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**[Improving Prenatal Care: Implementing Screening, Brief Intervention, and Referral to
Treatment Protocol for Women Using Opioids during Pregnancy**

AZITA AMIRI

by

Erin DeBruyn, MSN, RN, APRN, WHNP-BC

A DNP PROJECT

**Submitted in partial fulfillment of the requirements for the
Degree of Doctor of Nursing Practice
to
The School of Graduate Studies
of
The University of Alabama in Huntsville**

**HUNTSVILLE, ALABAMA
2019**

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Erin DeBrya 10/26/2019

Student Signature

Date

DNP PROJECT APPROVAL FORM

Submitted by Erin DeBruyn in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

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ABSTRACT
The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice _____ College: Nursing

Name of Candidate: Erin DeBruyn, MSN, RN, APRN, WHNP-BC

Title: Improving Prenatal Care: Implementing Screening, Brief Intervention, and Referral to Treatment Protocol for Women Using Opioids during Pregnancy

One of the most critical health care issues in the United States (US) is the opioid epidemic. The opioid epidemic has caused an increase in the number of pregnant women using opioids during pregnancy. The objective of this project was to determine if implementing the screening, brief intervention, and referral to treatment (SBIRT) protocol into prenatal care increases patient knowledge about prenatal substance use and to determine patient satisfaction with the program.

A mixed-method project was conducted. Data were collected from a single private obstetrical and gynecological practice. Participants were selected through the convenience sampling method. The participants completed the 5Ps screening tool, which stands for “parents, peers, partner, past, and present,” and screens for substance use. Any patient that answered “yes” to at least one question was eligible. In this project, the intervention was described as the use of the SBIRT protocol. An initial session and up to five follow up visits were conducted either in person during a scheduled prenatal visit or over the phone every two weeks. In each session, the participants were educated about the harmful effects of substance use during pregnancy. Pre-test/Post-test was used to assess the effectiveness of the educational component and patient satisfaction with the protocol implementation.

Thirty pregnant women who had a positive 5Ps screen consented to participate. Twenty-three pregnant women completed the project. The majority of participants (43.3%) were 18-24

years old, identified as White/Caucasian descent (63.3%), married (60%), and employed (56.7%). A majority of the women had Medicaid insurance (70%), began the project in the first trimester (46.7%), and were multigravida (63.3%). Participants acknowledged that the project strengthened the therapeutic relationship with their provider. One hundred percent of participants were satisfied with the educational program, thought that the intervention was helpful, and believed that it should be used to help women quit substance use during pregnancy.

After data collection, seventeen women (56.7%) were still pregnant and had not experienced any adverse maternal or fetal outcomes. Eight women (26.7%) had not experienced any adverse maternal health outcomes and delivered healthy infants. Two women (6.7%) experienced adverse maternal and fetal outcomes. Three women (10%) experienced first trimester losses (two miscarriages and one ectopic). In conclusion, implementation of the SBIRT protocol into prenatal care is feasible, acceptable by the participants, and effective in increasing patient knowledge about the dangers of prenatal substance use.

ACKNOWLEDGMENTS

I would like to acknowledge Dr. Jacqueline Rodier for allowing this project to be conducted in her practice. I would also like to acknowledge my clinical mentor, Dr. Anne Moore, and my faculty mentor, Dr. Azita Amiri, for their guidance and mentorship during the project. Moreover, I would like to acknowledge all the pregnant women who participated in the project for their participation.

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Improving Prenatal Care: Implementing SBIRT Protocol for Women Using Opioids during Pregnancy

Identification of the Problem

There are many critical health care issues in the United States (US) that need immediate attention. One of the most urgent and prominent issues is the opioid epidemic. Opioids are defined as a class of medications or illegal drugs that are derived from the opium poppy. Pharmacodynamically, opioids are a central nervous system (CNS) depressant that can reduce pain and induce sleep.

McHugh, Nielson, and Weiss (2015) state opioids rank the highest of prescription drugs in terms of abuse. Globally, opioids have the third highest prevalence ranking worldwide, account for 0.6-0.8% of the adult population or 26.4-36 million opioid users (World Health Organization (WHO), 2012). North America has a higher than global average prevalence of opioid use at 3.8-4.2% (WHO, 2012). Opioid abuse accounts for a significant portion of healthcare costs. The National Institute on Drug Abuse (NIDA) estimates the abuse of prescription opioids accounts for \$26 billion in healthcare costs and \$78.5 billion in overall economic costs (includes crime, lost productivity, and healthcare combined) (NIDA, 2017).

According to the *2015 National Survey on Drug Use and Health*, 12.5 million people misused prescription opioids, 2.1 million people misused prescription opioids for the first time, and 2 million people had a prescription opioid use disorder (U.S. Department of Health and Human Services, 2017). Men are more likely to use illicit substances than women; however, women are equally as likely to become addicted (NIDA, 2016b). Ailes et al. (2015) found that “opioid-containing medications are widely prescribed among reproductive-aged women with either private insurance or Medicaid” (p. 38). Medicaid-insured women filled prescriptions more

frequently than privately-insured women and non-Hispanic white women with Medicaid insurance were more likely to fill a prescription than other ethnicities (Ailes et al., 2015). Hydrocodone, codeine, and oxycodone are the most commonly prescribed opioids (Ailes et al., 2015). Geographically, opioid prescriptions are highest in the Southern United States and lowest in the Northeastern United States (Ailes et al., 2015).

The increased prevalence of opioid use among reproductive-aged women has led to an increase in the number of women who have used prescription drugs during pregnancy (Krans & Patrick, 2016). The American College of Obstetricians and Gynecologists (ACOG) (2017), defines opioid abuse during pregnancy as “the use of heroin and misuse of prescription opioid analgesic medications.” The Substance Abuse and Mental Health Services Administration (SAMHSA), a division of the Department of Health and Human Services, estimates that 5.4% of pregnant women aged 15-44 were current illicit drug users, with the 15-17 year age group having the highest percentage (14.6%) and the 26-44 year age group having the lowest percentage (3.2%) (SAMHSA, 2014).

