment to the appropriate source.

Research Design

I used a methodologic research design to frame the development of a treatment fidelity instrument used to measure the degree of adherence and competence with which frontline staff members implemented the IAC brief opportunistic substance-use targeted intervention in the simulated prenatal clinic setting. I also assessed measurement validity and reliability associated with use of this instrument.

Research protocol. I conducted this study in six phases, including (a) tool development, (b) standardized patient hiring and preparation, (c) rater hiring and training, (c) frontline prenatal clinic staff recruitment and preparation, (d) brief opportunistic intervention implementation simulation, and (e) treatment fidelity coding and scoring. Each of these phases is described in detail as follows:

Phase I: Tool development.

Step 1: Identification of essential elements of the IAC. I identified the essential elements involved in accurate implementation of the IAC brief opportunistic intervention from the manual describing the clinical protocol. Guided by the conceptual framework derived from the union of MI and SDT, I used these elements to develop the instrument that would be used to assess treatment fidelity during IAC implementation.

Step 2: Construction of scale items. Once I identified the essential components involved in IAC implementation, I translated them into statements of observable interventionist behavior. The statements were arranged in accordance with the order in which they were likely to be introduced during implementation. For any action that I judged to comprise both adherence and competence components, I constructed paired, sequenced statements using the same root phraseology to facilitate independent rater recognition and scoring of the behavioral elements during implementation, a pattern I adapted from the Yale Adherence and Competence Scale (Nuro et al., 2005).

Step 3: Development of item scaling Following development of the scale items, I selected an appropriate scaling option to reflect the occurrence or non-occurrence of the behaviors. I chose Likert scaling, which allows measurement of the intensity of behaviors along a continuum, because it was most congruent with the complexity and assumptions underlying the IAC treatment modality.

Step 4: Identification of coding units. The next step involved defining what was to be treated as a codeable unit. Possible approaches range from coding timed segments of a treatment session to identifying an entire session as a codeable unit. For this study, the segment of the audio recording involving IAC implementation comprised the codeable unit.

Step 5: Assessment of content validity. During this step of the tool development phase, I sought the opinions of content experts I. J. Chasnoff and R. F. McGourty, the co-developers of the IAC brief opportunistic intervention (Appendix A). I provided each with a content review questionnaire that enabled them to judge the instrument's specific adherence and competence components in terms of how comprehensively they

represented the underlying concepts of the IAC brief opportunistic intervention (Appendix B). The questionnaire included 4-point rating scales to capture the content reviewers' assessment of the clarity and sufficiency of each scale item (1 = not very clear or not sufficient, to 4 = clear or sufficient). The reviewers also judged the relevance of each item to the content domain to determine if it should be deleted or retained, and added comments as desired. The original draft contained 26 scale items (14 adherence components and 12 competence components) that were framed as questions, each with a 5-point Likert scale with the scale anchors "not at all," "a little," "somewhat," "quite a bit," and "extensively" (Appendix C).

Based on content expert feedback, I made several revisions to the first instrument draft. I changed scale items from questions to declarative statements, revised Likert scale anchors to reflect ordered levels of agreement, and included an "undecided" option to provide a neutral middle value. I changed the Likert scale anchors for the competence components to "strongly disagree," "disagree," "undecided," "agree," and "strongly disagree." For the adherence components, judged by the content experts to require a less-nuanced gradation, I assigned a 3-point scale labeled "disagree," "undecided," and "agree." In the second item, I changed the phrase "encouraging tone of voice" was changed to "positive tone of voice" to clarify and enhance audible recognition of this competence attribute. I developed new scale items to allow measurement of aspects of implementation that had not been adequately addressed in the first draft, and I deleted several items perceived to duplicate measurement of behaviors assessed by other items.

At this point, the revised instrument contained 19 items, 10 describing adherence behaviors and 9 addressing competence behaviors (Appendix D). Of these items, I

grouped 16 into sequenced pairs with an adherence statement describing implementation of a specific behavior followed by a competence statement describing the quality of implementation. I determined that item 7, “the interventionist conveys awareness of the woman’s willingness to hear information regarding the effects of prenatal substance use,” was a stand-alone overriding competence behavior. I judged that two remaining items described independent adherence IAC behaviors: item 12 involved providing openings for the woman to react, and item 15 addressed the referral of medical questions.

When the content experts reviewed the second draft of the IAC instrument, they suggested additional modifications, and I further revised the instrument in accordance with their comments. In items 13 and 14, I replaced the ambiguous phrase “providing feedback” with “responding to the women’s reaction.” The content experts recommended deleting item 15, “the interventionist verbalizes praise when acknowledging the woman’s decision to discuss her drug use” because it would not apply to those women who chose not to discuss their drug use. Moreover, they thought that acknowledging a woman’s decision was the key element of this aspect of the IAC, and this had already been addressed in item 14 as an adherence component. I made a final revision to the second draft in accordance with content experts’ recommendation concerning item 19, “the interventionist refers medical questions asked by the woman to the physician or nurse.” Recognizing that some women would not have these questions, I added a “not applicable” option. Finally, I incorporated these revisions into a third draft of the IAC treatment fidelity instrument. The content experts endorsed this version without recommending additional revisions (Appendix E).

Step 6: Item testing and revision. Once the content experts deemed the IAC treatment fidelity instrument satisfactory, I conducted preliminary testing. To accomplish this, I hired as a research assistant, a clinical social work therapist who was skilled in the implementation of the IAC brief opportunistic intervention. I used practice audio recordings, made during simulated IAC implementation sessions with standardized patients in the role of substance-using pregnant women and myself playing the role of a frontline prenatal clinic staff member (see research protocol phase II, step 3), to conduct the preliminary testing. Guided by the IAC treatment fidelity instrument, the therapist and I independently evaluated, coded, and scored each of the practice audio recordings. We then mutually reviewed our results and discussed the clarity and utility of the instrument. On the basis of our review, we recognized that the competence items that corresponded to adherence items needed a “not applicable” option to provide raters a scoring alternative when IAC behaviors did not occur. The content experts approved this revision, resulting in the fourth and final version of the IAC treatment fidelity instrument that I used during data collection (Appendix F).

Phase II: Standardized patients.

Step 1: Standardized patient hiring. I recruited nine nursing students from the associate degree nursing program of a local community college as standardized patients to portray substance-using pregnant women. These students were paid as research assistants.

Step 2: Standardized patient identities. I created realistic standardized patients identities (Appendix G). The identities contained fictitious identity elements (name, age, pregnancy history, partner status, medical history, history of substance use, and living

conditions) upon which the students based their responses during the simulated interviews. Three registered nurse prenatal clinic obstetric case managers evaluated the identity scripts to ensure that they were realistic and reflective of actual patient cases.

Step 3: Standardized patient preparation. I met with the nursing students twice to prepare them for their respective standardized patient roles. At the first meeting, I gave the nursing students their scripted, standardized patient identities and described the simulation plan. I held a second, individual meeting with each nursing student prior to the beginning of data collection. At this time, the students participated in practice simulation sessions during which I played the role of the frontline staff member. I conducted an abbreviated prenatal intake interview, culminating in IAC implementation, with the nursing students role-playing their standardized patient identities. I recorded these interviews for future use in preliminary testing and revision of the treatment fidelity instrument (see research protocol phase I, Step 6) and to facilitate rater training (see research protocol phase III, step 2).

Phase III: Raters.

Step 1: Rater recruitment. I recruited three adjunct nursing faculty members from the associate degree-nursing program of a local community college to serve as raters. The faculty members were paid as research assistants.

Step 2: Rater training. I trained the raters using a curriculum that included didactic training regarding the theoretical framework grounding brief interventions and detailed discussion of IAC brief intervention implementation strategies (Appendix H). I provided each of the raters with the IAC treatment manual that is used to train frontline staff member in IAC implementation and as a guide during IAC implementation. In

addition, I introduced the raters to the IAC treatment fidelity instrument and gave them an opportunity to code and score the practice audio recordings that had been made during standardized patient preparation (see research protocol phase II, step 3). To achieve consensus and increase the level of inter-rater agreement, the raters and I reviewed and discussed their codings and scores, with respect to the ratings that the therapist and I had assigned.

Phase IV: Participant preparation. The frontline staff members recruited to participate in the study had already received IAC brief opportunistic intervention education in accordance with their job training. Prior to conducting the simulated clinic interviews, I met with them as a group to review concepts associated with IAC implementation and introduce them to the audio recording process that would be used (Appendix I). At this meeting I sought guidance from the frontline staff participants regarding the components that they thought necessary in an abbreviated prenatal intake interview form that I planned to create for use during the simulations. Subsequent to the meeting, I created this form and sent it to the participants via email for their approval prior to their participation in the clinic simulations (Appendix J).

Phase V: Brief opportunistic intervention implementation. During the simulated prenatal clinic sessions, the frontline staff participants met individually with the simulated patients portraying their scripted identities. In private rooms arranged to resemble a clinic office, the participants conducted prenatal intake interviews in accordance with the same process used when performing their job duties in their prenatal clinic or office. Each room was stocked with an IAC treatment manual and a sufficient

number of prenatal intake forms for the participants to use when interviewing the standardized patients.

At the beginning of each interview, I initiated a digital audio recording by identifying the pseudonyms of the participant and the standardized patient. Because all of the scripted identities assigned to the standardized patients resulted in eventual disclosure of prenatal ATOD use during the course of the interview, each session contained a segment during which the IAC brief opportunistic intervention was implemented.

At the completion of each clinic session, I collected the audio recording devices and downloaded the digital files into a folder on my home office computer. I used the pseudonyms identifying the participant interventionist and the standardized patient to label each of the digital files.

Phase VI: Treatment fidelity coding and scoring. Subsequent to the completion of the simulated clinic sessions, this 5-week long phase involving treatment fidelity coding and scoring by the raters began. During each meeting, I gave the raters compact discs containing 12 or 13 digital audio recordings labeled with pseudonyms designating the participants and the standardized patients. In addition to the audio recordings, I supplied raters with a corresponding number of copies of the IAC treatment fidelity instrument. I shuffled the order of the audio recordings before creating each rater's compact disc to reduce the possibility of any systematic bias that could have affected the assignment of scores. I randomized each rater's weekly set of audio recordings using playing cards by: (a) shuffling the deck three times, (b) placing a card face-up from the top of the deck on slips of paper designating each of the audio recordings in order, and (c) reordering the set of audio recordings from the highest to the lowest ranking card. Suit

order from high to low was: spades, hearts, diamonds, and clubs; the ace was considered a numeral one.

I directed the raters to listen independently to the audio recordings to determine the section during which IAC implementation occurred and encouraged them to replay the recordings as often as they deemed necessary to conduct a comprehensive appraisal. Using the IAC treatment fidelity instrument, the raters assessed the adherence and competence with which the specific IAC brief opportunistic intervention behaviors were implemented and rated them according to the tool's measurement scale, recording their ratings on the tool. Raters used the IAC treatment manual to review implementation concepts as needed and wrote comments describing any difficulty they experienced assigning scores. I also evaluated and scored each of the audio recordings assigned to the raters each week. This afforded me the opportunity to experience rating issues first-hand and enhanced my ability to facilitate the weekly meetings. My ratings were used for educational purposes only and were not included in statistical analyses.

I met weekly with the raters. At this time, the raters returned the previous week's audio recordings and completed fidelity tools, and they received a new set of audio recordings and fidelity tools. During these meetings, to achieve and maintain high inter-rater reliability and prevent drift, the raters and I discussed in detail how their measurement decisions had been made and any problems they had experienced in assigning ratings the previous week. Ratings made prior to meetings were not changed during or after the meetings.

Setting

The study took place in a mid-sized county in central California. I developed the IAC treatment fidelity instrument and standardized patient scripts at a desk in my home office. The phases that involved preparation and training of standardized patients and participants took place in a nursing classroom on the campus of a local community college. The training meeting with the raters occurred in my home. The fifth phase, IAC brief opportunistic intervention implementation simulation, took place in offices in the nursing department of a community college arranged to simulate the physical environment found in primary care prenatal clinics. The final and sixth phase, during which the raters independently audited and scored the audio recordings, occurred in the raters' homes. The weekly meetings with the raters took place in my home.

Sample

Six participants comprised the convenience sample for this study. I recruited participants from among frontline office staff members employed by the county's community health center prenatal clinics or local private obstetrician offices. Inclusion criteria for the study were: (a) trained to implement the IAC brief opportunistic intervention according to prenatal clinic policy, (b) a minimum of 2 years experience in IAC implementation, (c) English-speaking, and (d) adequate hearing and vision to conduct an interview. No other criteria were used for inclusion in the study.

Sample size. The statistical sample for this study was the total number of IAC brief opportunistic intervention sessions implemented by the participants. The number of sessions determined as adequate for this study was based on calculation of the required sample size for inter-rater reliability, measured using the intra-class correlation

coefficient (ICC) (Walter, Eliasziw, & Donner, 1998). The key determinants of sample size in this calculation are: (a) the level of acceptable inter-rater agreement; (b) the level of anticipated inter-rater agreement, and (c) the difference between these two values (Walter et al., 1998). I used guidelines for differentiating ICC estimates of inter-rater reliability that are clinically meaningful from those that are not (Cicchetti, 1994; Landis & Koch, 1977). When the ICC is calculated to estimate levels of inter-rater agreement, guidelines recommend the following criteria for determining clinical significance: below 0.40 is poor; 0.40 to 0.59 is fair; 0.60 to 0.74 is good; and 0.75 to 1.00 is excellent (Cicchetti; Cicchetti & Sparrow, 1981). For my study, I judged 0.70 to be the minimum level of acceptable inter-rater agreement, a value generally recognized as satisfactory (Nunnally & Bernstein, 1994). I anticipated that inter-rater agreement would be 0.85 because higher levels are reasonably attained when strategies to achieve and maintain inter-rater reliability are implemented, including: comprehensive rater training, initial calibration through achievement of consensus on practice ratings, and regular recalibration meetings (Barber & Crits-Christoph, 1996; Hill, O'Grady, & Elkin, 1992; Perepletchikova et al., 2007; Tevyaw & Monti, 2004).

In accordance with these values, a sample size of 49 interviews was required to achieve 0.90 power with an alpha of 0.05 for a one-sided significance test, when acceptable inter-rater agreement is 0.70, anticipated inter-rater agreement is 0.85, and three raters are used. Each of the six participants recruited for the study were scheduled to conduct simulated interviews with each of the nine standardized patients, which would have resulted in 54 cases. This number was reduced by circumstances that occurred during this phase of the study including a personal conflict that prevented one of the

participants returning to conduct scheduled interviews with three of the standardized patients, and two audio recordings that were unintelligible. As a result, the precise minimum required sample size of 49 cases was achieved.

Participant recruitment. I mailed introductory letters describing the study to provider and frontline staff employed by the prenatal offices and clinics within the county (Appendix K). The following week, I contacted these agencies by telephone and spoke directly with frontline staff members whose job responsibilities included IAC brief opportunistic intervention. During these conversations, I introduced myself, answered questions about the study, and invited the staff members to contact me directly if they thought they might want to participate. Of the 10 individuals who subsequently contacted me to express interest, 6 eventually participated in the study. One interested frontline staff member did not meet the inclusion criteria, having had insufficient experience conducting the IAC intervention. Three other individuals who did meet the screening criteria had schedules that proved to be too demanding to accommodate study participation. Participants were compensated for their participation at an hourly rate commensurate with their normal employment.

Procedures for Protection of Human Participants

I sought approval for the study protocol from the Duquesne University Institutional Review Board. I obtained informed consent (Appendix M) from each of the frontline staff participants during their initial meeting with me. I informed participants that their involvement was totally voluntary and that there were no consequences for non-participation. There were no anticipated risks to participation and anticipated benefits included the dissemination of study findings to a larger health care audience. Consents

were not required of the therapist, the standardized patients, or the raters, because these individuals were employees rather than participants. Each rater signed a confidentiality statement (Appendix N). I used the following measures to protect the confidentiality and rights of the participants:

1. All study documents were kept confidential and free from participant identifiers. I assigned each participant a pseudonym that I used in analyzing the information that was obtained. Only I knew the matching names and the corresponding pseudonyms. The original list containing participant contact information and pseudonym cross-referencing was kept in a locked file cabinet in my home office throughout the duration of the study and will be destroyed when the results have been published.
2. I listened to the audio recordings to ensure that there were no referents that could have potentially identified the participants before the audio recordings were given to the raters. I labeled each audio recording with the specific participant's pseudonym. Compact discs containing audio recordings were kept in a locked file cabinet in my home office except when they were issued to the raters. The computer containing the digital audio recording files of the clinic simulations is situated in my home office and is not accessible by any individuals other than myself. I set a master password, known only to me, for this computer. All study materials will be destroyed at the end of the study with the exception of the de-identified files of the digital audio recordings and the de-identified database.

Procedures for Data Collection

I collected content validity evidence in conjunction with tool development and content expert judgment during phase one of the study. The remaining data comprised treatment fidelity scores assigned by the three raters.

Data collection instrument. During the first phase of the study, I developed the IAC treatment fidelity instrument that was used to collect research data. This instrument guided measurement of the adherence and competence behaviors associated with implementation of the IAC brief opportunistic intervention by the participants. I used a demographic tool to collect data describing age, gender, race, level of education, and years of experience of the participants (Appendix L).

Data analysis. I used the PASW Grad Pack 18.0 for Mac (formerly SPSS) to analyze descriptive and psychometric data. An assistant professor in the department of statistics from a state university provided professional statistical consultation.

Content validity. I. J. Chasnoff and R. F. McGourty, co-developers of the IAC brief opportunistic intervention, served as content experts for this study and conducted the content validity analysis described earlier (see research protocol phase I, steps 5 and 6). I used the clarity and sufficiency ratings assigned by the content experts to compute a content validity index (CVI) quantifying their extent of agreement. The CVI was computed by dividing the number of items rated as 4 for clarity (item is clear) and sufficiency (item is sufficient), by the total number of items on the instrument (Polit & Hungler, 1999; C. F. Waltz et al., 2005). Although a CVI of 0.80 or greater is generally considered acceptable (Davis, 1992), Lynn (1986) proposed that when content validity is assessed with fewer than six experts, perfect agreement should exist. Accordingly, I

continued the process of instrument revisions until I achieved a CVI of 1.0 for all scale items.

Inter-rater reliability. Inter-rater reliability is an estimate of the extent to which raters obtain the same result when independently using an instrument to measure an observation (Polit & Hungler, 1999). This form of reliability measures the proportion of variance in a set of ratings in relation to the total variance of the ratings (James, Demaree, & Wolf, 1984). The ICC allows assessment of rating reliability through a comparison of the variability of different ratings for a data set and is the statistic of choice for measuring levels of agreement between a consistent set of raters (Shrout & Fleiss, 1979). In addition, the ICC is the appropriate measure of inter-rater reliability with dimensionally scaled data (such as Likert-type scaling) and when more than two raters are used (Cicchetti, 1994). As stated earlier, the clinical significance of a given ICC value is interpreted as: below 0.40 is poor; 0.40 to 0.59 is fair; 0.60 to 0.74 is good; and 0.75 to 1.00 is excellent (Cicchetti; Cicchetti & Sparrow, 1981). I calculated the ICC as an index of the agreement between the adherence and competence scores assigned by the independent raters. Detailed findings regarding the inter-rater reliability results associated with use of the IAC treatment fidelity instrument are presented in chapter 4.