Because of the rise in prenatal substance abuse, complications from their use have also increased (Patrick & Schiff, 2017). Pregnant women using opioids during pregnancy can cause severe complications during pregnancy including premature rupture of membranes, preeclampsia, preterm labor and delivery, and placental abruption (NIDA, 2016a). Perinatal substance abuse also causes significant health problems for the fetus, including decreased or small head circumference, congenital disabilities, low birth weight, neonatal abstinence syndrome (NAS), premature birth, developmental and behavioral issues, and sudden infant death syndrome (SIDS) (NIDA, 2016a).

Neonatal abstinence syndrome (NAS) is defined as “a postnatal opioid withdrawal syndrome that can occur in 55 to 94% of newborns whose mothers were addicted to or treated with opioids while pregnant” (McQueen & Murphy-Oikonen, 2016). The incidence of NAS has risen dramatically in the last decade corresponding with the rise in opioid use during pregnancy (McQueen & Murphy-Oikonen, 2016). The ideal prevention strategy for NAS is to stop the mothers from using substances while pregnant. Pre-conception education and cessation of drug use before pregnancy is the best way to reduce the number of neonates born with NAS. If the mother is using substances while pregnant, the ideal prevention strategy for NAS is to carefully monitor the amount of drugs consumed and monitor the fetus during pregnancy with increased surveillance.

PICOT: In caring for women using opioids during pregnancy, does implementation of the *Screening, Brief Intervention, and Referral to Treatment (SBIRT)* protocol improve patient knowledge about the adverse effects of using substances?

Conceptual Framework

Applying Swanson’s *Theory of Caring* (Figure 1) in practice provides a theoretical framework for perinatal providers to establish a strong rapport with the patient. Successful treatment of substance abuse disorders depends on many factors, most importantly patient-health care provider rapport (Krans & Patrick, 2016). Often, pregnant women are a group of patients that are ostracized and condemned for using substances during pregnancy. Because of the condemnation that these women may have faced, it is imperative for their providers to exude “a caring and nonjudgmental attitude that can build a strong rapport, engender trust, and facilitate effective communication” (Jones et al., 2014, p. 303). Caring for these women and their unborn babies can be very difficult for providers. Because this population often feels overlooked and

misunderstood, providing care that gives the patient a “sense of wholeness”---where they feel respected, comforted, hopeful, and enabled; can help the practitioner in obtaining better, positive outcomes for mother and baby (Swanson, 2015).

The caring process begins with *Maintaining Belief* as the foundation. Swanson (1993) views *maintaining belief* as the ability of the nurse/provider to maintain unwavering faith, throughout the entire caring process, in the capacity of the client to get through a life event and come out on the other side, a better and transformed person. The provider maintains the belief that the mother can achieve a healthy pregnancy and a healthy baby. She may also be able to maintain her sobriety (if appropriate). Without a belief in the client, the caring process can be greatly hampered, and the client may not be able to achieve well-being.

The next step in the caring process is what Swanson calls *Knowing*. Swanson (1993) defines *knowing* as “striving to understand an event as it has meaning in the life of the other” (p. 355). This can be viewed as understanding the patient’s perspective. What are her feelings, emotions, fears, and goals? What does this pregnancy mean to her? Why did she start using substances originally? Does she have an understanding related to her addiction? Does she have a desire to get “clean”? Has she tried to get clean in the past and what methods has she tried? Even though they may have made many attempts to quit or to get help before pregnancy, sometimes their baby is the impetus and motivation that they need to seek help for their addiction. Establishing a robust patient-health care provider rapport increases the probability that the patient will provide honest answers about her substance use (Jones et al., 2014). This is a significant phase of the care process because it enables the provider to truly get to know and understand where the client is coming from.

Swanson describes *Being With* and *Doing For* as the next steps in the caring process. *Being with* is defined as “being emotionally present to the other” and *Doing for* is defined as “doing for the other what she would do for herself if it were possible” (Swanson, 1993, p. 355-356). *Being with* could be seen as the provider being with the patient for the duration of the pregnancy and postpartum period. The provider can be emotionally and physically present during each of the prenatal appointments and can be available by phone as much as needed by the patient. This includes being an empathetic, active listener and establishing and maintaining eye contact (Jones et al., 2014). *Doing for* may be one of the most active parts of the caring process. It may involve scheduling referrals to high-risk perinatologists, evaluations by psychologists or psychiatrists (if not already done), and counselors or therapists.

In some cases, it may be necessary to refer the patient to a detox center and then assisted living/healthy living center afterward. Maybe the most essential aspect of *doing for* involves being a cheerleader and encourager. A significant portion of patients with substance abuse disorders have poor self-esteem and do not believe in their ability to accomplish tasks, and the most crucial aspect of accomplishing a goal is having a desire to do it and believing that they can do it.

The final step in the caring process is *Enabling*. Swanson (1993) described *enabling* as “facilitating the other’s passage through life transitions and unfamiliar events” (p. 356). For pregnant women with substance abuse disorders, *enabling* could include the provider informing, explaining, teaching, and supporting throughout the pregnancy. It involves the provider giving anticipatory guidance of what to expect and what is to come in the pregnancy and care routine. Due to the high-risk pregnancy, these women often have closer monitoring with several more prenatal appointments, not just with the primary provider, but with other specialists as well. With

appropriate guidance, the patient will be able to maintain all appointments and ensure as healthy a pregnancy as possible. *Enabling* can also mean allowing the patient to express her feelings about her situation and for the provider to validate those feelings and give appropriate feedback. The provider allowing her expression of feelings and validation of those feelings enables the patient to feel cared for. Once the patient has successfully moved through the processes, the patient has been enabled to achieve wellbeing (Swanson, 1993).

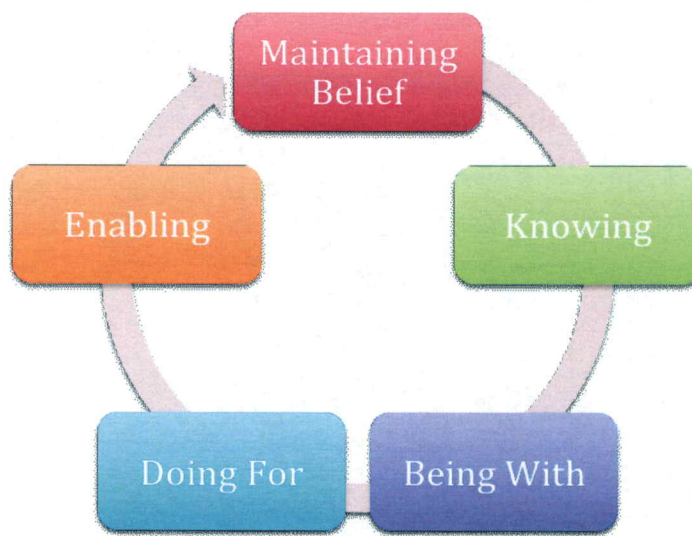


Fig 1. Swanson's *Theory of Caring*

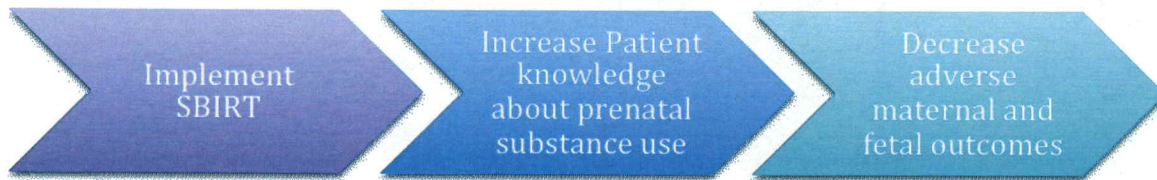


Fig 2. Conceptual Framework

Review of the Evidence

A structured literature review search was conducted to establish current evidence regarding protocols applied for women using opioids during pregnancy. Databases searched included PubMed/Medline, Cochrane, CINAHL, Proquest, and ScienceDirect. Keyword searches included pregnancy, substance abuse, opioids, SBIRT, and protocols. The literature search revealed gaps related to screening and appropriate prenatal care for women who use or abuse opioids during pregnancy. It is evident that this is a complex and challenging issue that has varying opinions on how best to screen, monitor, and treat. A majority of the current literature focuses on alcohol and tobacco use during pregnancy; however, research about opioid use during pregnancy is increasing. Limiters included research articles, systematic reviews, clinical practice guidelines, within the past fifteen years, peer-reviewed, evidence-based practice, English language, female gender, and adult population (18 and over).

The American College of Obstetricians and Gynecologists (ACOG) released the latest recommendations regarding opioid use and opioid use disorder in pregnancy in August 2017. ACOG recommends that universal screening of all pregnant women should be a part of comprehensive obstetric care. Early universal screening, brief intervention (such as engaging a patient in a short conversation, providing feedback and advice), and referral for treatment of pregnant women with opioid use and opioid use disorder improve maternal and infant outcomes (ACOG, 2017).

Chang et al. (2005) completed a study that sought to test the effectiveness of a brief intervention in the reduction of prenatal alcohol consumption by women when a partner is included. A randomized trial of a single session brief intervention was given by the study nurse or principal investigator to 304 pregnant women and their partners. All participants had positive

T-ACE (Tolerance, Annoyed, Cut down, Eye-opener) screen results, were considered at-risk for prenatal alcohol consumption, and completed initial diagnostic and postpartum interviews. Factors associated with prenatal alcohol use included higher education level, previous alcohol consumption, and social consumption temptation. Study results revealed that prenatal alcohol use declined in both the treatment and control groups. The brief intervention was most substantial for women with the highest alcohol consumption and women with partner participation. Limitations included the possibility of assembly bias and interviewers not blinded to treatment assignment. Authors recommend consistent screening for prenatal alcohol use with a validated instrument embedded inpatient intake form, diagnostic interview to reduce alcohol consumption and including partner in the brief intervention.

A randomized controlled trial by Martino et al. (2018) attempted to determine the efficacy of “screening, brief intervention and referral to treatment” (SBIRT) delivered either electronically or by a clinician. A sample size of four hundred thirty-nine women at two reproductive centers, who smoked cigarettes or misused alcohol, illicit drugs, or prescription medication were randomly assigned to either the SBIRT group or enhanced usual care group. Assessments were completed at baseline, 1, 3, and 6-months. Primary outcomes included days per month of primary substance use and post-intervention treatment utilization. One hundred forty-three women (16.8% pregnant) were allotted to the electronic-delivered SBIRT group, one hundred forty-five women (18.6% pregnant) in clinician-delivered SBIRT group, and one hundred fifty-one women (19.2% pregnant) in the enhanced usual care group. The retention rate was >84% at all follow-up assessments for all groups. Study results revealed electronic-SBIRT and clinician-SBIRT were more effective at reducing days of primary substance use over the follow-up period compared to enhanced usual care group. Results were similar for both pregnant

and non-pregnant women. Some of the strengths of the study included a large sample size with the use of a variety of substances, the inclusion of pregnant and non-pregnant women, and high follow-up rates. Limitations included limited generalizability (mostly non-Hispanic African American women), appropriately trained personnel, and decreased recruitment goals.

Wright et al. (2016) provided an overview of formal conclusions on using SBIRT for illicit drug use in the perinatal period. SBIRT, a public health initiative that delivers early interventions and treatment services for people with substance use disorders, has been widely recommended for use in emergency care, primary care, and obstetric settings for alcohol and tobacco use. The authors identified the goals of SBIRT: screening is to assess substance use and its severity, brief intervention is to increase intrinsic motivation in the patient to affect behavioral change, and referral to treatment is to provide those identified as needing more treatment access to specialty care. Screening is accomplished by using either patient or technology-administered instrument or direct provider questions and should be completed at the first prenatal visit and repeated at least every trimester (for patients who screen positive). The brief intervention consists of 1-5 patient-centered counseling sessions lasting <15 minutes using principals of motivational interviewing. Referral to treatment consists of referring the patient to specialized providers, such as perinatologists, psychiatrists, pain specialists, and involving community resources or programs.