Internal consistency reliability. Internal consistency reliability measures the extent of correlation between different items on an instrument that have been designed to measure the same construct (Polit & Hungler, 1999). Coefficient alpha is the most frequently used index of internal consistency (DeVon et al., 2007). An alpha coefficient of 0.70 is considered acceptable for a new scale (DeVellis, 2003); coefficients of 0.80 or higher are desirable for established scales (Nunnally & Bernstein, 1994). I calculated this

statistic for the combined adherence and competence ratings of the three raters to provide an estimate of the degree of interrelatedness associated with the IAC treatment fidelity instrument. Details of the internal consistency reliability findings are presented in chapter four.

Chapter 4

Results and Discussion

This chapter includes the findings of this study to develop the IAC treatment fidelity instrument and evaluate the psychometric characteristics associated with its use. I present a demographic profile of the study participants and describe the results and analyses associated with the research questions that address the validity and the reliability associated with the instrument. This chapter concludes with a discussion of the findings.

Recruitment of Study Participants

After receiving approval for this study from the Duquesne University Institutional Review Board, I secured a convenience sample of 6 frontline prenatal office staff members as previously described. The phase of the study protocol during which participants conducted interviews and implemented the IAC brief intervention with the standardized patients in a simulated prenatal clinic setting took place over a 3-week period in June 2010. Data collection occurred over a 5-week period in June and July 2010. During this phase, the raters used the IAC treatment fidelity instrument to assign scores that reflected their assessment of the fidelity with which participants implemented the IAC brief opportunistic intervention during the simulated clinics.

Characteristics of Study Participants

Demographic data for the sample are summarized in Table 1. The frontline staff participants in this study were female, ranging in age from 32 to 52 years. In terms of race, half described themselves as Hispanic/Latino and the rest as non-Hispanic White. Three of the participants reported high school as their highest level of education attained; the remaining three participants held an associate degree, bachelor's degree in health

science, and master’s degree in nursing. The composition of work positions held by the participants were 50% (n =3) medical assistant, 33% (n=2) perinatal educator, and 17% (n=1) nurse practitioner, reflecting the staffing structure found in primary care practice (Grumbach & Bodenheimer, 2004). In terms of prenatal primary care employment experience, participants reported 3 to 6 years (n=3), 7 to10 years (n=2), and over 10 years (n=1). Participants reported that they had been implementing the IAC brief intervention in their practices for 2 to 4 years (n=3), 5 to 7 years (n=1) and more than 7 years (n=2).

Table 1

Demographic Descriptions of Participants (N = 6)

Category	n
Age	
32 to 42	3
43 to 52	3
Gender	
Female	6
Race	
Non-Hispanic White	3
Hispanic/Latino	3
Highest Level of Education	
High School	3
Associate Degree	1
Bachelor’s Degree Health Science	1
Master’s Degree Nursing	1
Work Position	
Medical Assistant	3
Perinatal Educator	2
Nurse Practitioner	1
Years Worked in Prenatal Clinical or Office	
3 to 6	3
7 to 10	2
More than 10	1
Years Implementing IAC	
2 to 4	3
5 to 7	1
More than 7	2

Analysis of Research Questions

Research question 1: “What is the content validity associated with an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco, and other drugs by pregnant women?”

I conducted a content validity assessment to determine the degree to which the items included in the instrument adequately represented the fundamental concepts and behaviors associated with implementation of the IAC brief opportunistic intervention. I assessed content validity with the assistance of content experts I. J. Chasnoff and R. F. McGourty, who co-developed the IAC brief opportunistic intervention. I submitted each draft of the IAC treatment fidelity instrument for their recursive review until a final CVI of 1.0 reflected their complete accord regarding the clarity, sufficiency, and relevance of the scale items. The fourth and final version fulfilled this requirement and was the edition used by the raters during data collection (Appendix F).

Reliability test assumptions. The fulfillment of assumptions underlying the statistical tests chosen to analyze study data should be considered when evaluating the cogency of the statistical conclusions (Sheskin, 2003). I selected Cronbach’s alpha coefficient and the ICC to assess the reliability of the ratings that were assigned by the raters using the IAC treatment fidelity instrument. The primary assumptions of these parametric tests are that sample data will be distributed normally and will display variance comparable to the population to which the findings are generalized (Munro, 1997). In this study, there was a notable lack of variance among the scores assigned by the raters, resulting in an asymmetrical, negatively skewed distribution of data with the scores clustered toward the positive end of the scale. Because the ratings in this study

varied so little, there was no mechanism that could be applied to transform scale data in order to introduce variability and approximate the normal distribution necessary to meet the parametric assumptions underlying these tests (Cicchetti & Feinstein, 1990; Sheskin, 2003). When study data fail to meet the equal variance and normality assumptions required of parametric tests, use of nonparametric tests (that typically do not rely on assumptions of normal distribution of the variable in the population) should be considered (Sheskin, 2003). The Kuder-Richardson formulas (KR 20 and KR 21), which are the nonparametric measures of internal consistency analogous to Cronbach's alpha, are only suitable for measures with dichotomous variables (Allen & Yen, 2002), rendering these tests unsuitable for this study. Weighted kappa, the ICC's nonparametric equivalent, is mathematically identical to the ICC (Norman & Streiner, 2008) and is equally sensitive to the effects of uneven data distribution (Feinstein & Cicchetti, 1990). Accordingly, I used Cronbach's alpha and the ICC in the reliability analyses as specified in the study protocol. These parametric tests are consistent with the statistical approaches that have been described and recommended for use when developing a measure of treatment fidelity (Stein et al., 2007).

Research question 2: “What is the inter-rater reliability associated with use of an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco and other drugs by pregnant women?”

Inter-rater reliability describes the extent of agreement among the scores assigned by a group of raters assessing the same behaviors (James et al., 1984). The ICC measures the consistency of the relative rankings of scores among raters (Shrout & Fleiss, 1979)

and is contingent on the relationships among the ratings rather than relying on raters assigning the same scores. ICCs (followed by the 95% confidence interval bounds) calculated as indices of the reliability of the adherence and competence subscales in addition to each scale item are presented in Table 2. If these calculations were to be repeated with multiple samples, the computed confidence intervals are expected to encompass the true ICC population value 95% of the time (Munro, 1997).

Table 2

IAC Treatment Fidelity Instrument Inter-rater Reliability (N = 49)

Scale Items	ICC ^a	95% Confidence Interval	
		Lower	Upper
Adherence subscale (10 items)	0.64	0.42	0.78
Competence subscale (8 items)	0.62	0.39	0.77
1: Bridging comment – adherence	0.44	0.10	0.66
2: Bridging comment – competence	0.56	0.29	0.74
3: “I” message – adherence	0.21	0.00	0.53
4: “I” message – competence	0.15	-0.36	0.49
5: Attempts to share information – adherence	(0.00)	-	-
6: Attempts to share information - competence	0.51	0.22	0.71
7: Conveys awareness of willingness - competence	0.74	0.59	0.85
8: Explains effects of substance use - adherence	0.60	0.35	0.76
9: Explains effects of substance use - competence	0.80	0.67	0.88
10: Advocates drug abstinence – adherence	0.65	0.43	0.79
11: Advocates drug abstinence – competence	0.77	0.63	0.86
12: Provides openings to react – adherence	0.20	0.00	0.52
13: Responds to woman’s reaction – adherence	(-0.07)	-	-
14: Responds to woman’s reaction - competence	0.46	0.13	0.68
15: Acknowledges decision to discuss drugs - adherence	0.61	0.37	0.77
16: Offers referrals – adherence	0.81	0.69	0.89
17: Offers referrals – competence	0.80	0.67	0.88
18: Refers medical questions – adherence	0.70	0.52	0.82

Note. Values enclosed in parentheses represent paradoxically low ICC calculations. Dashes indicate that confidence intervals were not estimated.

^aICC = intraclass correlation coefficient

Guidelines developed by Cicchetti and Sparrow (1981) to examine levels of inter-rater agreement stipulate that an ICC below 0.40 is poor; 0.40 to 0.59 is fair; 0.60 to 0.74 is good, and 0.75 to 1.00 is excellent. Accordingly, the ICC values attained for the adherence (0.64) and competence (0.62) subscales correspond to a satisfactory level of inter-rater reliability.

The ICCs calculated for the individual items vary widely, ranging from -0.07 to 0.81. Ostensibly, the values at the lower end of the range would seem to indicate poor inter-rater reliability. To adequately calculate inter-rater reliability, ratings should be distributed across the breadth of the scale (C. F. Waltz et al., 2005). There is a well-known limitation associated with the ICC (which corresponds to the weighted kappa measured on an ordinal scale; Fleiss & Cohen, 1973) and other reliability test statistics described as the kappa “base rate problem” (Feinstein & Cicchetti, 1990). This problem occurs in the presence of data prevalence, when a high proportion of ratings fall under only a few of the scale scores (Hoehler, 2000). The paradoxical effects associated with data prevalence arise “when the overall proportion of positive results is substantially different from 50%” (Hoehler, 2000, p. 500). In this event, the amount of agreement that can be expected to occur by chance alone is increased and the size of the correlation coefficient correspondingly declines.

When low ICC scores are computed from high-prevalence measurement data, it is appropriate to additionally report the percentage of actual rater agreement as a further indicator of inter-rater reliability (Hoehler, 2000). Table 3 displays the observed percentage-agreement among the raters for each scale item accompanied by the obtained ICC for comparison. Overall, the high level of rater agreement is illustrated by the fact that, for all of the scale items, the incidence of no agreement among raters occurred no more than 6% of the time. The base rate problem is exemplified in item 5, which showed an ICC of 0.00 although the raters were in complete agreement 98% of the time. All of the low-ICC adherence items (3, 5, 12, and 13) are associated with levels of complete rater agreement of at least 86%. Complete rater agreement for item 4 (the sole

competence item showing a low ICC) is 55%. This does not differ significantly from the levels of complete rater agreement observed for other competence components, which range from 47% to 65%.

Table 3

IAC Treatment Fidelity Instrument Rater Agreement Percentage (N = 49)

Scale Item	Rater Agreement			ICC
	None	Two	Three	
1: Bridging comment – adherence	0.02	0.27	0.71	0.44
2: Bridging comment – competence	0.06	0.43	0.51	0.56
3: “I” message – adherence	0.00	0.14	0.86	0.21
4: “I” message – competence	0.04	0.41	0.55	0.15
5: Attempts to share information – adherence	0.00	0.02	0.98	0.00
6: Attempts to share information - competence	0.04	0.33	0.63	0.51
7: Conveys awareness of willingness - competence	0.06	0.41	0.53	0.74
8: Explains effects of substance use - adherence	0.00	0.20	0.80	0.60
9: Explains effects of substance use - competence	0.06	0.41	0.53	0.80
10: Advocates drug abstinence – adherence	0.00	0.16	0.84	0.65
11: Advocates drug abstinence – competence	0.02	0.51	0.47	0.77
12: Provides openings to react – adherence	0.02	0.10	0.88	0.20
13: Responds to woman’s reaction – adherence	0.00	0.10	0.90	-0.07
14: Responds to woman’s reaction - competence	0.06	0.33	0.61	0.46
15: Acknowledges decision to discuss drugs - adherence	0.00	0.33	0.67	0.61
16: Offers referrals – adherence	0.00	0.10	0.90	0.81
17: Offers referrals – competence	0.02	0.33	0.65	0.80
18: Refers medical questions – adherence	0.00	0.12	0.88	0.70

Note: Rater agreement values reflects the number of scores when raters were in agreement as a percent of the total possible scores (N = 49 for each scale item; None = no raters were in agreement; ICC = intraclass correlation coefficient; ICC values less than .40 are shown in boldface.

It is clear from direct appraisal of the values displayed in Table 3 that the rater agreement percentages alone cannot completely account for the paradoxical ICC results. For example, the ICC associated with item 13 is even lower at -0.07 than that obtained for item 5, although raters were in complete agreement less often for that item. It is also apparent that the high levels of agreement attained in items 16 and 18 did not produce contradictorily low ICCs.

Further analysis of the effect of high prevalence on the inter-rater reliability statistic can be evaluated through the direct examination of the raters’ scores. The rating

frequency of adherence and competence components among the raters is presented in Tables 4 and 5. Adherence items were rated on a 3-point scale, and competence items were measured on a 5-point scale.

Table 4

IAC Treatment Fidelity Instrument Adherence Items Rating Frequency (N = 49)

Scale Item	Rater	Adherence Scale Ratings				Mean	SD
		Disagree	Undecided	Agree	N/A		
1: Bridging comment	One	10	3	36		2.53	0.82
	Two	2	0	46		2.92	0.40
	Three	2	3	44		2.86	0.46
3: "I" message	One	3	0	46		2.88	0.48
	Two	1	0	48		2.96	0.29
	Three	4	0	45		2.84	0.55
5: Attempts to share information	One	0	1	48		2.98	0.14
	Two	0	0	49		3.00	0.00
	Three	0	0	49		3.00	0.00
8: Explains effects of use	One	4	0	45		2.84	0.55
	Two	1	2	46		2.92	0.34
	Three	5	3	41		2.73	0.64
10: Advocates abstinence	One	4	2	43		2.80	0.58
	Two	2	1	46		2.90	0.42
	Three	3	1	45		2.86	0.50
12: Provides opening to react	One	2	1	46		2.90	0.42
	Two	0	0	49		3.00	0.00
	Three	2	2	45		2.88	0.44
13: Responds to reaction	One	1	1	47		2.94	0.32
	Two	0	0	49		3.00	0.00
	Three	2	2	45		2.90	0.42
15: Acknowledges decision to discuss drugs	One	7	2	40		2.67	0.72
	Two	6	4	39		2.67	0.69
	Three	4	5	40		2.73	0.61
16: Offers referrals	One	4	1	44		2.82	0.57
	Two	1	1	47		2.94	0.32
	Three	3	1	45		2.86	0.50
18: Refers medical questions ^a	One	0	0	1	49	0.06	0.43
	Two	1	0	6	42	0.39	1.00
	Three	0	0	2	47	0.12	0.60

Note: Ratings values represent the frequency with which rater one, rater two, and rater three assigned scores for adherence scale items.

^a Only adherence component with a "not applicable" rating option

Table 5

IAC Treatment Fidelity Instrument Competence Items Rating Frequency (N = 49)

		Competence Scale Ratings						Mean	SD
Scale Item	Rater	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree	N/A		
2: Bridging comment	One	0	3	2	10	31	3	3.92	1.70
	Two	0	0	0	5	42	2	4.69	1.03
	Three	0	0	0	10	36	3	4.45	1.24
4: "I" message	One	0	0	0	18	30	1	4.53	0.82
	Two	0	0	0	5	43	1	4.80	0.77
	Three	1	0	3	6	38	1	4.57	1.02
6: Attempts to share information	One	0	0	0	13	36	0	4.73	0.45
	Two	0	0	1	4	44	0	4.88	0.39
	Three	0	0	1	11	37	0	4.73	0.49
7: Conveys awareness	One	0	1	3	12	33	0	4.57	0.71
	Two	0	0	3	9	37	0	4.69	0.59
	Three	0	1	2	10	36	0	4.65	0.66
9: Explains effects of use	One	0	2	0	12	33	2	4.43	1.16
	Two	0	0	0	3	45	1	4.84	0.75
	Three	0	0	1	3	42	3	4.59	1.24
11: Advocates abstinence	One	0	0	0	17	31	1	4.55	0.82
	Two	0	0	0	6	41	2	4.67	1.03
	Three	0	0	0	10	36	3	4.45	1.24
14: Responds to reaction	One	0	1	0	10	37	1	4.63	0.89
	Two	0	0	0	1	48	0	4.98	0.14
	Three	0	0	0	10	37	2	4.59	1.04
17: Offers referrals	One	0	0	1	10	33	5	4.22	1.55
	Two	0	0	0	1	46	2	4.78	1.01
	Three	0	0	1	2	43	3	4.61	1.24

Note: Ratings values represent the frequency with which rater one, rater two and rater three assigned scores for competence scale items.

It is apparent from the data displayed in Tables 4 and 5 that the preponderance of ratings is clustered under the positive end of the scale, resulting in a negatively skewed, sharply peaked distribution. Further evaluation of the prevalence effect can be achieved by computing the coefficient of variation (CV) associated with the ratings for each scale item. When the CV associated with a scale item is small, this further corroborates that ratings fall only under a few of the scale scores. Table 6 displays the mean CV of the scores assigned by the raters for each scale item, together with the percentage of

complete rater agreement and the calculated ICC for comparison.

Table 6

IAC Treatment Fidelity Instrument Inter-rater Reliability Results Comparison (N = 49)

Scale Item	CV	Complete Agreement	ICC
1: Bridging comment - adherence	20.67	0.71	0.44
2: Bridging comment - competence	31	0.51	0.56
3: "I" message - adherence	15.31	0.86	0.21
4: "I" message - competence	18.77	0.55	0.15
5: Attempts to share information - adherence	1.6	0.98	0.00
6: Attempts to share information - competence	9.26	0.63	0.51
7: Conveys awareness of willingness - competence	14.07	0.53	0.74
8: Explains effects of substance use - adherence	18.21	0.80	0.60
9: Explains effects of substance use - competence	22.83	0.53	0.80
10: Advocates drug abstinence - adherence	17.54	0.84	0.65
11: Advocates drug abstinence - competence	22.65	0.47	0.77
12: Provides openings to react - adherence	9.92	0.88	0.20
13: Responds to woman's reaction - adherence	8.43	0.90	-0.07
14: Responds to woman's reaction - competence	14.86	0.61	0.46
15: Acknowledges decision to discuss drugs - adherence	24.95	0.67	0.61
16: Offers referrals - adherence	16.1	0.90	0.81
17: Offers referrals - competence	28.18	0.65	0.80
18: Refers medical questions - adherence	490.13	0.88	0.70

Note: CV = coefficient of variation; CV values calculated from mean of raters' scores for each scale item; ICC = intraclass correlation coefficient; Complete agreement values reflect percentage when all raters selected same score; Values for scale items associated with ICCs less than .40 are shown in boldface.

All of the low-ICC adherence items (3, 5, 12, and 13) are associated with significantly lower CVs and higher levels of complete rater agreement in comparison to other adherence scale items. As a result, the inter-rater reliability statistics calculated from these data must be interpreted in light of the low data variance. This pattern is not replicated in the statistics associated with item 4, which is the only low-ICC competence item.

Research question 3: "What is the internal consistency associated with use of an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco, and other drugs by pregnant women?"

Internal consistency reliability assesses the communality of results across items within a scale and provides an estimate of the degree to which scale items designed to reflect the same construct produce similar results (Trochim & Donnelly, 2007). I evaluated the internal consistency reliability associated with use of the IAC treatment fidelity instrument using Cronbach’s coefficient alpha. The inter-correlations among scale items are presented in Table 7.

Table 7

IAC Treatment Fidelity Instrument Internal Consistency Reliability (N = 49)

Scale Items	Number of Items	Cronbach’s Alpha	Spearman-Brown Prophecy r_2
All scale items	18	0.72	0.84
Adherence subscale	10	0.54	0.70
Competence subscale	8	0.56	0.72

Note: Spearman-Brown prophecy reflects estimated reliability coefficient if scale were twice as long.