Significant barriers exist for implementation of SBIRT during pregnancy including lack of screening by providers or use of invalidated screening tools, patient's failure to disclose substance use, and limited SBIRT research and practice focusing on the use of illicit substances (Wright et al., 2016). The authors discussed the limitations of SBIRT including a need to identify an optimal screening tool/instrument and a menu of models and implementation strategies for

addressing substance use in the perinatal period. Even with these barriers and limitations, SBIRT protocols have been shown to improve pregnancy outcomes, such as reducing the incidence of low birth weight infants, pre-term labor, and neonatal intensive care (NICU) admissions (Wright et al., 2016).

O'Connor and Whaley (2007) conducted a randomized trial in order to evaluate the efficacy of brief intervention as a technique to help pregnant women achieve abstinence from alcohol and to assess newborn outcomes (gestational age, birth weight, birth length, viability) as a function of brief intervention. Three hundred forty-five pregnant women who were participants in Southern California's WIC agency and reported drinking alcohol were randomly assigned to the brief intervention group (n=162) or the assessment-only (control) group (n=183) and monitored through their third trimester. A total of two hundred fifty-five women (74%) of the three hundred forty-five women continued to return to be monitored through the third trimester. The brief intervention involved using 10-15 minute counseling sessions by a nutritionist.

Study results revealed the pregnant women in the brief intervention group were five times more likely to report abstinence from alcohol after the intervention when compared with women in the assessment-only group (O'Connor & Whaley, 2007). Furthermore, newborns of the women in the brief intervention group had higher birth weights and birth lengths and decreased fetal mortality rates when compared to the newborns of the assessment-only group (O'Connor & Whaley, 2007). The authors concluded brief interventions were effective at reducing women's alcohol consumption during pregnancy and improving newborn outcomes. Limitations included a lack of fully randomized controlled experiment design, attrition rate, and lack of generalizability due to a significant portion of the sample being comprised of low-income Hispanic women.

Montag et al. (2015) conducted a randomized controlled trial that sought to determine whether the SBIRT intervention might reduce risky drinking among American Indian/Alaska Native (AIAN) women in Southern California. Two hundred sixty-three women were recruited from one of three AIAN health clinics, completed a survey with questions related to alcohol consumption and contraceptive use, were randomized into the SBIRT intervention group or treatment as usual group (control). Follow-up was completed at 1, 3, and 6-months post-intervention. Two hundred forty-seven (93.9%) women completed follow-up data with sixteen (6.1%) lost to follow-up. Results revealed that both treatment groups decreased self-reported risky drinking behavior in the follow-up period. There was no statistically significant difference observed between the treatment groups and the authors concluded that participation alone could have been sufficient to encourage behavioral changes in these women, without the SBIRT intervention. Study limitations included lack of generalizability, flawed randomization procedure, self-reported data, shortened time frame between data collection, and mixed modal data collection procedure (pencil/paper and telephone).

Farr, Hutchings, Ondersma, and Creanga (2014) performed a systematic review of literature looking at brief interventions for illicit drug use during peripartum women. Authors searched PubMed, Embase, and PsychInfo databases using keywords related to illicit drug use, related interventions, and pregnancy or postpartum. The brief intervention was defined as consisting of 1-5 sessions lasting between 5 minutes to 1 hour each and included only studies related to pregnant women or women <1 year postpartum. In their review, the authors found four randomized controlled trials (RCT) that examined the effectiveness of brief interventions for illicit drug use during pregnancy or in the postpartum period; however, different modalities were used. Three used technology-based interventions without a health care provider; two used a

computerized brief intervention and another used telephone-based communication combined with electronic messaging. The authors had difficulty drawing any generalizations on the effectiveness of brief interventions due to the differences observed in the sample population, treatment modality, and number of sessions, provider, venue, and treatment outcomes.

Peterson Williams et al. (2015) performed a qualitative study that investigated health care workers' attitudes and perceptions about screening, brief intervention, and referral to treatment among pregnant women attending midwife obstetric units in Cape Town, South Africa. Forty-three healthcare providers were interviewed at two different public midwife obstetric units, using an open-ended, semi-structured interview designed to identify factors that support or hinder the implementation of SBIRT in these obstetrical settings. The consolidated framework for implementation research was the theoretical framework utilized by the authors in this study. Overall, providers agreed that there is a need for SBIRT and believe that the protocol could be integrated into routine prenatal care because there currently is a lack of formal protocol assisting them in caring for substance use and related risks. Providers identified barriers to implementation of SBIRT as patient non-disclosure of substance use, staff issues (additional work, poor communication styles or judgmental attitudes, lack of training, lack of interest, time constraints, staff shortages, and overburdened workloads). Limitations included lack of generalizability and participants' awareness of the intervention being implemented and supported by the local health department.

Methodology

The project was initiated following approval from the University of Alabama in Huntsville (UAH) Institutional Review Board (IRB) (FR201935). The project was conducted in its entirety at one private obstetrical/gynecological clinic located in Nashville, Tennessee. The

inclusion criteria for the project were pregnant women, 18 years old and older, who visit the selected private practice regularly, were able to read and speak English, and responded yes to at least one question of 5Ps screening tool (Figure 3, Appendix C). Exclusion criteria were pregnant women less than 18 years old, not able to read and speak English, and anyone who answered no to all questions on the 5Ps screening tool.

Procedures for identifying and recruiting subjects included completion of the 5Ps screening tool at the initial visit. All pregnant patients who visited the clinic were screened from April 29, 2019—September 10, 2019, and this tool was used as a standard clinical protocol during the implementation of this project. The completed screening tool became part of the patient's medical record. Patients, who agreed to participate in the project, signed the consent form, and the initial session began. The initial session lasted approximately 15-20 minutes (Stage 1). In this project, the intervention was described as the use of the SBIRT protocol. Up to five follow up visits were made (Stage 2) in person during a scheduled prenatal visit or over the phone every two weeks. Each follow-up session lasted approximately 5-10 minutes. Each session was conducted by the nurse practitioner (principal investigator). During each session, the participant was educated about the harmful effects of substance use during pregnancy (Appendix D). Pre-test/Post-test (Appendix E, Appendix F) was used to assess the educational component and patient satisfaction with the protocol implementation. Pre-test and Post-test were given to assess the patient's knowledge of the dangers of using substances during pregnancy. Pre-test/Post-test questionnaires were asked verbally in person or over the phone and recorded on pen/paper.