An internal consistency analysis using the ratings obtained for the entire scale yielded a coefficient of 0.72. While an alpha coefficient above 0.80 is desirable, a coefficient of 0.70 is considered an acceptable measure of internal consistency reliability for a new scale in the preliminary stages of development (DeVon et al., 2007). Because the IAC treatment fidelity instrument was designed to measure the complementary dimensions of adherence and competence during implementation, I also calculated Cronbach’s alphas separately for the scores obtained from each subscale. The internal consistency reliabilities for the adherence and competence subscales were 0.54 and 0.56 respectively.

A factor that directly impacts the measurement of alpha is instrument length; the greater the number of items included on an instrument, the higher the resulting alpha (C. F. Waltz et al., 2005). As a result, measures of internal consistency reliability are increased through the addition of further scale items (DeVellis, 2003). The Spearman-

Brown prophecy formula allows the estimation of instrument reliability at differing lengths based on the known reliability of the measure (Carmines & Zeller, 1979), assuming that the additional items retain the nature of the original test (C. F. Waltz et al., 2005). I used the Spearman-Brown formula to estimate what the reliabilities would be if the scales were doubled. The coefficients increased to 0.84 for the entire scale, 0.70 for the adherence subscale, and 0.72 for the competence subscale (see Table 7).

Table 8 presents further analysis of the internal consistency of the instrument adherence and competence subscales, accomplished by sequentially deleting items from each of the subscales and computing correlation coefficients for the modified subscale. Elimination of two items resulted in slightly higher alphas, although neither approached the requisite 0.70. For the adherence subscale, the deletion of item 18 produced a higher alpha (0.59), in comparison to that of the unmodified version (0.54). For the competence subscale, alpha was increased from 0.56 to 0.61 with the omission of item 17.

Table 8

IAC Treatment Fidelity Instrument Internal Consistency: Modified Subscales (N = 49)

Scale	Item Deleted	Cronbach's Alpha
Adherence subscale	1: Bridging comment	0.49
	3: "I" message	0.50
	5: Attempts to share information	0.54
	8: Explain effects of substance use	0.50
	10: Advocates drug abstinence	0.48
	12: Provides openings to react	0.49
	13: Responds to women's reaction	0.52
	15: Acknowledges decision to discuss drugs	0.49
	18: Refers medical questions	0.59
Competence subscale	2: Bridging comment	0.56
	4: "I" message	0.48
	6: Attempts to share information	0.53
	7: Conveys awareness of willingness	0.54
	9: Explain effects of substance use	0.46
	11: Advocates drug abstinence	0.52
	14: Responds to women's reaction	0.51
17: Offers referrals	0.61	

Note: Values reflect subscale internal consistency with deletion of specified items.

Discussion of Results

This section presents a discussion of the meaning of the results associated with the psychometric testing addressed in the research questions that provided the focus for this study. The conceptual framework that systematically guided both the development of the IAC treatment fidelity instrument and the measurement process that took place during this study integrated concepts derived from motivational interviewing and self-determination. Both of these theories are based on the fundamental assumption that individuals are inherently inclined toward positive change (Markland et al.; Vansteenkiste & Sheldon).

Research question 1: “What is the content validity associated with an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco, and other drugs by pregnant women?”

The evidence that I collected during this study established initial content validity associated with the IAC treatment fidelity instrument in relation to the content domain of the IAC treatment fidelity instrument. A CVI of 1.0 reflected the consensus judgment of two singularly qualified content experts regarding the clarity and quality of the items, the adequacy with which the items represented the IAC content domain, and the relevance of the items to the identified construct.

When using this instrument to evaluate IAC implementation, the raters reported they found it straightforward and inclusive of all of the behavioral elements that required their assessment. They reported no difficulty making a choice between the three rating options provided for the adherence items (agree, undecided, disagree), but did question the need for five levels of agreement for the competence items. The raters stated they

found it challenging to audibly identify behavioral nuances that allowed them to distinguish between ratings, such as agree and strongly agree, and they recommended using a simpler measuring system for competence items, such as the 3-point scale assigned to the adherence items.

The content validation process that I followed was a two-stage process of development and judgment recommended by Lynn (1986). The first stage of this process required me to become conversant with the content domain. To accomplish this, I conducted a comprehensive appraisal of the relevant literature that I judged to comprise the content domain, which included motivational interviewing, self-determination theory, and treatment fidelity, in addition to the IAC brief intervention. This rigorous review provided me a thorough awareness of the content foundation, upon which I relied as I developed the individual items that would eventually become the IAC treatment fidelity instrument. The depth and accuracy of this stage is considered an essential component in the process of content validation (C. F. Waltz et al., 2005).

Through conducting this study, my understanding of the process of measurement validity has been strengthened. Validity is a fundamental concept that involves ascertaining whether an instrument does actually measure the construct it was developed to measure (C. F. Waltz et al., 2005). When validity is defined thus, it is evident that construct validity is the unified whole that encompasses all other types of validity (Goodwin, 2002; C. F. Waltz et al., 2005)}. Content validation is a necessary theoretical step in tool development as it provides evidence regarding the relationship of the content domain to the intended interpretation of the scores (Goodwin, 2002). However, content validity is limited in that the methods used in the assessment of this type of validity do

not provide actual evidence that the scores obtained through measurement support the construct (Carmines & Zeller, 1979). Empirical support for the consistency with which an instrument's measures represent a content domain can be provided by accumulating validity evidence based on response processes, internal structure, relationships to other variables, or the consequences of testing (Goodwin, 2002). This type of validation assessment is appropriate during the development of a new instrument, as well as for a fully developed tool. A validity assessment based on evidence derived from test content alone is insufficient and should be substantiated by evidence collected from validation activities that allow assessment of the validity of the inferences derived from the scores obtained through the use of an instrument (Carmines & Zeller, 1979; Goodwin, 2002).

The focus of the first research question that I identified for this study, confined to the assessment of content validity, was too limited. A more appropriate research question, acknowledging the broader conceptualization of validity, would have been a more general inquiry regarding the existence of evidence for validity associated with the instrument. My assessment of the validity associated with the IAC treatment fidelity instrument would have been strengthened by designing the study to incorporate methods that allowed for a wider collection of additional validity evidence.

I have identified a method that could have been incorporated into the design of this study to provide additional evidence of validity. The contrasted or known groups approach is a method that can be used to provide evidence based on the empirical relationship of predictor scores to other variables (Goodwin, 2002). This strategy involves distinguishing two groups of individuals known to possess contrasting levels of the attribute the instrument proposes to measure. For this study, I would recruit a second

group of frontline staff members without any previous IAC experience. This group, in addition to the experienced frontline staff group, would conduct interviews with the standardized patients, culminating in IAC brief intervention implementation. If the treatment fidelity instrument is sensitive to varying levels of IAC implementation adherence and competence, presumably, the experienced group mean scores would be higher than those of the inexperienced group. A significant difference in mean scores between the groups would imply that the instrument is able to distinguish between their differing levels of IAC treatment fidelity, the construct that the instrument was developed to measure. An additional benefit that would be accrued from this modification to the study design is the heterogeneity it would introduce to the sample. This might increase the normality of data distribution and the resulting accuracy of the reliability analyses.

Research question 2: “What is the inter-rater reliability associated with use of an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco, and other drugs by pregnant women?”

Inter-rater reliability is a psychometric measure that provides an estimate of the degree of agreement among raters (C. F. Waltz et al., 2005). It is an attribute of the scores obtained through use of the instrument rather than a property of the instrument itself and should be assessed with each use of a scale (Guthrie, 2000). The ICCs that I calculated for the adherence and competence subscales of the IAC treatment fidelity instrument were acceptable for a new instrument at 0.64 and 0.62 respectively. These findings provide preliminary support for the use of this instrument to assess treatment fidelity

during implementation of the IAC brief opportunistic intervention.

The ICCs calculated for 13 of the 18 individual scale items ranged from 0.44 to 0.81; all of these values are within acceptable levels of inter-rater reliability (Cicchetti & Sparrow, 1981). The ICCs for the remaining scale items (3, 4, 5, 12, and 13), ranging from -0.7 to 0.21, correspond with less than satisfactory levels of inter-rater reliability. Respectively, these items were also associated with the highest levels of complete rater agreement (0.86, 0.98, 0.88, and 0.90) and lowest data variance as evidenced by the CVs calculated for each item (15.31, 1.6, 9.92, and 8.43). These conditions correspond to those that have been linked to the base-rate problem, known to generate paradoxically low inter-rater reliability statistics (Hoehler, 2000). As a result, I conclude that the low ICCs computed for these items are associated with these factors and fail to accurately reflect the true levels of inter-rater agreement.

The level of percentage agreement (0.55) and data variance (CV 18.77) associated with item 4, the remaining low-ICC scale component, did not demonstrate sufficient magnitude in comparison to other scale items to exert a similar paradoxical influence on the calculated inter-rater reliability statistic. Consequently, I believe that the ICC associated with this competence item (which addresses the positive tone of voice associated with interventionist delivery of the “I” message) is accurate.

During my weekly meetings with the raters, they frequently discussed and sought clarification on precisely what constituted both an “I” message and a positive tone of voice. The lack of clarity on this aspect of IAC implementation undoubtedly impacted the raters’ measurement of the “I” statement adherence statement (item 3) as well as the paired competence statement (item 4). Measurement of these items were further

complicated when interventionists used the pronoun “we” instead of “I” in sentences expressing their concern. When this occurred, raters expressed uncertainty regarding the authenticity of this statement as an “I” message and were inconsistent in their measurements of this behavior. Thus, despite the base-rate problem suspected to have exerted influence on the ICC calculated for item 3 as described above, I suspect that both item 3 and item 4 would benefit from revision.

When I developed the study protocol, I did not foresee the manner in which the actions designed to ensure accuracy of implementation of the IAC brief opportunistic intervention would influence the distribution of data. The frontline staff members that I recruited for the study were all experienced in conducting the IAC intervention and I further reviewed and discussed IAC implementation behaviors during my preparatory meeting with them to ensure consistency of application. As a result, the interventionists uniformly implemented the IAC brief opportunistic intervention with high fidelity, and the raters had little opportunity to measure instances of substandard implementation. Accordingly, the majority of the ratings they assigned were clustered at the positive end of the scale.

I designed the last three phases my study protocol to occur in successive increments, with each concluding prior to the subsequent phase. Once the simulated clinics had taken place and the interviews between the interventionists and the standardized patients had been recorded, I began to meet with the raters. Each week, when I met with the raters to discuss their scores, I was encouraged by the significant agreement that was evident among their ratings. I did not analyze the scores obtained through the raters’ use of the instrument until the data collection phase involving the

raters had concluded. As result, I did not recognize the impact that high-fidelity implementation had exerted on the reliability assessments until my statistical analyses were completed.

Retrospectively, I have identified alterations to my study protocol that would have increased sample heterogeneity and minimized the occurrence of paradoxically low reliability scores. Initially, this issue could have been addressed during the participant recruitment phase by eliminating the requirement that participants had at least 2 years experience in IAC implementation, a modification that would have the added benefit of increasing the number of qualified candidates. However, this presumes that frontline staff members with less experience would be correspondingly less faithful in their implementation of the IAC, an assumption that may not be substantiated. To ensure that the raters have opportunities to measure varying levels of treatment fidelity, I would ensure that some of the interventionists intentionally implemented the IAC with low fidelity during their simulated prenatal clinic sessions. This could be accomplished by using trained actors in addition to actual frontline staff members as interventionists. The actors could be directed to implement proscribed behaviors and refrain from prescribed behaviors associated with the IAC intervention. This would guarantee the occurrence of a range of implementation behaviors, fostering comprehensive use of the instrument's scales and a more accurate assessment of the instrument's reliability.

I have also considered another alteration in the design of my study that could have enhanced my study findings. During the sixth step in the first phase of my study, a clinical social work therapist and I independently evaluated, coded, and scored the IAC implementation behaviors for each of the 9 practice interviews I had conducted and

recorded earlier when training the standardized patients. I had devised this step to provide a trial use of the instrument to facilitate content revision. If I had designed this phase as a small pilot study and had calculated reliability statistics associated with the ratings we assigned, I might have become aware of the base rate problem before conducting the simulated clinics and could have redesigned the study protocol at that stage accordingly.

Research question 3: “What is the internal consistency reliability associated with use of an instrument developed to assess treatment fidelity in the delivery of a brief opportunistic intervention to decrease the use of alcohol, tobacco, and other drugs by pregnant women?”

The internal consistency reliability statistic provides an estimate of how well scale items designed to measure a particular characteristic produce similar results (Trochim & Donnelly, 2007). I calculated Chronbach’s coefficient alpha to evaluate the internal consistency of the ratings obtained through the use of the IAC treatment fidelity instrument during the study. The alpha level for the entire scale items was 0.72, considered an acceptable measure for a new instrument (DeVon et al., 2007). The internal consistency reliability estimates for both subscales fell below the acceptable range, indicating inadequate item intercorrelation.

I found that deleting two items slightly improved the internal consistency of the subscales. When item 18 was removed, the alpha value of the adherence subscale increased from 0.54 to 0.59. This item, which was developed to allow measurement of interventionists’ response when presented with medical questions outside of their scope, primarily concerns medical assistant practice. As the sole adherence item offering a not applicable rating option, this item was rated as not applicable in 94% of the cases. In

retrospect, this item reflects a practice issue that exists independent of IAC implementation and does not make a meaningful contribution to the assessment of IAC treatment fidelity.

The alpha of the competence subscale increased from 0.56 to 0.61 with the deletion of item 16. The intent of this item was to operationalize the desired quality of interventionist behavior, characterized as “respectful,” when offering referrals. During rater meetings that took place during data collection, ambiguity regarding the interpretation of the term “respectful” emerged during the weekly discussions of rating assignments. Raters expressed that they were uncertain how to identify this behavioral attribute audibly. This suggests that revision of this item may increase recognition of this behavior during implementation and improve the internal consistency of the competence subscale.

The length of the IAC treatment fidelity instrument is also a relevant factor that requires scrutiny when interpreting the computed internal consistency statistics. The sturdy relationship between test length and item intercorrelation is illustrated in this study in that the alpha coefficient computed for the entire 18-item scale, which encompasses both adherence and competence components, exceeds that of the alpha of either subscale, which were designed to make these complementary constructs manifest. Ideally, a scale developed to measure a specific construct will be composed of items measuring attributes of the construct (Polit & Hungler, 1999), producing a measure of internal consistency that results from items correlating highly with the designated construct rather than each other (DeVellis, 2003). According to the statistical corrections I computed using the Spearman-Brown prophecy formula, acceptable reliabilities could be attained by doubling the length

of the subscales. However, adding redundant items to an instrument for the sole purpose of inflating alpha may bloat the instrument without adding meaningfully to measurement of the construct (Kline, 1998). During the scale development phase of this study, several items that I included in the first draft were perceived as duplicating measures of behaviors concurrently assessed by other items. Accordingly, these were deleted as per the recommendations of the content experts. The desired end result was a compact instrument comprising items designed to reflect operationalization of distinct behaviors involved in the implementation of the IAC. Consequently, I surmise that the alphas of the resultant subscales were impacted by their length and may underestimate the true internal consistency reliability of the scores (Kline, 1998).

Additional factors that have been reported to influence the value of coefficient alpha should also be considered when interpreting internal consistency reliability results. Similar to the base-rate paradox described earlier in relation to the ICC, computation of the alpha coefficient relies on both variance and normal distribution of test scores (C. F. Waltz et al., 2005). Accordingly, data with a skewed distribution will result in paradoxically lower alpha values. As previously described, the ratings that arose from this study display a pattern of high rater agreement and low variance, mitigating factors that should be taken into consideration when evaluating the statistics calculated from the ratings of the adherence and competence scale items during this study. As such, it is difficult to determine whether the low alpha coefficients for these scales accurately reflected the degree to which the scale items correlated to the intended dimensions.

Chapter 5

Summary, Conclusions, and Recommendations

This chapter presents a summary and the conclusions of this study, which entailed the development and psychometric evaluation of a structured instrument to assess the treatment fidelity of the IAC brief opportunistic intervention designed to reduce prenatal substance use. Limitations of the study are identified. The chapter concludes with recommendations for future research and implications for nursing practice.

Summary

The IAC brief opportunistic intervention, designed to reduce prenatal substance use, is currently implemented by frontline staff (typically registered nurses, licensed vocational nurses, or medical assistants) in several areas of the United States (Chasnoff et al., 2008; Children's Research Triangle, 2008). Evaluation of treatment fidelity, to determine if this and other behavioral interventions are delivered as intended, is essential to controlled research (Bellg et al., 2004; Dane & Schneider, 1998; Moncher & Prinz, 1991; J. Waltz et al., 1993). The specific aims of this study were to develop an instrument to measure the treatment fidelity of the IAC brief opportunistic intervention implementation, and establish the validity and reliability associated with use of the instrument. The long-term goal of this study is to use this instrument in a randomized clinical trial assessing the efficacy of the IAC in reducing prenatal ATOD use.

The conceptual framework that guided this study was a blend of concepts derived from motivational interviewing and self-determination theory. Throughout the process of instrument development, I drew upon these conceptual frameworks to inform

operationalization of the IAC behavioral elements that ultimately took shape as the IAC treatment fidelity instrument.

I conducted this study in six phases. Phase one, tool development, involved identification of the essential elements involved in implementation of the IAC and translation of these elements into observable behaviors, selection of appropriate scaling options, and assessment of content validity. In the second phase, I enlisted nursing students as standardized patients and prepared them to portray ATOD-using pregnant women. I recruited and trained nursing instructors as independent raters in the third phase. During phase four, I recruited experienced frontline prenatal clinic staff members who were currently implementing the IAC in practice as study participants. In the fifth phase, the participants implemented the IAC with the standardized patients in a simulated clinic setting. During the final phase, raters used the instrument developed during the course of the study to independently assess the treatment fidelity with which the frontline staff implemented the IAC. To estimate the reliability associated with the scores assigned by the raters, I used the ICC to calculate inter-rater agreement and Cronbach's alpha to measure internal consistency. The study protocol was consistent with methods that have been identified as essential in the development of a treatment fidelity instrument (Stein et al., 2007).

Conclusions

The content validity evidence that I collected during the tool development gives credence to the adequacy with which the IAC treatment fidelity instrument represented the IAC content domain. The structure of the tool, with paired adherence and competence components formatted as declarations accompanied by Likert-scaled rating selections,

was found to be effective.

The inter-rater reliability statistics I calculated for ratings associated with the instrument subscales and most of the individual scale items were satisfactory, findings that indicated consistent use of the instrument by the raters during this study (Cicchetti & Sparrow, 1981). Based on the secondary analysis I conducted to examine the proportion of rater agreement and prevalence associated with each item, factors known to be associated with the base-rate problem (Hoehler, 2000), I have concluded that the ICC values calculated for the low-ICC adherence items (3, 5, 12, and 13) were erroneously low. Consequently, the inter-rater reliability associated with these items cannot be adequately assessed through the ratings obtained from this sample.