Objectives:

The objectives of this project are:

1. How does the use of the SBIRT protocol affect the patients' knowledge about substance use during pregnancy?
2. How satisfied are the patients with using the SBIRT protocol in each perinatal visit?

Instrumentation

The following instruments were used to implement this project:

SBIRT—the protocol being implemented into prenatal care

5Ps—this screener will be used to screen patients for potential substance use. 5Ps tool is an instrument that has been developed to screen for alcohol, tobacco, and illicit drug use. 5Ps stand for parents, partners, past, pregnancy, and peers. The 5Ps tool was originally adapted by the Massachusetts Institute for Health and Recovery from Dr. Hope Ewing's 4Ps in 2007 and adapted again by the Southern Oregon Perinatal Task Force in 2013. The 5Ps tool is available online through the SBIRT Oregon website and permission to use the tool was granted by Dr. John Muench.

Educational assessment—10-question survey to see if the protocol implementation has increased patient's knowledge regarding substance use during pregnancy

Patient Satisfaction—6-question survey included on the Post-test to assess patients' satisfaction with the project

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Section II

I. Professional Journal Selection

A. Scope of Journal. *Women's Healthcare: A Clinical Journal for NPs* is a comprehensive peer-reviewed journal about relevant topics specific to women's health. The journal provides vital clinical data, information, news and insight from experts that will enhance patient care and provide NPs with a wide variety of information ranging from clinical to policy and best practices.

B. Aims of Journal. *Women's Healthcare: A Clinical Journal for NPs* aims to inform nurse practitioners and other providers in the women's health community about relevant topics specific to women's health care. Each issue includes clinical, practical articles, as well as active links to additional valuable resources

Title: Improving Prenatal Care: Implementing SBIRT Protocol for Women Using
Opioids during Pregnancy

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Abstract

One of the most critical health care issues in the United States (US) is the opioid epidemic. The opioid epidemic has caused an increase in the number of pregnant women using opioids during pregnancy. The objective of this project was to determine if implementing the screening, brief intervention, and referral to treatment (SBIRT) protocol into prenatal care increases patient knowledge about prenatal substance use and to determine patient satisfaction with the program.

A mixed-method project was conducted. Data were collected from a single private obstetrical and gynecological practice. Participants were selected through the convenience sampling method. The participants completed the 5Ps screening tool, which stands for “parents, peers, partner, past, and present,” and screens for substance use. Any patient that answered “yes” to at least one question was eligible. In this project, the intervention was described as the use of the SBIRT protocol. An initial session and up to five follow up visits were conducted either in person during a scheduled prenatal visit or over the phone every two weeks. In each session, the participants were educated about the harmful effects of substance use during pregnancy. Pre-test/Post-test was used to assess the effectiveness of the educational component and patient satisfaction with the protocol implementation.

Thirty pregnant women who had a positive 5Ps screen consented to participate. Twenty-three pregnant women completed the project. The majority of participants (43.3%) were 18-24 years old, identified as White/Caucasian descent (63.3%), married (60%), and employed (56.7%). A majority of the women had Medicaid insurance (70%), began the project in the first trimester (46.7%), and were multigravida (63.3%). Participants acknowledged that the project strengthened the therapeutic relationship with their provider. One hundred percent of participants

were satisfied with the educational program, thought that the intervention was helpful, and believed that it should be used to help women quit substance use during pregnancy.

After data collection, seventeen women (56.7%) were still pregnant and had not experienced any adverse maternal or fetal outcomes. Eight women (26.7%) had not experienced any adverse maternal health outcomes and delivered healthy infants. Two women (6.7%) experienced adverse maternal and fetal outcomes. Three women (10%) experienced first trimester losses (two miscarriages and one ectopic). In conclusion, implementation of the SBIRT protocol into prenatal care is feasible, acceptable by the participants, and effective in increasing patient knowledge about the dangers of prenatal substance use.

Key Words

Pregnancy, substance abuse, opioids, SBIRT, and protocols

Introduction

One of the most important issues facing women's healthcare today is the opioid epidemic. Opioid abuse accounts for a significant portion of healthcare costs. The National Institute on Drug Abuse (NIDA) estimates the abuse of prescription opioids accounts for \$26 billion in healthcare costs and \$78.5 billion in overall economic costs (includes crime, lost productivity, and healthcare combined).¹ The increased prevalence of opioid use among reproductive-aged women has led to an increase in the number of women who have used prescription drugs during pregnancy.² Because of the rise in prenatal substance abuse, complications from their use have also increased.³ Pregnant women using opioids during pregnancy can cause serious complications during pregnancy including premature rupture of membranes, preeclampsia, preterm labor and delivery, and placental abruption.⁴ Perinatal substance abuse also causes significant health problems for the fetus, including decreased or small head circumference, congenital disabilities, low birth weight, neonatal abstinence syndrome (NAS), premature birth, developmental and behavioral issues, and sudden infant death syndrome (SIDS).⁴

Most healthcare providers are aware of the significant impact of the opioid crisis. Even with this awareness, some providers still do not screen their patients for substance use or substance use disorders citing lack of time, lack of resources or referrals, and lack of a universal screening tool as the most common reasons for not screening their patients. The American College of Obstetricians and Gynecologists (ACOG) recommends universal screening of all pregnant women. Screening should be included as part of comprehensive obstetric care and should be done at the first prenatal visit in cooperation with the patient.⁵ Brief intervention (such as engaging a patient in a short conversation, providing feedback and advice), and referral for

treatment of pregnant women with opioid use and opioid use disorder improve maternal and infant outcomes.⁵ The purpose of this project was to implement the Screening, Brief Intervention, and Referral to Treatment (SBIRT) protocol into routine prenatal care to improve patient knowledge and determine patient satisfaction with the program.