Because the remaining low-ICC item (4), a component of the competence subscale, was not conspicuous for either rater agreement or prevalence levels, I conclude that the ICC calculated for this item is an accurate estimate of inter-rater reliability. This item and its counterpart (low-ICC item 3) were designed to jointly measure the adherence and competence with which interventionists express an “I” message. I believe that both of these items would benefit from revision to increase their clarity.

The Cronbach’s alpha coefficient calculated for the ratings obtained for the entire instrument, indicated an acceptable level of internal consistency reliability for a new tool (DeVon et al., 2007). The significance of this finding is attenuated by the fact that the alpha coefficients for the adherence and competence subscales were low. However, the blunting influence of high prevalence and low variance of the measurements must also be taken into consideration when evaluating the implications of the alpha levels (C. F. Waltz et al., 2005). Until this instrument is used to measure ratings obtained with a more

heterogeneous sample, enabling a more normal distribution of scores, the question of whether internal consistency reliability will improve through item revision remains uncertain. The exception I would make to this conclusion is associated with the findings discussed earlier in relation to the alphas calculated with the sequential deletion of ratings associated with each item. When item ratings associated with items 16 and 18 were removed from the study data, this did afford a modest increase in the alphas calculated for each subscale. Based on my analysis, I recommend revising item 16 and removing item 18 to enhance subscale internal consistency reliability results.

Limitations of the Study

The primary limitation of this study was my protocol, which used only experienced interventionists to implement the IAC in a simulated clinic setting. This contributed to the consistently high level of treatment fidelity and resulting uniformity of ratings that characterized this study's data and influenced the reliability analyses. Because the interventionists were so dependable in their implementation of the IAC, the raters had little opportunity to witness instances when implementation occurred with low fidelity. Thus all of the ratings were clustered under the positive scale scores. This tool development study would have been impractical to conduct in an actual treatment setting. In addition to the challenge of recruiting and consenting a sufficient group of participants, obtaining the necessary sample size of 49 audio-recorded instances of IAC implementation would have taken an inordinate amount of time to achieve, because most prenatal interviews do not involve the disclosure of prenatal ATOD use. In a clinical setting, increased test score variance could be anticipated, but not guaranteed. Implementation by a pool of experienced interventionists could produce data distribution

similar to that present in this study that resulted in undependable reliability findings.

Another potential limitation was related to sample size. The calculation of desired sample size required an assumption about the anticipated level of inter-rater agreement that would be achieved. Thus, a sample size of 49 was the number required to reject the implied null hypothesis (the inter-rater agreement is 0.70) versus the implied alternative hypothesis (the inter-rater agreement is greater than 0.70 with power 0.90, alpha 0.05, and anticipated agreement 0.85). Consequently, this sample size would be large enough to reject the null hypothesis 90% of the time when the observed difference between the null value and the anticipated value was 0.15 (0.85 minus 0.70). After data collection had concluded and the statistical analysis was complete, it became evident that my a priori assumption regarding the anticipated level of inter-rater agreement was not substantiated, because none of the observed ICCs calculated for the subscales or the individual items approached 0.85. Questioning whether increasing the number of participants would have had an appreciable impact on the ICCs, I concluded that it was sample homogeneity, rather than sample size, that was the issue. When the high proportion of rater agreements are taken into consideration in tandem with the observed ICCs, this supports the probability that these were paradoxical results that can be attributed to the prevalence effect (Hoehler, 2000).

Recommendations for Future Research

The results of this study support ongoing evaluation of the IAC treatment fidelity instrument. Before this instrument can be relied upon as a measure of IAC treatment fidelity, it must be subjected to revision and further psychometric testing to gather empirical evidence of validity and reliability associated with the instruments measures.

Further development of the instrument should involve study in a simulated setting using a known contrasted groups design, one group with IAC experience and one without. This method will allow assessment of construct validity through an analysis of the extent to which the instrument's measurement is able to distinguish the two groups. This important psychometric step is needed to establish the treatment fidelity linkage between the instrument's measurement and the theoretical constructs that underpin implementation of the IAC intervention before the tool is tested in an actual clinical setting.

The outcomes of future reliability testing will depend on obtaining heterogeneous samples and normally distributed data to minimize the occurrence of paradoxically low reliability scores. This could be accomplished by instructing some interventionists to deliberately implement the IAC with low fidelity. Based on the findings of these further validity and reliability analyses, the instrument items should be reviewed to determine if they adequately represent and measure the IAC content domain.

I encourage researchers who take on the challenge of instrument development to embrace a wider view of validity and design their research questions accordingly. The process involved in the assessment of content validity is meaningful and essential to the development of an instrument designed to reflect a specific content domain. However, content validity alone does not offer the necessary precision needed to serve as a benchmark of the validity of the instrument's measurements. Determination of the degree to which an instrument actually measures in accordance with theoretically derived expectations requires using results obtained from the tool to make judgments about validity. Doing so will allow valid inferences to be made regarding the consequences of the use of an instrument.

Implications for Nursing Practice

A goal of nursing research is the discovery of stable relationships that can be used to improve the human condition (M. E. Rogers, 1970). This study was a first step in the development of an instrument to measure the treatment fidelity of the IAC brief opportunistic intervention, which was designed to reduce the prenatal use of potentially harmful substances. This tool requires further refinement and psychometric testing before it can be used in the clinical setting. Therefore, there are no specific nursing practice implications at this time.

References

- Allen, M. J., & Yen, W. M. (2002). *Introduction to measurement theory*. Long Grove, IL: Waveland Press.
- American Academy of Pediatrics. (2002). *Guidelines for perinatal care* (5th ed.). Elk Grove Village, IL: American Academy of Pediatrics.
- American College of Obstetricians and Gynecologists. (2008). ACOG Committee Opinion No. 422: At-risk drinking and illicit drug use: Ethical issues in obstetric and gynecologic practice. *Obstetrics & Gynecology*, *112*, 1449-1460.
- American College of Obstetricians and Gynecologists Committee on Ethics. (2004). ACOG Committee Opinion. At-risk drinking and illicit drug use: Ethical issues in obstetric and gynecologic practice. *Obstetrics & Gynecology*, *103*, 1021-1031.
- American Society of Addiction Medicine. (1989). Public policy statement on chemically dependent women and pregnancy. Retrieved January 18, 2008, from <http://www.asam.org/ppol>
- Amrhein, P. C., Miller, W. R., Yahne, C. E., Palmer, M., & Fulcher, L. (2003). Client commitment language during motivational interviewing predicts drug use outcomes. *Journal of Consulting and Clinical Psychology*, *71*, 862-878.
- Anonymous. (2004). Rising costs force primary care practices to raise productivity ceiling. *Performance Improvement Advisor*, *8*, 111-114.
- Armstrong, M. A., Gonzales Osejo, V., Lieberman, L., Carpenter, D. M., Pantoja, P. M., & Escobar, G. J. (2003). Perinatal substance abuse intervention in obstetric clinics decreases adverse neonatal outcomes. *Journal of Perinatology*, *23*, 3-9.
- Babor, T. E., Higgins-Biddle, J., Dauser, D., Higgins, P., & Burleson, J. A. (2005). Alcohol screening and brief intervention in primary care settings: Implementation models and predictors. *Journal of Studies on Alcohol*, *66*, 361-368.
- Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, *84*, 191-215.
- Bandura, A. (2007). *Self-efficacy: The exercise of control* (9th ed.). New York, NY: Macmillan.
- Barber, J. P., & Crits-Christoph, P. (1996). Development of a therapist adherence/competence rating scale for supportive-expressive dynamic psychotherapy: A preliminary report. *Psychotherapy Research*, *6*, 81.
- Barber, J. P., Liese, B. S., & Abrams, M. J. (2003). Development of the cognitive therapy adherence and competence scale. *Psychotherapy Research*, *13*, 205.

- Barnhart, C. L., & Barnhart, R. K. (Eds.). (1984). *The World Book Dictionary* (Vol. 2). Chicago, IL: World Book Publishing.
- Barr, H. M., & Streissguth, A. P. (2001). Identifying maternal self-reported alcohol use associated with fetal alcohol spectrum disorders. *Alcoholism: Clinical and Experimental Research, 25*, 283-287.
- Beck, A., Wright, F. D., Newman, C. F., & Liese, B. S. (1993). *Cognitive therapy of substance abuse*. New York, NY: Guilford Press.
- Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M.,... Czajkowski, S. (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychology, 23*, 443.
- Bem, D. J. (1967). Self-perception: An alternative interpretation of cognitive dissonance phenomena. *Psychological Review, 74*, 183-200.
- Bennett, A. D. (1999). Perinatal substance abuse and the drug-exposed neonate. *Advance for Nurse Practitioners, 7*, 32-36.
- Bien, T. H., Miller, W. R., & Tonigan, J. S. (1993). Brief interventions for alcohol problems: A review. *Addiction, 88*, 315-335.
- Bohart, A. C., Elliott, R., Greenberg, L. S., & Watson, J. C. (2002). Empathy. In J. C. Norcross (Ed.), *Psychotherapy relationships that work: Therapist contributions and responsiveness to patients* (pp. 89-108). New York, NY: Oxford University Press.
- Borden, W. (1999). *Comparative approaches in brief dynamic psychotherapy*. New York, NY: Haworth Press.
- Borrelli, B., Sepinwall, D., Ernst, D., Bellg, A. J., Czajkowski, S., Breger, R.,... Orwig, D. (2005). A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *Journal of Consulting & Clinical Psychology, 73*, 852-860.
- Botvin, G. J., Baker, E., Dusenbury, L., & Tortu, S. (1990). Preventing adolescent drug abuse through a multimodal cognitive-behavioral approach: Results of a 3-year study. *Journal of Consulting and Clinical Psychology, 58*, 437-446.
- Brady, T. M., & Ashley, O. S. (2005). Women in substance abuse treatment: Results from the alcohol and drug services study. [Electronic Version]. Retrieved from <http://www.oas.samhsa.gov/WomenTX/WomenTX.htm>
- Burchfield, D. J., Lucas, V. W., Abrams, R. M., Miller, R. L., & DeVane, C. L. (1991). Disposition and pharmacodynamics of methamphetamine in pregnant sheep. *JAMA, 265*, 1968-1973.

- Burke, B. L., Arkowitz, H., & Menchola, M. (2003). The efficacy of motivational interviewing: A meta-analysis of controlled clinical trials. *Journal of Consulting and Clinical Psychology, 71*, 843.
- Campbell, D. T., & Stanley, J. C. (1966). *Experimental and quasi-experimental designs for research*. Chicago, IL: Rand McNally.
- Carey, K. B., Scott-Sheldon, L. A. J., Carey, M. P., & DeMartini, K. S. (2007). Individual-level interventions to reduce college student drinking: A meta-analytic review. *Addictive Behaviors, 32*, 2469-2494.
- Carmines, E. G., & Zeller, R. A. (1979). *Reliability and validity assessment*. Thousand Oaks, CA: Sage.
- Carroll, K. M., Kadden, R. M., Donovan, D. M., & Zweben, A. (1994). Implementing treatment and protecting the validity of the independent variable in treatment matching studies. *Journal of Studies on Alcohol 12*, 149-155.
- Carroll, K. M., Nich, C., & Rounsaville, B. J. (1998). Utility of therapist session checklists to monitor delivery of coping skills treatment for cocaine abusers. *Psychotherapy Research, 8*, 307.
- Carroll, K. M., Nich, C., Sifry, R. L., Nuro, K. F., Frankforter, T. L., Ball, S. A.,...Rounsaville, B. J. (2000). A general system for evaluating therapist adherence and competence in psychotherapy research in the addictions. *Drug & Alcohol Dependence, 57*, 225-238.
- Carroll, K. M., & Rounsaville, B. (1990). Can a technology model of psychotherapy research be applied to cocaine abuse treatment? *NIDA Research Monograph, 104*, 91-104.
- Carroll, K. M., & Rounsaville, B. J. (2007). A vision of the next generation of behavioral therapies research in the addictions. *Addiction, 102*, 850-862; discussion 863-859.
- Carter, C. S. (2002). Perinatal care for women who are addicted: Implications for empowerment. *Health and Social Work, 27*, 166-174.
- Centers for Disease Control and Prevention. (2000). *Healthy people 2010: Maternal, infant and child health (objective 16)*. Retrieved June 9, 2008, from <http://www.healthypeople.gov/document/HTML/Volume2/16MICH.htm>
- Chambless, D. L., & Hollon, S. D. (1998). Defining empirically supported therapies. *Journal of Consulting & Clinical Psychology, 66*, 7-18.
- Chang, G. (2004). Screening and brief intervention in prenatal care settings. *Alcohol Research & Health: The Journal of the National Institute on Alcohol Abuse & Alcoholism, 28*, 80-84.

- Chang, G., McNamara, T. K., Orav, E. J., Koby, D., Lavigne, A., Ludman, B.,... Wilkins-Haug, L. (2005). Brief intervention for prenatal alcohol use: A randomized trial. *Obstetrics and Gynecology*, *105*, 991-998.
- Chang, G., Wilkins-Haug, L., Berman, S., & Goetz, M. A. (1999). Brief intervention for alcohol use in pregnancy: A randomized trial. *Addiction*, *94*, 1499-1508.
- Chasnoff, I. J., Landress, H. J., & Barrett, M. E. (1990). The prevalence of illicit-drug or alcohol use during pregnancy and discrepancies in mandatory reporting in Pinellas County, Florida. *New England Journal of Medicine*, *322*, 1202-1206.
- Chasnoff, I. J., & McGourty, R. F. (2003). *I am concerned. Pre-treatment: A brief intervention for the primary prenatal care setting*. Chicago, IL: National Training Institute.
- Chasnoff, I. J., McGourty, R. F., Wells, A. M., & McCurties, S. (2008). *Perinatal substance use screening in California: Screening and assessment with the 4Ps Plus screen for substance use in pregnancy*. Retrieved, from <http://www.cdph.ca.gov/programs/perinatalsubstanceuse/Pages/default.aspx>
- Chasnoff, I. J., Neuman, K., Thornton, C., & Callaghan, M. A. (2001). Screening for substance use in pregnancy: A practical approach for the primary care physician. *American Journal of Obstetrics & Gynecology*, *184*, 752-758.
- Chasnoff, I. J., Wells, A. M., McGourty, R. F., & Bailey, L. K. (2007). Validation of the 4P's Plus screen for substance use in pregnancy. *Journal of Perinatology*, *27*, 744-748.
- Chevron, E. S., & Rounsaville, B. J. (1983). Evaluating the clinical skills of psychotherapists. A comparison of techniques. *Archives of General Psychiatry*, *40*, 1129-1132.
- Children's Research Triangle. (2008). Research at CRT. Retrieved January 11, 2008, from <http://www.childstudy.org/research.php>
- Cicchetti, D. V. (1994). Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychological Assessment*, *6*, 284-290.
- Cicchetti, D. V., & Feinstein, A. R. (1990). High agreement but low kappa: II. Resolving the paradoxes. *Journal of Clinical Epidemiology*, *43*, 551-558.
- Cicchetti, D. V., & Sparrow, S. A. (1981). Developing criteria for establishing interrater reliability of specific items: Applications to assessment of adaptive behavior. *American Journal of Mental Deficiency*, *86*, 127-137.
- Clay, R. A. (2010, May). *Screening, brief intervention, and referral to treatment: New populations, new effectiveness data*. from www.samhsa.gov/samhsaNewsletter.

- Curet, L. B., & Hsi, A. C. (2002). Drug abuse during pregnancy. *Clinical Obstetrics and Gynecology*, 45, 73-88.
- Daley, M., Argeriou, M., & McCarty, D. (1998). Substance abuse treatment for pregnant women: A window of opportunity? *Addictive Behaviors*, 23, 239.
- Dane, A. V., & Schneider, B. H. (1998). Program integrity in primary and early secondary prevention: Are implementation effects out of control? *Clinical Psychology Review*, 18, 23.
- Davis, L. L. (1992). Instrument review: Getting the most from a panel of experts. *Applied Nursing Research*, 5, 194-197.
- Deci, E. L., & Ryan, R. M. (2000). The "what" and "why" of goal pursuits: Human needs and the self-determination of behavior. *Psychological Inquiry*, 11, 227-268.
- Deci, E. L., & Ryan, R. M. (Eds.). (2002). *Handbook of self-determination research*. Rochester, NY: University of Rochester Press.
- Deglin, J. H., & Vallerand, A. H. (2009). *Davis's drug guide for nurses* (11th ed.). Philadelphia, PA: F.A. Davis.
- DeVellis, R. F. (2003). *Scale development: Theory and applications* (2nd ed. Vol. 26). Thousand Oaks, CA: Sage.
- DeVon, H. A., Block, M. E., Moyle-Wright, P., Ernst, D. M., Hayden, S. J., Lazzara, D., ...Kostas-Polston, E. (2007). A psychometric toolbox for testing validity and reliability. *Journal of Nursing Scholarship*, 39, 155-164.
- Draycott, S., & Dabbs, A. (1998). Cognitive dissonance 2: A theoretical grounding of motivational interviewing. *British Journal of Clinical Psychology*, 37, 355-364.
- Dumas, J. E., Lynch, A. M., Laughlin, J. E., Smith, E. P., & Prinz, R. J. (2001). Promoting intervention fidelity: Conceptual issues, methods, and preliminary results from the Early Alliance prevention trial. *American Journal of Preventive Medicine*, 20, 38.
- Dusenbury, L., Brannigan, R., Falco, M., & Hansen, W. B. (2003). A review of research on fidelity of implementation: Implications for drug abuse prevention in school settings. *Health Education Research*, 18, 237.
- Emmen, M. J., Schippers, G. M., Bleijenberg, G., & Wollersheim, H. (2004). Effectiveness of opportunistic brief interventions for problem drinking in a general hospital setting: Systematic review. *BMJ*, 328, 318.
- Ettlinger, T. (2000). In harm's way: recognizing and addressing alcohol risk for rural disadvantaged pregnant mothers. *Public Health Nursing*, 17, 207-210.

- Eysenck, H. J. (1952). The effects of psychotherapy: An evaluation. *Journal of Consulting Psychology, 16*, 319-324.
- Feinstein, A. R., & Cicchetti, D. (1990). High agreement but low kappa: I. The problems of two paradoxes. *Journal of Clinical Epidemiology, 43*, 543-549.
- Ferreira-Borges, C. (2005). Effectiveness of a brief counseling and behavioral intervention for smoking cessation in pregnant women. *Preventive Medicine 41*, 295-302.
- Festinger, L., & Carlsmith, J. M. (1959). Cognitive consequences of forced compliance. *The Journal of Abnormal and Social Psychology, 58*, 203-210.
- Fleiss, J. L., & Cohen, J. (1973). The equivalence of weighted kappa and the intraclass correlation coefficient as measure of reliability. *Educational and Psychological Measurement, 33*, 613-619.
- Fleming, M. F., Mundt, M. P., French, M. T., Manwell, L. B., Stauffacher, E. A., & Barry, K. L. (2002). Brief physician advice for problem drinkers: Long-term efficacy and benefit-cost analysis. *Alcoholism: Clinical & Experimental Research, 26*, 36-43.
- Foote, J., DeLuca, A., Magura, S., Warner, A., Grand, A., Rosenblum, A., & Stahl, S. (1999). A group motivational treatment for chemical dependency. *Journal of Substance Abuse Treatment, 17*, 181-192.
- Fried, P. A. (2002). The consequences of marijuana use during pregnancy: A review of the human literature. *Journal of Cannabis Therapeutics, 2*, 85-104.
- Ginsburg, J. I. D., Mann, R. E., Rotgers, F., & Weekes, J. R. (2002). Motivational interviewing with criminal justice populations. In W. R. Miller & S. Rollnick (Eds.), *Motivational interviewing: Preparing people to change addictive behavior* (2nd ed., pp. 333-346). New York, NY: Guilford Press.
- Goodlett, C. R., Horn, K. H., & Zhou, F. C. (2005). Alcohol teratogenesis: Mechanisms of damage and strategies for intervention. *Experimental Biology & Medicine, 230*, 394-406.
- Goodwin, L. D. (2002). Changing conceptions of measurement validity. *Journal of Nursing Education, 36*, 102-107.
- Greene, C. M., & Goodman, M. H. (2003). Neonatal abstinence syndrome: Strategies for care of the drug-exposed infant. *Neonatal Network - Journal of Neonatal Nursing, 22*, 15-25.
- Grol, R., & Grimshaw, J. (2003). From best evidence to best practice: Effective implementation of change in patients' care. *Lancet 362*, 1225-1230.

- Grumbach, K., & Bodenheimer, T. (2004). Can health care teams improve primary care practice? *JAMA*, *291*, 1246-1251.
- Grumbach, K., Osmond, D., Vranizan, K., Jaffe, D., & Bindman, A. B. (1998). Primary care physicians' experience of financial incentives in managed-care systems. *New England Journal of Medicine*, *339*, 1516-1521.
- Gurman, A. S., & Messer, S. B. (2005). *Essential psychotherapies: Theory and practice* (2nd ed.). New York, NY: Guilford Press.
- Guthrie, A. (2000, January). *A review of coefficient alpha and some basic tenets of classical measurement theory*. Paper presented at the Annual Meeting of the Southwest Educational Research Association, Dallas, TX.
- Handmaker, N. S., Miller, W. R., & Manicke, M. (1999). Findings of a pilot study of motivational interviewing with pregnant drinkers. *Journal of Studies on Alcohol*, *60*, 285-287.
- Haug, N. A., Svikis, D. S., & DiClemente, C. (2004). Motivational enhancement therapy for nicotine dependence in methadone-maintained pregnant women. *Psychology of Addictive Behaviors*, *18*, 289-292.
- Hettema, J., Steele, J., & Miller, W. R. (2005). Motivational interviewing. *Annual Review of Clinical Psychology*, *1*, 91.
- Hill, C. E., O'Grady, K. E., & Elkin, I. (1992). Applying the Collaborative Study Psychotherapy Rating Scale to rate therapist adherence in cognitive-behavior therapy, interpersonal therapy, and clinical management. *Journal of Consulting & Clinical Psychology*, *60*, 73-79.
- Hoehler, F. K. (2000). Bias and prevalence effects on kappa viewed in terms of sensitivity and specificity. *Journal of Clinical Epidemiology*, *53*, 499-503.
- Hogue, A., Liddle, H. A., & Rowe, C. (1996). Treatment adherence process research in family therapy: A rationale and some practical guidelines. *Psychotherapy: Theory, Research, Practice, Training*, *33*, 332.
- Hogue, A., Liddle, H. A., Singer, A., & Leckrone, J. (2005). Intervention fidelity in family-based prevention counseling for adolescent problem behaviors. *Journal of Community Psychology*, *33*, 191.
- Holzman, C., & Paneth, N. (1994). Maternal cocaine use during pregnancy and perinatal outcomes. *Epidemiologic Reviews*, *16*, 315-334.
- Howell, E. M., & Chasnoff, I. J. (1999). Perinatal substance abuse treatment. Findings from focus groups with clients and providers. *Journal of Substance Abuse Treatment*, *17*, 139-148.

- James, L. R., Demaree, R. G., & Wolf, G. (1984). Estimating within-group interrater reliability with and without response bias. *Journal of Applied Psychology, 69*, 85-98.
- Jessup, M. A., Humphreys, J. C., Brindis, C. D., & Lee, K. A. (2003). Extrinsic barriers to substance abuse treatment among pregnant drug dependent women. *Journal of Drug Issues, 33*, 285-304.
- Johnson, M. O. (2001). Mother-infant interaction and maternal substance use/abuse: An integrative review of research literature in the 1990s. *Worldviews on Evidence-based Nursing, 8*, 19-36.
- Kaner, E. F. S., Dickinson, H. O., Beyer, F. R., Campbell, F., Schlesinger, C., Heather, N.,...Pienaar, E. D. (2007). Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database of Systematic Reviews (2)*, CD004148.
- Kenner, C., Dreyer, L., & Amlung, S. (2000). Identification and care of substance-dependent neonates. *Journal of IV Nursing, 23*, 105-111.
- Kline, P. (1998). *The new psychometrics*. London, England: Routledge.
- Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *Biometrics, 33*, 159-174.
- Leake, G. J., & King, A. S. (1977). Effect of counselor expectations on alcoholic recovery. *Alcohol Health & Research World, 1*, 16-22.
- Lester, B. M., Andreozzi, L., & Appiah, L. (2004). Substance use during pregnancy: Time for policy to catch up with research [Electronic Version]. *Harm Reduction Journal, 44*. Retrieved from <http://www.harmreductionjournal.com/content/pdf/1477-7517-1-5.pdf>
- Lester, B. M., ElSohly, M., Wright, L. L., Smeriglio, V. L., Verter, J., Bauer, C. R., ...Maza, P. L. (2001). The Maternal Lifestyle Study: Drug use by meconium toxicology and maternal self-report. *Pediatrics, 107*, 309-317.
- Lester, B. M., Tronick, E. Z., LaGasse, L., Seifer, R., Bauer, C. R., Shankaran, S.,...Lu, J. (2004). Summary statistics of Neonatal Intensive Care Unit Network Neurobehavioral Scale scores from the Maternal Lifestyle Study: A quasinormative sample. *Pediatrics, 113*, 668-675.
- Little, B. B., & VanBeveren, T. T. (1996). Placental transfer of selected substances of abuse. *Seminars in Perinatology, 20*, 147-153.
- Luborsky, L., McLellan, A. T., Woody, G. E., O'Brien, C. P., & Auerbach, A. (1985). Therapist success and its determinants. *Archives of General Psychiatry, 42*, 602-611.

- Luborsky, L., Singer, B., & Luborsky, L. (1975). Comparative studies of psychotherapies: Is it true that 'everyone has won and all must have prizes'? *Archives of General Psychiatry*, *32*, 995-1008.
- Ludlow, J. P., Evans, S. F., & Hulse, G. (2004). Obstetric and perinatal outcomes in pregnancies associated with illicit substance abuse. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, *44*, 302-306.
- Lynn, M. R. (1986). Determination and quantification of content validity. *Nursing Research*, *35*, 382-385.
- Mahony, D. L. (1998). Infant and maternal outcomes associated with self-reported illicit drug use during pregnancy. *Journal of Addictions Nursing*, *10*, 115-122.
- Markland, D., Ryan, R. M., Tobin, V. J., & Rollnick, S. (2005). Motivational interviewing and self-determination theory. *Journal of Social & Clinical Psychology*, *24*, 811-831.
- Medoff-Cooper, B., & Verklan, T. (1992). Substance abuse. *NAACOG's Clinical Issues in Perinatal and Women's Health Nursing*, *3*, 114-128.
- Meschke, L. L., Holl, J. A., & Messelt, S. (2003). Assessing the risk of fetal alcohol syndrome: Understanding substance use among pregnant women. *Neurotoxicology & Teratology*, *25*, 667-674.
- Miles, D. R., Lanni, S., Jansson, L., & Svikis, D. (2006). Smoking and illicit drug use during pregnancy: Impact on neonatal outcome. *Journal of Reproductive Medicine*, *51*, 567-572.
- Miller, W. R. (1983). Motivational interviewing with problem drinkers. *Behavioural Psychotherapy*, *11*, 147-172.
- Miller, W. R., Benefield, R. G., & Tonigan, J. S. (1993). Enhancing motivation for change in problem drinking: A controlled comparison of two therapist styles. *Journal of Consulting and Clinical Psychology*, *61*, 455.
- Miller, W. R., & Rollnick, S. (1991). *Motivational interviewing: Preparing people to change addictive behavior*. New York, NY: Guilford Press.
- Miller, W. R., & Rollnick, S. (2002). *Motivational interviewing: Preparing people for change* (2nd ed.). New York, NY: Guilford Press.
- Miller, W. R., & Rollnick, S. (2009). MI Bibliography 1983 - 2009. *Motivational Interviewing Page*. Retrieved June 17, 2009, from <http://motivationalinterview.org/library/biblio.html>
- Miller, W. R., & Rose, G. S. (2009). Toward a theory of motivational interviewing. *American Psychologist*, *64*, 527-537.

- Miller, W. R., Taylor, C. A., & West, J. C. (1980). Focused versus broad-spectrum behavior therapy for problem drinkers. *Journal of Consulting & Clinical Psychology, 48*, 590-601.
- Miller, W. R., & Wilbourne, P. L. (2001). Mesa Grande: A methodological analysis of clinical trials of treatment for alcohol use disorders. *Addiction, 97*, 265-277.
- Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical Psychology Review, 11*, 247-266.
- Moras, K., & Hill, C. E. (1991). Rater selection for psychotherapy process research: An evaluation of the state of the art. *Psychotherapy Research, 1*, 113-123.
- Mowbray, C. T., Holter, M. C., Teague, G. B., & Bybee, D. (2003). Fidelity criteria: Development, measurement, and validation. *The American Journal of Evaluation, 24*, 315-340.
- Moyer, A., Finney, J. W., Swearingen, C. E., & Vergun, P. (2002). Brief interventions for alcohol problems: A meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. *Addiction, 97*, 279-292.
- Munro, B. (1997). *Statistical methods for health care research* (3rd ed.). Philadelphia: Lippincott.
- National Center for Health Statistics. (1999). *Healthy People 2000 Review, 1998-99*. Hyattsville, MD: Public Health Service.
- National Institute on Drug Abuse. (2009). *NIDA infofacts: Methamphetamine*. Retrieved July 18, 2009, from <http://www.nida.nih.gov/InfoFacts/methamphetamine.html>
- Norman, G. R., & Streiner, D. I. (2008). *Biostatistics: The bare essentials* (3rd ed.). Hamilton, ON, Canada: BC Decker.
- Nunnally, J. C., & Bernstein, I. (1994). *Psychometric Theory* (3rd ed.). Columbus, OH: McGraw-Hill.
- Nuro, K. F., Maccarelli, L. M., Ball, S. A., Martino, S., Baker, S. M., Rounsavile, B. J., & Carroll, K. M. (2005). *Yale adherence and competence scale (YACSII) guidelines* (2nd ed.). West Haven, CT: Yale University Psychotherapy Development Center.
- O'Connor, M. J., & Whaley, S. E. (2006). Health care provider advice and risk factors associated with alcohol consumption following pregnancy recognition. *Journal of Studies on Alcohol, 67*, 22-31.
- O'Connor, M. J., & Whaley, S. E. (2007). Brief intervention for alcohol use by pregnant women. *American Journal of Public Health, 97*, 252-258.

- Oei, J., & Lui, K. (2007). Management of the newborn infant affected by maternal opiates and other drugs of dependency. *Journal of Paediatrics & Child Health*, 43, 9-18.
- Ogrodniczuk, J. S., & Piper, W. E. (1999). Measuring therapist technique in psychodynamic psychotherapies: Development and use of a new scale. *Journal of Psychotherapy Practice & Research*, 8, 142-154.
- Orwin, R. G. (2000). Assessing program fidelity in substance abuse health services research. *Addiction*, 95, S309.
- Pagana, K. D., & Pagana, T. J. (2009). *Mosby's diagnostic and laboratory test reference* (9th ed.). St. Louis, MO: Mosby Elsevier.
- Parker, M. W., Winstead, D. K., & Willi, F. J. P. (1979). Patient autonomy in alcohol rehabilitation. 1. Literature review. *International Journal of the Addictions (USA)*, 14, 1015-1022.
- Pastrakuljic, A., Derewlany, L. O., Knie, B., & Koren, G. (2000). The effects of cocaine and nicotine on amino acid transport across the human placental cotyledon perfused in vitro. *Journal of Pharmacology & Experimental Therapeutics*, 294, 141-146.
- Perepletchikova, F., Treat, T. A., & Kazdin, A. E. (2007). Treatment integrity in psychotherapy research: Analysis of the studies and examination of the associated factors. *Journal of Consulting and Clinical Psychology*, 75, 829-841.
- Perl, H. I. (2001). Numerous studies demonstrate effectiveness of brief interventions for reducing alcohol use. *Outcomes, Innovations & Best Practices*, 2(2), 4-8.
- Peterson, L., Homer, A. L., & Wonderlich, S. A. (1982). The integrity of independent variables in behavior analysis. *Journal of Applied Behavior Analysis*, 15, 477-492.
- Plessinger, M. A., & Woods, J. R., Jr. (1993). Maternal, placental, and fetal pathophysiology of cocaine exposure during pregnancy. *Clinical Obstetrics & Gynecology*, 36, 267-278.
- Plessinger, M. A., & Woods, J. R., Jr. (1998). Cocaine in pregnancy. Recent data on maternal and fetal risks. *Obstetrics & Gynecology Clinics of North America*, 25, 99-118.
- Polit, D. F., & Hungler, B. P. (1999). *Nursing research: Principles and methods* (6th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.
- Prochaska, J. O., & DiClemente, C. C. (1982). Transtheoretical therapy: Toward a more integrative model of change. *Psychotherapy: Theory, Research & Practice*, 19, 276-288.

- Prochaska, J. O., DiClemente, C. C., & Norcross, J. C. (1992). In search of how people change. Applications to addictive behaviors. *American Psychologist*, *47*, 1102-1114.
- Project MATCH Research Group. (1998). Matching alcoholism treatments to client heterogeneity: Treatment main effects and matching effects on drinking during treatment. *Journal of Studies on Alcohol*, *59*, 631-639.
- Redding, B. A., & Selleck, C. S. (1993). Perinatal substance abuse: Assessment and management of the pregnant woman and her children. *Nurse Practitioner Forum*, *4*, 216-223.
- Reis, J., Mills-Thomas, B., Robinson, D., & Anderson, V. (1992). An inner-city community's perspective on infant mortality and prenatal care. *Public Health Nursing*, *9*, 248-256.
- Resnick, B., Bellg, A. J., Borrelli, B., Defrancesco, C., Breger, R., Hecht, J., ... Czajkowski, S. (2005). Examples of implementation and evaluation of treatment fidelity in the BCC studies: Where we are and where we need to go. *Annals of Behavioral Medicine*, *29*(Supplement), 46-54.
- Riley, E. P., McGee, C. L., & Sowell, E. R. (2004). Teratogenic effects of alcohol: A decade of brain imaging. *American Journal of Medical Genetics Part C, Seminars in Medical Genetics*, *127*, 35-41.
- Rogers, C. R. (1956). Client-centered theory. *Journal of Counseling Psychology*, *3*, 115-120.
- Rogers, C. R., Kirschenbaum, H., & Henderson, V. L. (1989). *The Carl Rogers reader*. Boston, MA: Houghton, Mifflin and Company.
- Rogers, M. E. (1970). *An introduction to the theoretical basis of nursing*. Philadelphia, PA: F. A. Davis.
- Rounsaville, B. J., Carroll, K. M., & Onken, L. S. (2001). A stage model of behavioral therapies research: Getting started and moving on from stage I. *Clinical Psychology: Science and Practice*, *8*, 133-142.
- Rubak, S., Sandbaek, A., Lauritzen, T., & Christensen, B. (2005). Motivational interviewing: A systematic review and meta-analysis. *British Journal of General Practice*, *55*, 305-312.
- Ruckebusch, Y., Gaujoux, M., & Eghbali, B. (1976). Placental transfer of central nervous system depressants in sheep. *European Journal of Pharmacology*, *37*, 193-196.
- Ryan, R. M., & Connell, J. P. (1989). Perceived locus of causality and internalization: Examining reasons for acting in two domains. *Journal of Personality & Social Psychology*, *57*, 749-761.

- Ryan, R. M., & Deci, E. L. (2000). Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist*, *55*, 68-78.
- Ryan, R. M., & Deci, E. L. (2006). Self-regulation and the problem of human autonomy: Does psychology need choice, self-determination, and will? *Journal of Personality*, *74*, 1557-1585.
- Santacroce, S. J., Maccarelli, L. M., & Grey, M. (2004). Intervention fidelity. *Nursing Research*, *53*, 63.
- Selleck, C. S., & Redding, B. A. (1998). Knowledge and attitudes of registered nurses toward perinatal substance abuse. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, *27*, 70-77.
- Sheskin, D. J. (2003). *Handbook of parametric and nonparametric statistics* (3rd ed.). London, UK: Chapman & Hall/CRC.
- Shiono, P. H. (1996). Revisiting the issues: Prevalence of drug-exposed infants. *The Future of Children*, *6*, 159-163.
- Shiono, P. H., Klebanoff, M. A., Nugent, R. P., Cotch, M. F., Wilkins, D. G., Rollins, D., ... Behrman, R. E. (1995). The impact of cocaine and marijuana use on low birth weight and preterm birth: a multicenter study. *American Journal of Obstetrics & Gynecology*, *172*, 19-27.
- Shiono, P. H., Klebanoff, M. A., & Rhoads, G. G. (1986). Smoking and drinking during pregnancy. Their effects on preterm birth. *JAMA*, *255*, 82-84.
- Shrout, P. E., & Fleiss, J. L. (1979). Intraclass correlations: Uses in assessing rater reliability. *Psychological Bulletin*, *86*, 420-428.
- Sidani, S. (1998). Measuring the intervention in effectiveness research. *Western Journal of Nursing Research*, *20*, 621-635.
- Smith, L., Yonekura, M. L., Wallace, T., Berman, N., Kuo, J., & Berkowitz, C. (2003). Effects of prenatal methamphetamine exposure on fetal growth and drug withdrawal symptoms in infants born at term. *Journal of Developmental & Behavioral Pediatrics*, *24*, 17-23.
- Spillane, V., Byrne, M. C., Byrne, M., Leathem, C. S., O'Malley, M., & Cupples, M. E. (2007). Monitoring treatment fidelity in a randomized controlled trial of a complex intervention. *Journal of advanced nursing*, *60*, 343-352.
- Stein, K. F., Sargent, J. T., & Rafaels, N. (2007). Intervention research: Establishing fidelity of the independent variable in nursing clinical trials. *Nursing Research*, *56*, 54.