Methodology

The project was initiated following approval from the University of Alabama in Huntsville (UAH) Institutional Review Board (IRB) (FR201935). The project was conducted in its entirety at one private obstetrical/gynecological clinic located in Nashville, Tennessee. The inclusion criteria for the project were pregnant women, 18 years old and older, who visit the selected private practice regularly, were able to read and speak English, and responded yes to at least one question of 5Ps screening tool (Figure 3, Appendix C). Exclusion criteria were pregnant women less than 18 years old, not able to read and speak English, and anyone who answered no to all questions on the 5Ps screening tool.

Procedures for identifying and recruiting subjects included completion of the 5Ps screening tool at the initial visit. All pregnant patients who visited the clinic were screened from April 29, 2019—September 10, 2019, and this tool was used as a standard clinical protocol during the implementation of this project. The completed screening tool became part of the patient's medical record. Patients, who agreed to participate in the project, signed the consent form, and the initial session began. The initial session lasted approximately 15-20 minutes (Stage 1). In this project, the intervention was described as the use of the SBIRT protocol. Up to five follow up visits were made (Stage 2) in person during a scheduled prenatal visit or over the phone every two weeks. Each follow-up session lasted approximately 5-10 minutes. Each session was conducted by the nurse practitioner (principal investigator). During each session, the

participant was educated about the harmful effects of substance use during pregnancy (Appendix D). Pre-test/Post-test (Appendix E, Appendix F) was used to assess the educational component and patient satisfaction with the protocol implementation. Pre-test and Post-test were given to assess the patient's knowledge of the dangers of using substances during pregnancy. Pre-test/Post-test questionnaires were asked verbally in person or over the phone and recorded on pen/paper.

Objectives

1. How does the use of the SBIRT protocol affect the patients' knowledge about substance use during pregnancy?
2. How satisfied are the patients with using the SBIRT protocol in each perinatal visit?

Data Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SSPS) version 26.0. Fifty women were screened for substance use during pregnancy from April 29, 2019, to September 10, 2019. Twelve women had negative screens and were excluded from the project. Eight women had positive screens and declined the invitation to participate. Thirty women had positive screens and accepted the invitation to participate. Table 1 depicts the 5Ps tool that was used to screen patients for substance abuse. A majority of the patients (74%) stated at least one parent had a problem with alcohol and/or drug use; 37% indicated that their friends had a problem with alcohol and/or drug use; 45% admitted that their partners had a problem with alcohol and/or drug use; only 13% disclosed personal difficulties in the past due to alcohol and/or drug use; 45% divulged to drinking alcohol and/or using drugs within the past month; and 47% acknowledged smoking cigarettes or other tobacco products in the past 3 months. In addition to screening for substance use, 42% had experienced adverse effects on their emotional

health within the past few weeks and 29% had experienced some form of intimate partner violence in the past or in their current relationship.

Results

Demographics

Demographic data were analyzed to describe sample characteristics such as age, race, marital status, employment status, type of insurance, gestational age during the initial interview, and gravidity. Data were analyzed using descriptive statistics of the designated variables. Table 2 depicts the demographic data of the sample. Frequency data reveals that the majority of the participants (43.3%), were between 18-24 years old. A majority of the sample identified as White/Caucasian descent (63.3%), married (60%), and employed (56.7%). A majority of the women had Medicaid insurance (70%). Almost half of the sample (46.7%) began the project in the first trimester (<14 weeks gestation), and a majority of the women (63.3%) were multigravida.

How does the use of SBIRT affect the patients' knowledge about substance use during pregnancy?

Table 3 depicts the alcohol and substance use during pregnancy questionnaire that was used to assess the patient's knowledge of the dangers of using substances during pregnancy. The mean pretest ($N=30$) score was 9.47, with a minimum score of 6 and a maximum score of 10. The mean posttest ($N=23$) score was 9.65, with a minimum score of 8 and a maximum score of 10. The educational portion of the project was analyzed using the Wilcoxon Signed-Rank Test (Fig. 4). Six patients displayed a positive difference, three patients displayed a negative difference, and fourteen patients displayed no difference (this does not include the seven

participants who did not complete the posttest). Data indicates that the post-test scores were not statistically significantly higher than the pre-test scores ($Z=31.5$, $p<.248$).

For the six patients with positive differentials on the educational assessment: all patients were between ages of 24-30, were multigravida, denied histories of trauma/violence and were established patients in practice prior to this pregnancy. In comparison, the three patients with negative differentials on the educational assessment: two of the patients were under 24 years old and were primigravidas, and one patient was in the 30-34 year age group and a multigravida. All three patients were new to the practice and admitted to using multiple substances. Two of the patients had histories of co-existing psychiatric disorders and had experienced trauma/violence in their past. This seems to indicate that patients who are new to the practice, younger than 24 years old and older than 30 years old, and primigravidas may have a broader knowledge deficit and need some extra time and attention during the educational sessions.

When comparing the responses on the pre-test and post-test scores, half of the questions (50%) had a positive differential, four of the questions had no change, and one question had a negative differential. It is worth noting on the four questions without any improvement that one hundred percent of the participants answered the question correctly on the pre-test and post-test. Question number six related to over-the-counter medications and was missed by the highest percentage of participants. This indicates the need for prenatal providers to educate patients on the dangers of over-the-counter medications, in addition to the illicit substances.

How satisfied are the patients with using SBIRT in each perinatal visit?

Patient Satisfaction.

The therapeutic relationship or therapeutic alliance refers to the relationship between the healthcare provider and the patient. Building a strong therapeutic relationship between provider

and patient is essential for patient satisfaction and pregnant patients with substance abuse. In this project, the therapeutic relationship was analyzed using two qualitative measures: direct observation and patient interviews. During the sessions that occurred in the office, patients were observed making good eye contact with the provider, having upright body posture, verbally engaging and showing an interest in the material being presented, and responding with appropriate questions. Multiple patients indicated that they felt “a sense of trust” with their prenatal providers, describing the relationship as a “safe space” and felt they could be open and honest about their substance use without fear of being judged or reprimanded. Throughout data collection, patients frequently called the office (outside of the scheduled brief interventions) to discuss their progress and reveal their excitement in being able to discontinue substance use. Some patients stated that they liked the increased attention that the project afforded them and felt it made them more accountable. Patients also specified they would likely refer their friends and family members, who became pregnant and had problems with substance use, to our practice because of the care that they received.