- Streissguth, A. P., Aase, J. M., Clarren, S. K., Randels, S. P., LaDue, R. A., & Smith, D. F. (1991). Fetal alcohol syndrome in adolescents and adults. *JAMA*, *265*, 1961-1967.
- Streissguth, A. P., & Finnegan, L. P. (1996). Effects of prenatal alcohol and drugs. In J. Kinney (Ed.), *Clinical manual of substance abuse* (pp. 254-271). St. Louis: MO: Mosby.
- Substance Abuse and Mental Health Services Administration. (2003). *Results from the 2002 national survey on drug use and health: National findings* (Office of Applied Studies, DHHS Publication No. SMA 03-3836, NSUDH Series H-22). Rockville, MD.
- Substance Abuse and Mental Health Services Administration. (2004). *Results from the 2003 national survey on drug use and health: National findings* (Office of Applied Studies, DHHS Publication No. SMA 04-3964, NSUDH Series H-25). Rockville, MD.
- Substance Abuse and Mental Health Services Administration. (2005). *Results from the 2004 national survey on drug use and health: National findings* (Office of Applied Studies, DHHS Publication No. SMA 05-4062, NSUDH Series H-28). Rockville, MD.
- Substance Abuse and Mental Health Services Administration. (2006). *Results from the 2005 national survey on drug use and health: National findings* (Office of Applied Studies, DHHS Publication No. SMA 06-4194, NSUDH Series H-30). Rockville, MD.
- Substance Abuse and Mental Health Services Administration. (2007). *Results from the 2006 national survey on drug use and health: National findings* (Office of Applied Studies, DHHS Publication No. SMA 07-4293, NSUDH Series H-32). Rockville, MD.
- Substance Abuse and Mental Health Services Administration. (2008). *Results from the 2007 national survey on drug use and health: National findings* (Office of Applied Studies, DHHS Publication No. SMA 08-4343, NSUDH Series H-34). Rockville, MD.
- Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 national survey on drug use and health: National findings* (Office of Applied Studies, NSUDH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.
- Substance Abuse and Mental Health Services Administration. (2010). *Results from the 2009 national survey on drug use and health: Volume I. Summary of National Findings* (Office of Applied Studies, NSUDH Series H-38A, HHS Publication No. SMA 10-4586Findings). Rockville, MD.

- Suellentrop, K., Morrow, B., Williams, L., & D'Angelo, D. (2006). Monitoring progress toward achieving Maternal and Infant Healthy People 2010 objectives--19 states, Pregnancy Risk Assessment Monitoring System (PRAMS), 2000-2003. *Morbidity & Mortality Weekly Report*, *55*, 1-11.
- Sun, A. (2004). Principles for practice with substance-abusing pregnant women: A framework based on the five social work intervention roles. *Social Work*, *49*, 383-394.
- Talbot, P. (2008). In vitro assessment of reproductive toxicity of tobacco smoke and its constituents. *Birth Defects Research, Part C*, 61-72.
- Tevyaw, T. O. L., & Monti, P. M. (2004). Motivational enhancement and other brief interventions for adolescent substance abuse: Foundations, applications and evaluations. *Addiction*, *99*, 63.
- Tillett, J., & Osborne, K. (2001). Substance abuse by pregnant women: Legal and ethical concerns. *Journal of Perinatal and Neonatal Nursing*, *14*, 1-11.
- Tomson, Y., Romelsjo, A., & Aberg, H. (1998). Excessive drinking--brief intervention by a primary health care nurse. A randomized controlled trial. *Scandinavian Journal of Primary Health Care*, *16*, 188-192.
- Tranmer, J. E. (1985). Disposition of ethanol in maternal venous blood and the amniotic fluid. *JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing*, *14*, 484-490.
- Trochim, W. M. K., & Donnelly, J. P. (2007). *Research methods knowledge base* (3rd ed.). Mason, OH: Thomson.
- U.S. Drug Enforcement Administration. (2009). *Chapter 4: Narcotics*. Retrieved July 21, 2009, from <http://www.usdoj.gov/dea/pubs/abuse/4-narc.htm>.
- Vansteenkiste, M., & Sheldon, K. M. (2006). There's nothing more practical than a good theory: Integrating motivational interviewing and self-determination theory. *The British Journal of Clinical Psychology*, *45*, 63.
- Vasilaki, E. I., Hosier, S. G., & Cox, W. M. (2006). The efficacy of motivational interviewing as a brief intervention for excessive drinking: A meta-analytic review. *Alcohol & Alcoholism*, *41*, 328-335.
- Vega, W. A., Kolody, B., Hwang, J., & Noble, A. (1993). Prevalence and magnitude of perinatal substance exposures in California. *New England Journal of Medicine*, *329*, 850-854.
- Wallace, C. J., & Savitz, L. (2008). Estimating waste in frontline health care worker activities. *Journal of Evaluation in Clinical Practice*, *14*, 178-180.

- Walter, S. D., Eliasziw, M., & Donner, A. (1998). Sample size and optimal designs for reliability studies. *Statistics in Medicine*, *17*, 101-110.
- Waltz, C. F., Strickland, O. L., & Lenz, E. R. (2005). *Measurement in nursing and health research* (3rd ed.). New York, NY: Springer.
- Waltz, J., Addis, M. E., Koerner, K., & Jacobson, N. S. (1993). Testing the integrity of a psychotherapy protocol: Assessment of adherence and competence. *Journal of Consulting and Clinical Psychology*, *61*, 620-630.
- Wilk, A. I., Jensen, N. M., & Havighurst, T. C. (1997). Meta-analysis of randomized control trials addressing brief interventions in heavy alcohol drinkers. *Journal of General Internal Medicine*, *12*, 274-283.
- Wills, R. M., Faltler, S. L., & Snyder, D. K. (1987). Distinctiveness of behavioral versus insight-oriented marital therapy: An empirical analysis. *Journal of Consulting & Clinical Psychology*, *55*, 685-690.
- Wolfe, E. L., Davis, T., Guydish, J., & Delucchi, K. L. (2005). Mortality risk associated with perinatal drug and alcohol use in California. *Journal of Perinatology*, *25*, 93-100.
- Woods, J. R., Jr., Plessinger, M. A., & Clark, K. E. (1987). Effect of cocaine on uterine blood flow and fetal oxygenation. *JAMA*, *257*, 957-961.
- Woules, T., LaGasse, L., Sheridan, J., & Lester, B. (2004). Maternal methamphetamine use during pregnancy and child outcome: What do we know? *New Zealand Medical Journal*, *117*, U1180.
- Yeaton, W. H., & Sechrest, L. (1981). Critical dimensions in the choice and maintenance of successful treatments: Strength, integrity, and effectiveness. *Journal of Consulting & Clinical Psychology*, *49*, 156-167.
- Zellman, G. L., Bell, R. M., Archie, C., DuPlessis, H., Hoube, J., & Miu, A. (1999). Physician response to prenatal substance exposure. *Maternal and Child Health Journal*, *3*, 29-83.

Appendix A

Content Validity Review Request

Antonia Torrey RN, MSN
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February 14, 2010

Dear Dr. McGourty and Dr. Chasnoff:

Thank you again for agreeing to review the “I Am Concerned” (IAC) Fidelity Instrument and providing feedback related to its content validity. My intent is to provide an instrument that accurately reflects the dimensions of the IAC and can be used to assess the faithfulness of its implementation. Guided by a conceptual framework derived from motivational interviewing and self-determination theory, I designed this instrument to measure both the adherence and competence components associated with IAC implementation and believe the result to be consistent with the complexity and assumptions underlying the IAC.

I am sending you two documents. One is a first draft of the actual instrument that will be used by raters to assess the faithfulness of IAC implementation. This will allow you to see the manner in which I have formatted items with their associated Likert-scaled responses. In addition, I am sending you a content review questionnaire, which will allow you to rate each item in terms of its clarity, sufficiency, and relevance; I have also included an area to insert optional comments. Your respective ratings will allow me to compute a content validity index. I will continue to revise the instrument in accordance with your ratings until perfect agreement has been achieved.

Please let me know if you have any questions. I welcome any and all feedback and look forward to your review.

Sincerely,

Toni Torrey

Appendix B

Content Review Questionnaire

Reviewer: _____

Please rate each item's clarity, sufficiency, and relevance and comment as needed.

Item	Clarity	Sufficiency	Relevance
1. To what extent did the interventionist use a bridging comment when indicated to move the conversation from interview to pre-treatment? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
2. To what extent did the interventionist use an encouraging tone of voice when verbalizing bridging comments? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
3. To what extent did the interventionist use an "I" message when indicated? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
4. To what extent did the interventionist use a positive tone of voice when verbalizing “I” messages? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
5. To what extent did the interventionist attempt to share information regarding the effects of prenatal substance use? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
6. To what extent did the interventionist use a supportive, warm approach when attempting to share information regarding the effects of prenatal substance use? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
7. To what extent did the interventionist convey awareness of the woman's willingness to hear information regarding the effects of prenatal substance use? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
8. To what extent did the interventionist respectfully convey awareness of the woman's willingness to hear information regarding the effects of prenatal substance use? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
9. To what extent did the interventionist provide feedback? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
10. To what extent did the interventionist use a supportive tone of voice when providing feedback? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
11. To what extent did the interventionist explain the effects that prenatal substance use can have on the mother, baby, and child? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
12. To what extent did the interventionist use a nonjudgmental approach when explaining the effects that prenatal substance use can have on the mother, baby, and child? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
13. To what extent did the interventionist describe the potential negative consequences of the woman's substance use? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
14. To what extent did the interventionist convey empathic sensitivity through words and tone of voice when describing the potential negative consequences of the woman's substance use? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
15. To what extent did the interventionist advocate a goal of abstinence rather than reduction of drug use? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
16. To what extent did the interventionist use a supportive tone of voice when advocating abstinence rather than reduction of drug use? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
17. To what extent did the interventionist acknowledge the woman's autonomy and personal choice? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
18. To what extent did the interventionist respectfully acknowledge the woman's autonomy and personal choice? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
19. To what extent did the interventionist convey that the discussion was a collaborative interaction in contrast to one where the interventionist is in charge? ADHERENCE	<ol style="list-style-type: none"> 1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear 	<ol style="list-style-type: none"> 1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient 	<ol style="list-style-type: none"> 1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
20. To what extent did the interventionist use a supportive approach when conveying that the discussion was a collaborative interaction in contrast to one where the interventionist is in charge? COMPETENCE	<ol style="list-style-type: none"> 1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear 	<ol style="list-style-type: none"> 1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient 	<ol style="list-style-type: none"> 1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
21. To what extent did the interventionist emphasize the greater importance of the woman's own decisions, confidence, and perception of the importance of changing? ADHERENCE	<ol style="list-style-type: none"> 1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear 	<ol style="list-style-type: none"> 1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient 	<ol style="list-style-type: none"> 1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
22. To what extent did the interventionist convey empathic sensitivity when emphasizing the greater importance of the woman's own decisions, confidence, and perception of the importance of changing. COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
23. To what extent did the interventionist acknowledge the woman's decision to discuss her drug use? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
24. To what extent did the interventionist verbalize praise when acknowledging the woman's decision to discuss her drug use? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Item	Clarity	Sufficiency	Relevance
25. To what extent did the interventionist offer indicated referrals? ADHERENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2
Item	Clarity	Sufficiency	Relevance
26. To what extent did the interventionist respectfully offer indicated referrals? COMPETENCE	1. Item is not clear 2. Item needs major revision to be clear 3. Item needs minor revision to be clear 4. Item is clear	1. Item is not sufficient 2. Item needs major revision to be sufficient 3. Item needs minor revision to be sufficient 4. Item is sufficient	1. Item is not relevant and should be deleted 2. Item is relevant and should be retained
Comment:	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Appendix C

IAC TREATMENT FIDELITY INSTRUMENT – Draft 1

1. To what extent did the interventionist use a bridging comment when indicated to move the conversation from interview to pre-treatment?

ADHERENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

2. To what extent did the interventionist use an encouraging tone of voice when verbalizing bridging comments?

COMPETENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

3. To what extent did the interventionist use an “I” message when indicated?

ADHERENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

4. To what extent did the interventionist use a positive tone of voice when verbalizing “I” messages?

COMPETENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

5. To what extent did the interventionist attempt to share information regarding the effects of prenatal substance use?

ADHERENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

6. To what extent did the interventionist use a supportive, warm approach when attempting to share information regarding the effects of prenatal substance use?

COMPETENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

7. To what extent did the interventionist convey awareness of the woman's willingness to hear information regarding the effects of prenatal substance use?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

8. To what extent did the interventionist respectfully convey awareness of the woman's willingness to hear information regarding the effects of prenatal substance use?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

9. To what extent did the interventionist provide feedback?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

10. To what extent did the interventionist use a supportive tone of voice when providing feedback?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

11. To what extent did the interventionist explain the effects that prenatal substance use can have on the mother, baby, and child?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

12. To what extent did the interventionist use a nonjudgmental approach when explaining the effects that prenatal substance use can have on the mother, baby, and child?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

13. To what extent did the interventionist describe the potential negative consequences of the woman's substance use?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

14. To what extent did the interventionist convey empathic sensitivity through words and tone of voice when describing the potential negative consequences of the woman's substance use?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

15. To what extent did the interventionist advocate a goal of abstinence rather than reduction of drug use?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

16. To what extent did the interventionist use a supportive tone of voice when advocating abstinence rather than reduction of drug use?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

17. To what extent did the interventionist acknowledge the woman's autonomy and personal choice?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

18. To what extent did the interventionist respectfully acknowledge the woman's autonomy and personal choice?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

19. To what extent did the interventionist convey that the discussion was a collaborative interaction in contrast to one where the interventionist is in charge?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

20. To what extent did the interventionist use a supportive approach when conveying that the discussion was a collaborative interaction in contrast to one where the interventionist is in charge?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

21. To what extent did the interventionist emphasize the greater importance of the woman's own decisions, confidence, and perception of the importance of changing?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

22. To what extent did the interventionist convey empathic sensitivity when emphasizing the greater importance of the woman's own decisions, confidence, and perception of the importance of changing.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

23. To what extent did the interventionist acknowledge the woman's decision to discuss her drug use?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

24. To what extent did the interventionist verbalize praise when acknowledging the woman's decision to discuss her drug use?

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

25. To what extent did the interventionist offer indicated referrals to the woman?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

26. To what extent did the interventionist respectfully offer indicated referrals to the woman?

ADHERENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Not at all A Little Somewhat Quite a Bit Extensively

Appendix D

IAC TREATMENT FIDELITY INSTRUMENT – Draft 2

1. The interventionist uses a bridging comment when indicated to move the conversation from interview to pre-treatment.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

2. The interventionist uses a positive tone of voice when verbalizing a bridging comment.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

3. The interventionist uses an “I” message when indicated.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

4. The interventionist uses a positive tone of voice when verbalizing “I” messages.

COMPETENCE

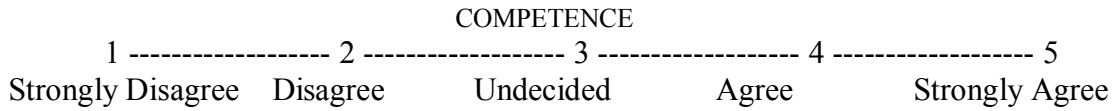
1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

5. The interventionist attempts to share information regarding the effects of prenatal substance use.

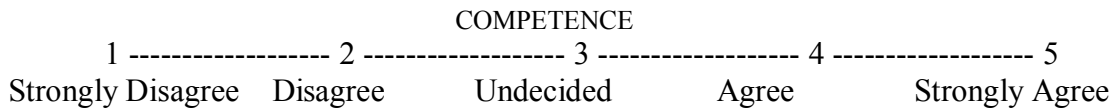
ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

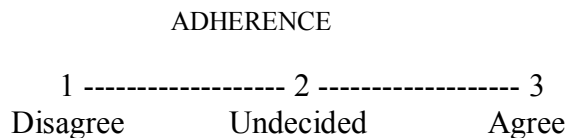
6. The interventionist uses a supportive approach when attempting to share information regarding the effects of prenatal substance use.



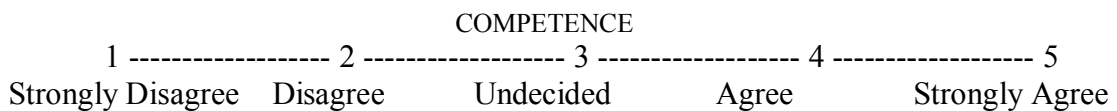
7. The interventionist conveys awareness of the woman's willingness to hear information regarding the effects of prenatal substance use.



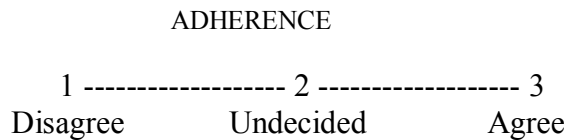
8. The interventionist explains the effects that prenatal substance use can have on the mother, baby, and child.



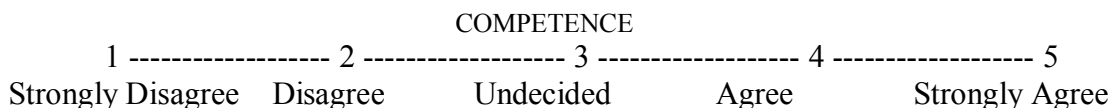
9. The interventionist use a nonjudgmental approach when explaining the effects that prenatal substance use can have on the mother, baby, and child.



10. The interventionist advocates a goal of abstinence rather than reduction of drug use.



11. The interventionist uses a supportive tone of voice when advocating abstinence rather than reduction of drug use.



12. The interventionist provides openings for the woman to react as information is shared.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

13. The interventionist provides feedback.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

14. The interventionist uses a supportive tone of voice when providing feedback.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

15. The interventionist refers medical questions appropriately to the physician or nurse.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

16. The interventionist acknowledges the woman's decision to discuss her drug use.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

17. The interventionist verbalizes praise when acknowledging the woman's decision to discuss her drug use.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

18. The interventionist offers indicated referrals to the woman.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

19. The interventionist respectfully offers indicated referrals to the woman.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

Appendix E

IAC TREATMENT FIDELITY INSTRUMENT – Draft 3

Interviewer: _____ Patient: _____ Rater: _____

1. The interventionist uses a bridging comment when indicated to move the conversation from interview to pre-treatment.

ADHERENCE
1 ----- 2 ----- 3
Disagree Undecided Agree

2. The interventionist uses a positive tone of voice when verbalizing a bridging comment.

COMPETENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

3. The interventionist uses an “I” message when indicated.

ADHERENCE
1 ----- 2 ----- 3
Disagree Undecided Agree

4. The interventionist uses a positive tone of voice when verbalizing “I” messages.

COMPETENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

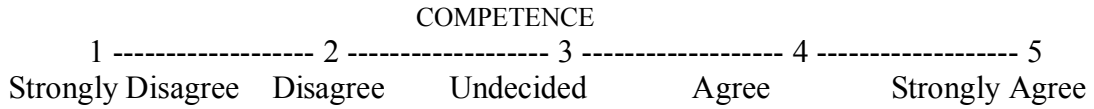
5. The interventionist attempts to share information regarding the effects of prenatal substance use.

ADHERENCE
1 ----- 2 ----- 3
Disagree Undecided Agree

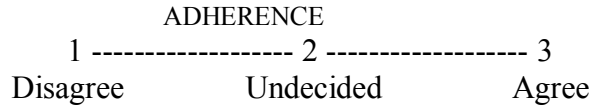
6. The interventionist uses a supportive approach when attempting to share information regarding the effects of prenatal substance use.