Twenty-three women completed the project. Seven women were lost to follow-up: three dropped out of the project, one was unable to be contacted for final session/post-test, two women experienced miscarriages, and one woman experienced an ectopic pregnancy after the first session. Table 4 below displays the post-test questionnaire that was given to assess patient satisfaction. One hundred percent of patients were satisfied with the educational program, thought that the intervention was helpful, and it should be used to help women quit substance use during pregnancy. The patients specifically mentioned that they “liked the information that was presented,” “learning about the effects of substance use in pregnant women and their babies,” materials/handouts used, one-on-one teaching, and the brevity of the sessions. A few of the

patients mentioned disliking that they had to “read the handouts” and one patient stated that she thought videos would be another helpful way to present the information because “videos would get more attention from the pregnant user”

Retention Rates. Retention rates were analyzed by reviewing the appointment schedule from April 29, 2019—September 10, 2019. One hundred forty-four appointments routine prenatal appointments were scheduled during this time for the thirty participants who began the project. No additional appointments were scheduled solely for this project. One hundred thirty-four (93%) of the appointments were attended and only ten (7%) appointments were missed. Even though seven (23%) patients were lost to follow-up in the project, no patients transferred out of practice.

Maternal and Fetal Outcomes

As discussed earlier, prenatal substance use can cause significant adverse maternal and fetal outcomes. Maternal complications assessed during the project included premature rupture of membranes, placental abruption, pre-eclampsia, hypertensive crisis, premature labor and delivery, and miscarriage. Fetal or neonatal outcomes assessed during the project included neonatal abstinence syndrome, fetal alcohol syndrome, congenital birth defects, low birth weight, and intrauterine growth restriction. After data collection, seventeen women (56.7%) were still pregnant and had not experienced any of these adverse maternal or fetal outcomes. Intrauterine fetal well-being was monitored by routine sonograms. Eight women (26.7%) had not experienced any adverse maternal outcomes and had delivered healthy infants. Two women (6.7%) experienced adverse maternal outcomes and fetal outcomes: (1) severe pre-eclampsia, preterm labor and delivery, intrauterine growth restriction (IUGR) and preterm birth, and (2)

preterm delivery, preterm birth, IUGR, and neonatal abstinence syndrome (NAS)). Three women (10%) experienced first trimester losses (two miscarriages and one ectopic).

Discussion

There are numerous screening tools available for providers to use to screen patients for substance use and substance use disorders. In contrast, there are very few protocols available to help providers identify patients with risky substance use behaviors or substance use disorders. As the opioid epidemic continues to worsen, it is imperative that all women's healthcare providers have a protocol in place that screens for substance use and substance use disorders.

Implementing a protocol that is straightforward, patient-centered, acceptable to the patients, and can be effective at increasing patient knowledge about the dangers of prenatal substance use are of utmost importance. The SBIRT protocol is an evidenced-based approach for identifying patients with risky alcohol or substance use behaviors that has been historically used in non-pregnant patients. SBIRT has also traditionally been effective in patients with risky alcohol behaviors and tobacco use; however, there is an increasing amount of literature showing the effectiveness of SBIRT for risky drug use.^{6,7} Research has also shown that brief interventions (the second step in SBIRT) are low cost, effective, and are most useful among persons with less severe problems.⁸ SBIRT protocol was preferred over other protocols because it is evidenced-based, time and cost-efficient, and relatively easy to learn. The education component was added into the protocol to address the knowledge gap that exists in patients about the dangers of prenatal substance use.

While the SBIRT protocol has been traditionally used in healthcare settings that do not have pregnant patients, implementing SBIRT protocol into prenatal practice is applicable, feasible, and acceptable based on the project findings. Even though the data

results of the educational part of the project were not statistically significant, it does not mean the education was not beneficial. Participants indicated satisfaction with the educational portion, a desire to learn about the effects of prenatal substance use, and thought it would be beneficial to include as part of prenatal care for other pregnant women. Due to these reasons, healthcare providers should not be dissuaded from providing education to their patients as part of the protocol. The author recommends for all prenatal providers to implement SBIRT protocol into routine practice in order to establish a therapeutic relationship with new patients or strengthen an existing therapeutic relationship, increase patient knowledge about the consequences of prenatal substance use, and increase patient satisfaction and retention.

Limitations of this project include a small sample size, a short implementation period, a single provider, and time constraints. In the future, the author would want to extend the project duration to screen more patients, monitor the patients through the entire pregnancy, and continue to follow the neonates for any developmental and behavioral issues through the first year of life. It is important to note that only one provider implemented this project. For SBIRT implementation to be successful, it would be necessary for multiple staff members to participate and contribute. Using multiple providers also decreases the time constraints on each provider.

Multiple studies have mentioned several barriers to SBIRT implementation or poor implementation. These include time constraints, the need to focus upon more medically urgent issues, poor or insufficient training, and negative provider and staff attitudes and perceptions.^{9, 10} Healthcare providers that want to implement SBIRT into prenatal care must be aware of these barriers in order to avoid them. Practices that were able to implement SBIRT successfully and have sustained the protocol identified several key factors related to program sustainability.

Factors mentioned included securing funding, having champions, adapting and making system changes and managing program staffing challenges.¹¹ To help make the implementation phase easier, the Substance Abuse and Mental Health Services Administration provides a website with guidelines, training guides, tools, and resources for healthcare providers to be able to successfully implement SBIRT.

This project provides evidence of the importance of implementing a protocol to screen women for prenatal substance use. As the number of reproductive-aged women using substances during pregnancy increases, it is imperative for women's health providers to implement a care protocol into prenatal practice that provides screening, brief interventions, and referral to treatment. An important aspect of the SBIRT protocol is that it allows for brief sessions of patient education. The time spent with pregnant patients or patients planning to get pregnant in educating them about the dangers of prenatal substance use can encourage them to reduce their substance use or ideally stop their substance use completely. Women with reproductive potential, who have been identified as having risky substance use behaviors or a known substance use disorder, should be counseled and strongly encouraged to use long-term reversible contraception (LARC). If pregnancy is desired, the patient should be counseled and educated about the dangers of prenatal substance use and encouraged to discontinue substance use or receive treatment prior to conception in order to maximize the potential for healthy maternal and fetal outcomes.