COMPETENCE
1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

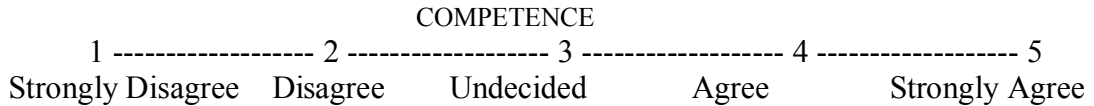
7. The interventionist conveys awareness of the woman's willingness to hear information regarding the effects of prenatal substance use.



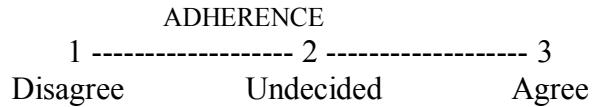
8. The interventionist explains the effects that prenatal substance use can have on the mother, baby, and child.



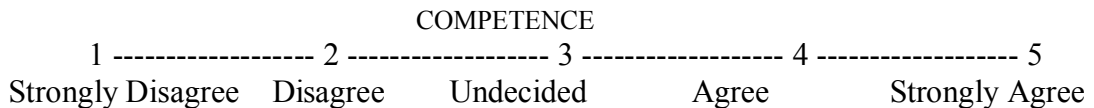
9. The interventionist use a nonjudgmental approach when explaining the effects that prenatal substance use can have on the mother, baby, and child.



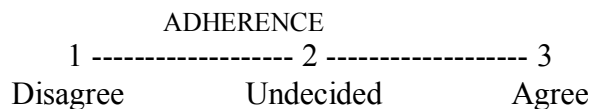
10. The interventionist advocates a goal of abstinence rather than reduction of drug use.



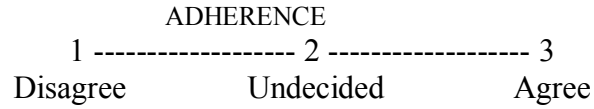
11. The interventionist uses a supportive tone of voice when advocating abstinence rather than reduction of drug use.



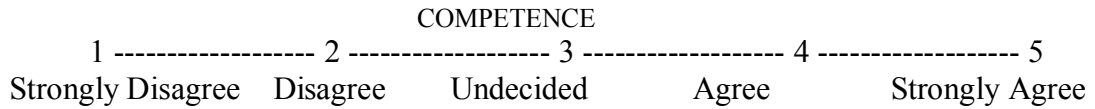
12. The interventionist provides openings for the woman to react as information is shared.



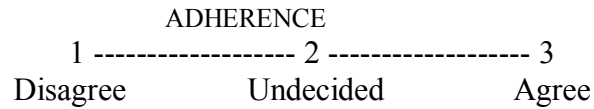
13. The interventionist responds to the woman's reaction.



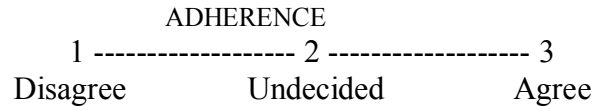
14. The interventionist uses a supportive tone of voice when responding to the woman's reaction.



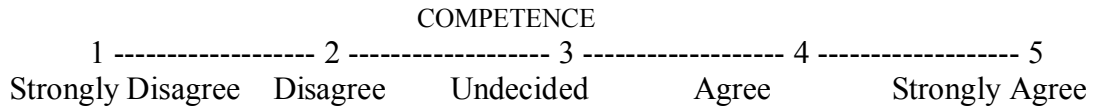
15. The interventionist acknowledges the woman's decision to discuss her drug use.



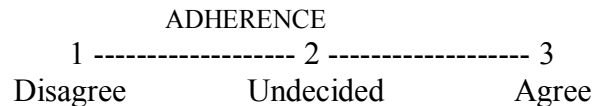
17. The interventionist offers indicated referrals to the woman.



18. The interventionist respectfully offers indicated referrals to the woman.



19. The interventionist refers medical questions asked by the woman to the physician or nurse.



Appendix F

IAC TREATMENT FIDELITY INSTRUMENT – Final Version

Interviewer: _____ Patient: _____ Rater: _____

1. The interventionist uses a bridging comment when indicated to move the conversation from interview to pre-treatment.

ADHERENCE

1 ----- 2 ----- 3

Disagree Undecided Agree

2. The interventionist uses a positive tone of voice when verbalizing a bridging comment.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5

Strongly Disagree Disagree Undecided Agree Strongly Agree

Not applicable; no bridging comment was verbalized

3. The interventionist uses an “I” message to express concern when indicated.

ADHERENCE

1 ----- 2 ----- 3

Disagree Undecided Agree

4. The interventionist uses a positive tone of voice when verbalizing “I” messages.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5

Strongly Disagree Disagree Undecided Agree Strongly Agree

Not applicable; no “I” message was verbalized

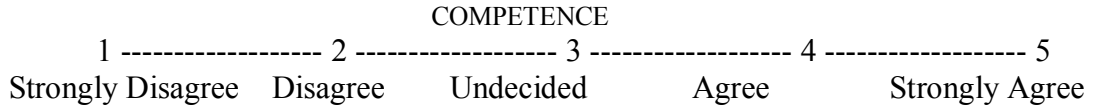
5. The interventionist attempts to share information regarding the effects of prenatal substance use.

ADHERENCE

1 ----- 2 ----- 3

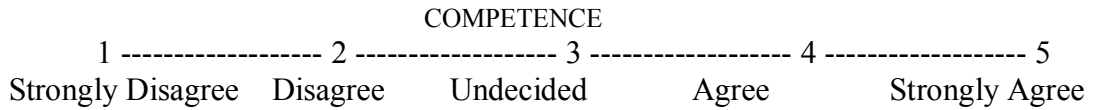
Disagree Undecided Agree

6. The interventionist uses a supportive approach when attempting to share information regarding the effects of prenatal substance use.

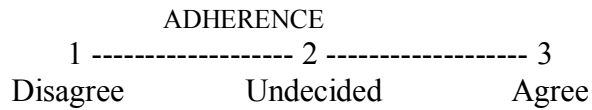


Not applicable; the interventionist did not attempt to share this information.

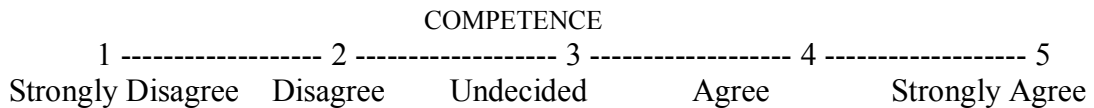
7. The interventionist conveys awareness of the woman's willingness to hear information regarding the effects of prenatal substance use.



8. The interventionist explains the effects that prenatal substance use can have on the mother, baby, and child.

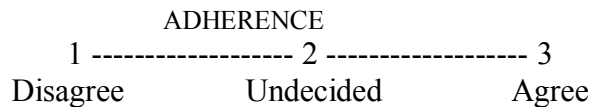


9. The interventionist use a nonjudgmental approach when explaining the effects that prenatal substance use can have on the mother, baby, and child.



Not applicable; the interventionist did not explain the effects of prenatal substance use.

10. The interventionist advocates a goal of abstinence rather than reduction of drug use.



11. The interventionist uses a supportive tone of voice when advocating abstinence rather than reduction of drug use.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

Not applicable; a goal of abstinence was not advocated

12. The interventionist provides openings for the woman to react as information is shared.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

13. The interventionist responds to the woman's reaction.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

14. The interventionist uses a supportive tone of voice when responding to the woman's reaction.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5
Strongly Disagree Disagree Undecided Agree Strongly Agree

Not applicable; the interventionist did not respond to the women's reaction

15. The interventionist acknowledges the woman's decision to discuss her drug use.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

16. The interventionist offers indicated referrals to the woman.

ADHERENCE

1 ----- 2 ----- 3
Disagree Undecided Agree

17. The interventionist respectfully offers indicated referrals to the woman.

COMPETENCE

1 ----- 2 ----- 3 ----- 4 ----- 5

Strongly Disagree Disagree Undecided Agree Strongly Agree

Not applicable; no referrals were offered to the woman

18. The interventionist refers medical questions asked by the woman to the physician or nurse.

ADHERENCE

1 ----- 2 ----- 3

Disagree Undecided Agree

Not applicable; interventionist is a physician or nurse.

Not applicable; no medical questions were asked by the woman

Appendix G

Standardized Patient Identities

Standardized Patient - 1

Name	Emma Abbott
DOB - Age	September 3, 1971 – 38 years
G/P GPTAL	3/0 3 – 0 – 0 – 2 - 0
LMP	March 28, 2010
EDD	January 1, 2010
Partner status	You are no longer involved with the father of your baby
Obstetric hx	You had two therapeutic abortions in your twenties.
Medical hx	Allergic to tetracycline - reaction is hives and difficulty breathing. You have had irritable bowel syndrome for several years with abdominal pain, bloating, and gas. You take hyoscyamine one tablet (0.125 mg) every 4 hours as needed for cramping
Substance use history	You have a long history of alcohol use and you continue to drink every day, including hard liquor. You do not like to be preached to about drinking because your mom drank when she was pregnant with you and you turned out ok.
Response to interviewer	Alcohol: 2 or 3 drinks/day – you have continued since learning you were pregnant Tobacco: you quit smoking 10 years ago Drugs: no drug use IAC Intervention: You are resistant to the IAC and become angry when the interviewer tells you about the consequences of prenatal alcohol exposure. Referrals: You refuse all referrals and you are insulted that the interviewer is suggesting that you need help.
Nutrition	You eat a balanced diet overall
General demeanor	You are resistant to any criticism of your alcohol intake and you communicate this to the interviewer in no uncertain terms.
Housing Environment	You rent a house in Templeton and live alone
Physical Needs	You have MediCal coverage for your pregnancy
Support System	You have good support from family and friends in the area
Vocation	You have a part-time job working in a feed store in Templeton

Standardized Patient - 2

Name	Cathy Silverman
DOB - Age	October 19, 1987 – 22 years
G/P GPTAL	5/1 2 – 1 – 0 – 2 - 2
LMP	January 11, 2010
EDD	October 18, 2010

Partner status	You are not involved with the father of this baby (who is also the father of your other children) and he is unaware of this pregnancy. He was physically and verbally abusive to you and your daughters and you left him and the relationship before you discovered you were expecting. You do not want him to know where you are.
Obstetric hx	You had a therapeutic abortion in 2003 and a miscarriage the next year. You have two-year-old twin daughters, Jill and Jamie. They were born in 2008 by C/S at 35 weeks gestation and stayed in the NICU for 10 days. You considered terminating this pregnancy for some time but you have decided to keep the baby.
Medical hx	NKA – no significant history
Substance use history	You have a history of substance use. You are currently smoking 10 cigarettes daily. You smoke marijuana and use methamphetamines and now that you have decided to keep the baby you have also decided that you will not use drugs and will cut down on your smoking. You are not initially truthful about this when the interviewer asks you.
Response to interviewer	Alcohol: you rarely drank before learning of your pregnancy and none since Tobacco: 1 pack/day for 4 years. 10/day since learning you were pregnant Marijuana: 1/day for several years. You tell the interviewer that you quit when you learned you were pregnant although this is not true as you continue to smoke it once or twice a week. Methamphetamine: 4 or 5 times/week for 2 years. You tell the interviewer that you quit when you learned you were pregnant although this is not true, as you have used it several times since you learned of your pregnancy. IAC Intervention: You accept the IAC intervention. When the interviewer shows you a picture of a baby exposed to methamphetamine, you look away and are visibly upset. Subsequently, you will admit to your use when/if the interviewer asks you about this Referrals: You will accept all offered referrals and state that you are through using and will try to quit smoking.
Nutrition	You try to make sure that you and your girls are we eat a balanced diet. You have WIC, as well as food stamps and welfare
General demeanor	You are pleasant, well groomed, and polite.
Housing Environment	You moved to this are from Southern California in February to escape an abusive relationship. You discovered you were pregnant after you arrived on the central coast. You are staying at the homeless center and you are working on getting housing.

Physical Needs	You have MediCal coverage, welfare, food stamps and WIC
Support System	You do not have any real social support. Your parents were divorced when you were young. Your father remarried and you have not had much contact with him in recent years. Your mother lives in Los Angeles and you talk to her on the phone from time to time. She has physical health issues and is also having a hard time making ends meet. You are trying to be a good mother to your two daughters and are good about seeking any assistance for which you are eligible.
Vocation	Unemployed

Standardized Patient - 3

Name	Samantha Carey
DOB - Age	September 24, 1983 – 26 years
G/P GPTAL	1/0 1 – 0 – 0 – 0 - 0
LMP	April 1, 2010
EDD	January 5, 2011
Partner status	You do not live with the father of your baby, James, but he is very involved and supportive.
Obstetric hx	1 st pregnancy.
Medical hx	No significant medical hx – No known allergies
Substance use history	You like to drink beer and have had a few beers since you became pregnant. You read somewhere that it is okay to have a glass of beer now and then when pregnant. Candid about use and did not think this was a problem.
Response to Interviewer	Alcohol: 1 or 2 beers/day for 3 years – 2 or 3 beers/wk since aware of pregnancy Tobacco: you have never smoked Drugs: none IAC Intervention: You accept the intervention and are shocked when you learn about the effects of prenatal alcohol use. Referrals: you do not accept any referrals, as you do not think you need any help.
Nutrition	You do not exercise and drink 3 to 4 sodas per day, down from 5 or 6. You are attempting to reduce your fast food intake. You have maintained your weight at 220 for the last 3 weeks. You are concerned that your baby will not get enough nutrition if you are not gaining weight.
General demeanor	This pregnancy is unplanned but wanted. You smile frequently during visit and are open and candid.
Housing Environment	You currently live with your grandmother in Arroyo Grande
Physical Needs	You have a WIC appointment. Your friends are giving you a baby shower next month.
Support System	Father of baby is supportive and employed in Arroyo Grande. You have a couple of close girlfriends and rely on them for emotional

	support.
Vocation	You are on disability after being injured on the job as a stocker at Wal-Mart. You receive \$875/mo from state disability.

Standardized Patient - 4

Name	Grace Downs
DOB - Age	March 11, 1977 – 33 years
G/P GPTAL	3/2 1 -0- 2 - 0 - 2
LMP	February 11, 2010
EDD	November 18, 2011
Partner status	You are currently with your boyfriend Ronald Cole. He is not the father of any of your children. You met him at the homeless shelter when you were two months pregnant.
Obstetric hx	You have two older children, 13 and 11, born 10/15/96 and 5/10/99. You had no problem during pregnancy or delivery and both were born vaginally at term. They were removed from your care after Child Welfare Services became involved six years ago and you have had only occasional contact with them since.
Medical hx	Allergic to tegretol (rash) and have a history of mental health disorders (bipolar, depression) and have been taking Zoloft (50 mg qd) and lithium (slow release 450 mg bid) for some time.
Substance use history	You have smoked marijuana for several years and continue during pregnancy and, although you have tried to stop the use of other drugs, you have had several relapses on oxycontin and methamphetamine. You are currently enrolled in POEG (Perinatal Outpatient Extended Group is a community-based perinatal substance use treatment program) in the south county and are at risk of being terminated from the program due to “dirty” drug tests.
Response to interviewer	Alcohol: you drink a beer once in awhile but have not had any since you became pregnant Tobacco: you have not smoked for years Drugs: Marijuana daily for several years – you continue to smoke marijuana daily during pregnancy Oxycontin and methamphetamine 2 or 3/wk when you could get it – you have used both a few times since becoming aware of pregnancy IAC Intervention: You accept the intervention and act shocked when you hear about the effects of drug use (although you already have heard this information before) Referrals: you will accept any offered referrals and will promise to follow through
Nutrition	You have not gained much weight with your pregnancy and were underweight to begin with. You have noticed that you have been hungrier of late. You eat irregularly and your meals are obtained

	through various services such as People’s Kitchen and churches. You no longer are able to receive services through the community health center “Healthcare for the Homeless Program” due to noncompliance with meds, appointments and frequent outbursts and rages at the staff.
General demeanor	You present well and are neat and clean. You minimize your drug use and its consequences. You can be very manipulative and charming and are very experienced with service agencies.
Housing Environment	You are living with your boyfriend in section 8 housing (government-subsidized program that allows lower income families the opportunity to rent decent, safe and adequate housing that may not be available to them otherwise).
Physical Needs	You are hooked up with WIC and are receiving food stamps and welfare payment support.
Support System	Boyfriend – you are estranged from your parents and siblings.
Vocation	Unemployed

Standardized Patient - 5

Name	Yvonne Castro
DOB - Age	October 10, 1980 – 29 years
G/P GPTAL	1/0 1 –0– 0 – 0 - 0
LMP	March 20, 2010
EDD	December 24, 2010
Partner status	You are married but separated from your husband. Your boyfriend, Victorio, is the father your baby. He is an illegal immigrant from Mexico.
Obstetric hx	First pregnancy
Medical hx	No known allergies. You have high blood pressure and had been taking 25 mg of atenolol daily, but quit when you found out you were pregnant. You have been monitoring your blood pressure daily and it was 110/70 today. Your OB/GYN is aware that you are not taking your medication. You have a history of depression and anxiety that continues through your pregnancy, though the frequency and severity have decreased. You occasionally have panic attacks when you feel you must escape. You had been taking Celexa but quit when you found out you were pregnant.
Substance use history	You have been a heavy methamphetamine and alcohol user in the past but you cut down a lot when you found out you were pregnant and have been completely clean for the past 2 weeks. You have gone to a couple of Narcotics Anonymous meetings. You do not feel that you need any help to stay sober and clean at this time.
Response to interviewer	Alcohol: 2 or 3 glasses wine or mixed drinks daily – 2 or 3 /wk since you became pregnant and none recently Tobacco: you do not smoke Drugs: methamphetamine daily at times for the last few years– you

	<p>have used both a few times since becoming aware of pregnancy but not in the last 2 weeks.</p> <p>IAC Intervention: You accept the intervention and become tearful and depressed when you hear about the effects of alcohol and drug use. Referrals: you refuse offered referrals and feel you are on the right track and do not need any help to stay clean.</p>
Nutrition	You love to eat junk food and have 3 Snickers and a soda daily. You listen to information but laugh and say that you understand the interviewer is trying to help but, in all honesty, you love your junk food too much to quit.
General demeanor	You are very polite to the interviewer but have been known to get angry and yell at others. You are a young woman who masks her insecurity and desire for love with a tough, yet funny persona.
Housing Environment	You are living with your aunt right now. She is supporting you but you have to sleep on her couch, as there is not a bed for you.
Physical Needs	You have MediCal.
Support System	You grew up in an abusive and drug-using home. When your mom abandoned you at age 12, you lived with your grandmother who uses drugs as well. Your boyfriend is possessive, mistrustful and abusive.
Vocation	Unemployed

Standardized Patient - 6

Name	Helen Parker
DOB - Age	October 10, 1974 – 35 years
G/P GPTAL	1/0 1 –0– 0 – 0 - 0
LMP	February 12, 2010
EDD	November 19, 2010
Partner status	You think that Ken Jenkins is most likely the father your baby. He is homeless, jobless, and lives in his car. He is 44 years old and questions paternity. You are not actually sure who the father is but none of the potential fathers can be relied upon for support.
Obstetric hx	First pregnancy
Medical hx	No known allergies. You have a history of herpes simplex virus II, human papilloma virus, and cervical cancer, high blood pressure and had been taking 25 mg of atenolol daily, but quit when you found out you were pregnant. You have a history of severe endometriosis and have been taking Percocet twice a day. You also have a history of depression and a suicide attempt. You were prescribed Zoloft but are not taking it for fears of the effects on your baby.
Substance use history	You have a history of drug use and have used methadone, cocaine, methamphetamine, and marijuana. Your last “heavy” drug use was 2008/2009. You were in rehab in Santa Barbara in 2009 but left because you could not afford the costs, which were \$600/month. You have been nauseous occasionally and have been using marijuana now and then to help with this.

Response to interviewer	<p>Alcohol: 2 or 3 drinks month – none since you became pregnant Tobacco: you do not smoke Drugs: marijuana daily– you have continued to use a few times/week since becoming aware of pregnancy</p> <p>IAC Intervention: You accept the intervention and are surprised and a little skeptical to hear that prenatal marijuana use can affect your baby. Referrals: You are not interested receiving drug & alcohol services and really don't want to hear about them. You do not feel that you need any help to stay sober and clean at this time.</p>
Nutrition	You are trying to eat healthy, take vitamins, and avoid hard drugs.
General demeanor	Your affect is flat and you tell your story with a matter-of-fact tone. You are stubborn and don't like to hear advice that contradicts what you believe and want for yourself, but you are not outwardly rude. You are depressed and insecure. You are not happy about being pregnant but you are dealing with it the best way you know how. You did not think you could get pregnant because of your severe endometriosis.
Housing Environment	You are living with a friend and sleeping on a couch in the living room. Your friend will only let you live there temporarily until other living arrangements can be made. Your social worker gave you a list of housing resources but you have not called any of them.
Physical Needs	You went to ALPHA Pregnancy Counseling & Support (a nonprofit organization) for maternity clothes. You are applying for MediCal but have not filed all of the necessary paperwork to receive your benefits at this time.
Support System	Your mom is trying to help you but is unhappy with your life choices. Now she is trying to be a parent, when she should have been setting limits 10 years ago. You feel resentful towards her but have no one else who is supportive of you.
Vocation	Unemployed

Standardized Patient - 7

Name	Sara Deming
DOB - Age	April 30, 1974 – 36 years
G/P GPTAL	1/0 1 –0– 0 – 0 - 0
LMP	January 25, 2010
EDD	November 1, 2010
Partner status	You have been married to Tom Deming for 6 years. This is your second marriage. Tom's 10 year-old son from a previous marriage lives with his ex-wife.
\	
Obstetric hx	First pregnancy
Medical hx	No known allergies. You were in a serious motor vehicle accident

	(MVA) at age 32 and spent a month in the hospital recovering from various injuries. You have been unable to return to your work as a medical secretary as sitting in front of a computer screen for any prolonged length of time produces neck pain.
Substance use history	Your doctors have prescribed a variety of medications to help you deal with post-MVA sequelae. These include narcotic pain medications (Oxycontin Percocet, Darvocet, and Vicodin) and anti-anxiety medications (Valium and Xanax). You have been using these drugs for the last few years to battle depression and loneliness and have continued to use them after learning of your pregnancy. You have tried to stop on your own but have been unable to do so. Your husband is unaware of the extent of your use and does not know that you are continuing to take medications since you became pregnant. The general practitioner (GP) who has been prescribing these drugs does not know that you are pregnant.
Response to interviewer	Alcohol: none Tobacco: none Opiates/Valium: daily for three years – 3-4/wk since pregnant IAC intervention: You will accept the IAC and when the interviewer describes the consequences of prenatal opiate use and shows you photos of infants who have been Oxycontin-exposed, you are tearful and ashamed. Referrals: If offered referrals, you tentatively accept them. You realize that you might need help.
Nutrition	You have been trying to eat better since you learned you were pregnant.
General demeanor	You are very reluctant to disclose your drug use since becoming pregnant and are evasive and obviously ill at ease when asked about this. When you do finally acknowledge that you have been using, you are remorseful but do not fully seem to understand your responsibility.
Housing Environment	You live in an apartment in Atascadero with your husband.
Physical Needs	Your husband is employed as an accounting clerk and is going to school to become a CPA. He will graduate right after the baby is born and has been offered a well-paying job in the agency in which he works. Money is somewhat tight but you are managing - the apartment in which you live is owned by your mother and your rent is quite low. You qualify for MediCal and WIC.
Support System	This was a planned pregnancy. Your husband wanted a large family and both sets of parents really want grandchildren. You hoped that becoming pregnant would help you get your act together and make you feel happier. Your husband is very excited about the baby who is a boy.

Vocation	Unemployed
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Standardized Patient - 8

Name	Jennifer Hansen
DOB - Age	February 3, 1988 – 22 years
G/P GPTAL	2/0 2 – 0 – 0 – 1 - 0
LMP	March 10, 2010
EDD	December 14, 2010
Partner status	Father of baby, Rodney, is supportive
Obstetric hx	This was an unplanned pregnancy. You had a therapeutic abortion last year.
Medical hx	NKA
Substance use history	You were taking approximately 160 mg of Oxycontin w/o a prescription up until a month ago. Since then, you have been taking 20 mg of methadone (off the street) in an attempt to get off the Oxycontin. You have not had any methadone for the last 4 days. Alcohol: you drink alcohol very rarely and have not had anything to drink since learning of your pregnancy Tobacco: 15 cigarettes daily for 5 years – you have cut down to 7 cigarettes per day currently.
Response to interviewer	IAC Intervention: You accept the IAC intervention and become very quiet when the interviewer discusses the consequences of prenatal use Referrals: You accept referrals to a drug and alcohol counselor and a public health nurse. You do not accept a referral to smoking cessation but do accept pamphlets.
Nutrition	You are thin and undernourished. You have not gained any weight since becoming pregnant. You want to have a healthy baby but you are afraid because of your drug use.
General demeanor	You are distracted, impatient, agitated and tired.
Housing Environment	You are living with your boyfriend in a garage/apartment at your father's house.
Physical Needs	You have MediCal coverage. Your boyfriend is working at a local grocery store and earns enough to cover your expenses.
Support System	Your parents are divorced. Your father is a recovering alcoholic and heroin addict who has been clean for 13 years. Your mother is a prescription drug addict. You do not feel close to either of your parents.
Vocation	Unemployed

Standardized Patient - 9

Name	Angela Meister
DOB - Age	February 5, 1973 – 37 years
G/P GPTAL	5/3 5 – 1 – 2 – 1 - 3

LMP	February 7, 2010
EDD	November 24, 2010
Partner status	You divorced the father of your children in 2005; you share custody of the children. You have lived with Danny Harris, the father of this baby, for two years – he is a committed partner. This is his 1 st child and he is excited.
Obstetric hx	This is your 5 th pregnancy; it was unplanned. All your deliveries have been vaginal 1995: girl – full term – 8 lbs - no complications 1997: girl – full term – 7 lb 9 oz – no complications 1998: Miscarriage at 8 weeks followed by D&C 2000: boy - 37 weeks – 6 lb 3 oz - was induced early due to problems with high blood pressure
Medical hx	No significant medical hx – No known allergies
Substance use history	Started smoking after divorce but quit when you found out about this pregnancy. Drinks a glass of wine once in awhile and you have never used other drugs. You did not think that an occasional glass of wine was a problem.
Response to interviewer	Alcohol: 1 glass of wine two or three times a week – this has continued since learning of pregnancy. Tobacco: ½ pack daily for five years – quit when learning of pregnancy Drugs: none IAC Intervention: You accept the IAC intervention and become upset when the interviewer discusses the consequences of prenatal alcohol use. You do not really believe what she is telling you as you drank moderately with your other children and they turned out fine. Referrals: You do not accept any referrals as you do not think you need it.
Nutrition	You eat well and have gained an appropriate amount of weight since becoming pregnant. You like to cook and eat a balanced diet.
General demeanor	Happy about this pregnancy and your children are excited about having a little brother or sister.
Housing Environment	You and your children are living with Danny in a large four-bedroom home in a nice neighborhood that he owns. He has a business as a house painter and makes a decent living.
Physical Needs	You have MediCal coverage for your pregnancy
Support System	You have several good friends and you are close to your sister who lives nearby.
Vocation	You clean houses on a part-time. You like this as it gives you flexibility and allows you to be home with your children.

Appendix H

Rater Training Agenda

- Study Background
- Confidentiality Agreement
- Consequences of Prenatal Substance Exposure
- Screening and Assessment for Prenatal Use of Alcohol, Tobacco, and Other Drugs
- Motivational Interviewing
- “I Am Concerned” (IAC) Brief Opportunistic Intervention
 - IAC DVD
 - IAC Treatment Manual Distribution
 - Implementing the IAC
- IAC Treatment Fidelity Instrument
- IAC Treatment Fidelity Rating Practice
- Rating Practice Review
- Weekly Meeting Schedule
- Distribution of Initial Audio Recording CDs and Fidelity Instruments

Appendix I

Participant Preparation Meeting Agenda

- Introductions
- Study Background
- IAC Implementation Review
- Prenatal Intake Interview Form Adaptation
- Pseudonym Selection
- Intervention Practice
- Demographic Information
- Informed Consent
- Simulated Clinic Schedule
- Audio Recording Process
- Tour of Clinic Locations

Appendix J

Prenatal Intake Interview Form

NAME:		BIRTH DATE: ___ / ___ / ___			AGE:				
RACE:		MARITAL STATUS: S M W D SEP							
OCCUPATION: <input type="checkbox"/> HOMEMAKER <input type="checkbox"/> STUDENT <input type="checkbox"/> OUTSIDE WORK TYPE OF WORK:									
EDUCATION (LAST GRADE COMPLETED):									
HUSBAND/FATHER OF BABY:									
LMP ___ / ___ / ___ <input type="checkbox"/> DEFINITE <input type="checkbox"/> APPROXIMATE <input type="checkbox"/> UNKNOWN EDD ___ / ___ / ___									
TOTAL PREG	FULL TERM	PREMATURE	AB INDUCED	AB SPONT	ECTOPIC	MULT BIRTHS	LIVING		
PAST PREGNANCIES									
Date	GA Wks	Length of Labor	Birth Weight	Sex M/F	Type Delivery	Anes	Place of Delivery	PT Labor Yes/No	Comments/Complications
PAST MEDICAL HISTORY									
		0 Neg + Pos	DETAILS				0 Neg + Pos	DETAILS	
1. DIABETES				16. D (Rh) SENSITIZED					
2. HYPERTENSION				17. PULMONARY (TB, ASTHMA)					
3. HEART DISEASE				18. ALLERGIES (DRUGS)					
4. AUTOIMM DISORDER				19. BREAST					
5. KIDNEY DIS/ UTI				20. GYN SURGERY					
6. NEURO/EPILEPSY				21. OPERATION/HOSPITALIZATION					
7. PSYCHIATRIC				22. ANESTHETIC COMPLICATIONS					
8. HEPATITIS/LIVER DIS				23. HISTORY OF ABNORMAL PAP					
9. VARICOS/PHLEBITIS				24. UTERINE ANOMALIES/DES					
10. THYROID DYS				25. INFERTILITY					
11. TRAUMA/DOM VIOL				26. RELEVANT FAMILY HX					
12. HX BLOOD TRANS				27. OTHER					
COMMENTS:									

GENETIC SCREENING/TERATOLOGY COUNSELING					
INCLUDES PATIENT, BABY'S FATHER, OR ANYONE IN EITHER FAMILY					
	YES	NO		YES	NO
PATIENT'S AGE ≥ 35 YEARS			CYSTIC FIBROSIS		
THALESSEMI			HUNTINGTON CHOREA		
NEURAL TUBE DEFECT			MENTAL RETARDATION/AUTISM		
CONGENITAL HEART DEFECT			IF YES, TESTED FOR FRAGILE X?		
DOWN SYNDROME			OTHER GENETIC/CHROM DISORDER		
TAY-SACHS			MATERNAL METABOLIC DISORDER		
SICKLE CELL DISEASE/TRAIT			PT OR FOB HAD CHILD WITH BIRTH DEFECT NOT LISTED ABOVE?		
HEMOPHILIA			RECURRENT PREGNANCY LOSS, OR STILLBIRTH		
MUSCULAR DYSTROPHY			ANY OTHER		

COMMENTS/COUNSELING: _____

INFECTION HISTORY	YES	NO		YES	NO
HIGH RISK HEPATITS B/IMMUNIZED?			RASH/VIRAL ILLNESS SINCE LMP		
EXPOSED TO TB			HISTORY OF STI, GC, HPV, SYPHILIS		
PT/PARTNER HX GENTIAL HERPES			OTHER (SEE COMMENTS)		

COMMENTS/: _____

NUTRITION

Number of times per day usually eats?
 1 2 3 4 5 6 7 more often

Daily liquid intake (# of cups/glasses/cans):
 water ____ juice ____ milk ____
 decaffeinated coffee/tea ____
 regular coffee/tea ____
 regular soda/punch ____ decaf soda ____

Allergic to foods? No
 Yes, describe:

Any foods or food groups avoided? No
 (such as dairy, meat, etc)
 Yes, list which foods and note reason:

Ever eat raw eggs/fish/meat, soft cheeses, No
 canned tuna or fish caught by friends or family?
 Yes, describe:

Food or non-food cravings? No
 (examples of non-foods are ice, plaster,
 cornstarch, dirt, clay, laundry starch)
 Yes, describe:

Planning to breastfeed?
 No combine with formula not sure Yes

Knowledge or experience with breastfeeding?
 none observed friends/family took class
 personal experience? Circle and comment:
 negative positive

Currently taking prenatal vitamins? Yes
 No, needs vitamins:

Currently taking (if yes; type, amount, frequency): None

In addition to prenatal vitamins:
 over-the-counter drugs:
 prescription medications:
 dietary supplements:
 home remedies:
 other:

Already enrolled in WIC? Yes
 WIC site: _____
 No, needs referral

Ever run out of food? No
 Yes, describe

Current discomforts? <input type="checkbox"/> nausea <input type="checkbox"/> vomiting <input type="checkbox"/> edema <input type="checkbox"/> diarrhea <input type="checkbox"/> heartburn <input type="checkbox"/> constipation	<input type="checkbox"/> No <input type="checkbox"/> other	Have access to a working kitchen? <input type="checkbox"/> Yes <input type="checkbox"/> No. Way to cook food? Comment: Physically active at least 3 times each week? <input type="checkbox"/> Yes, comment: <input type="checkbox"/> No, comment: Pre-pregnancy weight: _____ lb Height: _____ Today's weight _____ lb
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Appendix K

Participant Recruitment Letter



600 FORBES AVENUE
PITTSBURGH, PA 15282

Dear Care Provider,

I am conducting a research study for my dissertation. The research is to develop a tool that will measure implementation of the “I Am Concerned” (IAC) intervention that is conducted when a pregnant woman screens positively for prenatal use of alcohol, tobacco or illicit drugs. This study is an important first step towards future research to determine how effective the IAC is in reducing women’s use of harmful substances.

I am looking for front office staff members (MA, LVN, RN), whose job duties have included IAC implementation for at least 2 years, to participate in the study. Participants will attend a half-day IAC refresher training session with me. The actual study portion is estimated to last 2 days and will take place in a simulated clinic setting at Cuesta College. Participants will be reimbursed for lost wages for work hours missed due to participation in the study.

Please call or email me if you are interested in being a part of this research and I can tell you more about the study and answer any questions you have.

I sincerely welcome your involvement in this worthwhile effort,

Antonia Torrey RN, MSN
Duquesne University School of Nursing

Phone: 805 769 6705
Email: torreya@duq.edu

Appendix L

Participant Demographic Tool

What is your age in years as of your last birthday?

What is your gender? (Circle number.)

Female

Male

Transgender

What is your race?

Non-Hispanic White

Non-Hispanic Black

Hispanic/Latino

Asian & Pacific Islander

American Indian & Alaska Native

Other

What is your present position?

What is the total number of years you have worked in a prenatal clinic or office?

What is the total number of years you have implemented the “I Am Concerned” intervention?

_____ -

What is your highest level of education?

High School

Diploma

Associate degree

Bachelor’s degree in _____

Master’s degree in _____

Doctorate in _____

Appendix M



DUQUESNE UNIVERSITY
600 FORBES AVENUE ♦ PITTSBURGH, PA 15282
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Development and Psychometric Evaluation of a Structured Instrument to Assess the Treatment Fidelity of a Brief Opportunistic Intervention Designed to Reduce Substance Use Among Pregnant Women

INVESTIGATOR/ADVISOR Linda Goodfellow PhD, RN
Associate Professor
Duquesne University School of Nursing
School of Nursing
517 Fisher Hall
Pittsburgh, PA 15282
412-396-6548

STUDENT CO-INVESTIGATOR: Antonia Torrey, RN, MSN
8315 Portola Road
Atascadero, CA 93422

SOURCE OF SUPPORT: This study is being performed as partial fulfillment of the requirements for the Doctor of Philosophy in Nursing at Duquesne University

PURPOSE: You are being asked to participate in a research project to investigate the usefulness of a research instrument that measures the faithfulness with which an intervention, designed to reduce prenatal use of alcohol, tobacco and other drugs, is performed. If you decide to participate in this research, you will conduct prenatal interviews in a simulated prenatal clinic setting with nursing students portraying pregnant women. You will follow the process that you use when performing your job duties in the prenatal clinic or office in which you work, including substance use screening and conducting the "I Am Concerned" brief opportunistic intervention. Interviews will be audio recorded and these recordings will be used during the study to evaluate the quality of the research instrument referred to above.

RISKS AND BENEFITS: There are no known risks greater than everyday activities or direct benefits from participating in this

study. However, you will have the knowledge that you will help the researchers examine the usefulness of a research instrument that measures the faithfulness with which an intervention, designed to reduce prenatal use of alcohol, tobacco and other drugs, is performed. An indirect benefit is the potential reduction in fetal substances exposure through dissemination of these study findings to a larger health care audience.

COMPENSATION:

You will be compensated at approximately your normal hourly rate (MA/\$12, LVN/\$15, RN/\$20) for wages lost as a result of work hours missed while directly participating in this study.

CONFIDENTIALITY:

Your name will never appear on any survey or research instruments. Your identity will not be revealed in the data analysis. All written materials, audiotapes, and consent forms will be stored in a locked file cabinet in the researcher's office. The consent forms will be kept separate from the other research materials. All materials will be destroyed at the completion of the research.

RIGHT TO WITHDRAW:

You are under no obligation to participate in this study. You are free to withdraw your consent to participate at any time.

SUMMARY OF RESULTS:

A summary of the results of this research will be supplied to you, at no cost, upon request.

VOLUNTARY CONSENT:

I have read the above statements and understand what is being requested of me. I also understand that my participation is voluntary and that I am free to withdraw my consent at any time, for any reason. On these terms, I certify that I am willing to participate in this research project. I understand that should I have any further questions about my participation in this study, I may call the Principle Investigator and Advisor, Dr. Linda Goodfellow, 412-396-6548, the Student Co-Investigator, Antonia Torrey at 805-769-6705, or Dr. Paul Richer, Chair of the Duquesne University Institutional Review Board at (412) 396-6326.

Participant's Signature

Date

Researcher Signature

Date