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TABLES

Table 1. Behavioral Health Risks Screening Tool (N=38)		
	<i>n</i>	%
Did any of your parents have a problem with alcohol and/or other drug use?	28	74
Do any of your friends have a problem with alcohol and/or other drug use?	14	37
Does your partner have a problem with alcohol and/or other drug use?	17	45
In the past, have you had difficulties in your life due to alcohol and/or other drugs, including prescription medications?	5	13
In the past month, have you drunk any alcohol or used other drugs?	17	45
Have you smoked any cigarettes or used any tobacco products in the past 3 months?	18	47
Over the last few weeks, has worry/anxiety/depression/sadness made it difficult for you to do your work, get along with others, or take care of things at home?	16	42
Are you currently or have you ever been in a relationship where you were physically hurt, choked, threatened, controlled or made to feel afraid?	11	29

Table 2. Demographics (N=30)			
		<i>n</i>	%
Age	18-24 yrs	13	43.3
	25-29 yrs	8	26.7
	30-34 yrs	5	16.7
	35+ yrs	4	13.3
Race	White or Caucasian	19	63.3
	Black or African American	9	30
	Hispanic or Latino	2	6.7
Marital Status	Single (never married)	18	60
	Single (divorced)	1	3.3
	Married	10	33.3
	Widowed	1	3.3
Insurance	Commercial	6	20
	Medicaid	21	70
	Commercial and Medicaid	3	10
Employment Status	Employed	17	56.7
	Unemployed	13	43.3
Gestational Age	1st Trimester (<14 weeks)	14	46.7
	2 nd Trimester (14-28 weeks)	9	30
	3 rd Trimester (> 28 weeks)	7	23.3
Gravidity	Primigravida	11	36.7
	Multigravida	19	63.3

Question	Pre-test (N=30)		Post-test (N=23)		% Diff
	True	False	True	False	
1. Pregnant women who smoke are less likely to have miscarriages and deliver low birth weight infants.	4	26	2	21	+3.5
2. Studies have shown that infants of women who smoke have an increased risk of sudden infant death syndrome (SIDS) and of developing asthma.	2	28	1	22	+2.1
3. Smoking after your baby is born won't harm the child.	2	28	0	23	+2.1
4. It's safe to drink alcohol during pregnancy as long as you don't drink a lot or every day.	2	28	0	23	+2.1
5. A woman who drinks alcohol while pregnant puts her baby at risk for physical or behavioral problems.	29	1	1	22	-1.2
6. Aspirin and ibuprofen are not safe to take while pregnant.	23	7	20	3	+10
7. Babies born to women who used narcotics while they were pregnant can have withdrawal symptoms.	30	0	23	0	0
8. Women who inject drugs intravenously while pregnant risk becoming infected with hepatitis B or HIV, which can be passed on to their babies.	30	0	23	0	0
9. Babies born to women who used heroin during pregnancy can have mental and behavioral problems, low-birth weight, and an addiction to the drug.	30	0	23	0	0
10. It's safe for a pregnant woman to take tranquilizers, sleeping pills, or amphetamines.	30	0	0	23	0

Table 4. Patient Satisfaction Survey (N=23)

Question	Responses	#	%
Did you find this educational program helpful?	Yes	23	100
Do you feel satisfied with the program?	Yes	23	100
Is there anything that could have been done differently to make this program more satisfying?	No	22	96
	Use of videos in addition to handouts	1	4
Do you think this intervention should be used to help pregnant women with quitting substance abuse during pregnancy?	Yes	23	100
Which part of the program did you like the most?	No answer	6	26
	All of it	2	9
	Learning about effects of substance use on mother and baby	11	48
	Brevity of sessions	1	4.25
	Handouts/Materials used, One-on-one teaching	1	4.25
	It helps pregnant women	1	4.25
	Answered my questions	1	4.25
Which part of the program did you like the least?	No answer	11	48
	Nothing	10	43
	Reading	2	9

	<i>n</i>	%
Attended	134	93
Missed/No-Show	10	7

Table 6. Maternal and Fetal Outcomes (N=30)		
	<i>n</i>	%
Pregnant, no adverse complications	17	56.7
Delivered without adverse complications	8	26.7
Delivered with maternal and fetal adverse complications	2	6.7
First trimester loss	3	10

FIGURES



Fig 1. Swanson's *Theory of Caring*

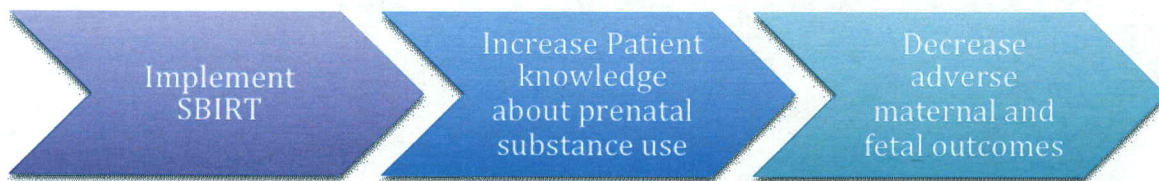


Fig 2. Conceptual Framework

BEHAVIORAL HEALTH RISKS SCREENING TOOL

For Pregnant Women

Patient/Client Name _____ DOB _____
 Is patient pregnant? YES NO Gestational Age _____ Date _____
 Provider Site _____ Screener Name _____

Women and their children's health can be affected by emotional problems, alcohol, tobacco, other drug use and violence. Women and their children's health are also affected when these same problems are present in people who are close to them. Alcohol includes beer, wine, wine coolers, liquor and spirits. Tobacco products include cigarettes, cigars, snuff and chewing tobacco.

1. Did any of your parents have a problem with alcohol or other drug use?	PARENTS	<input type="checkbox"/> YES <input type="checkbox"/> NO
2. Do any of your friends have a problem with alcohol or other drug use?	PEERS	<input type="checkbox"/> YES <input type="checkbox"/> NO
3. Does your partner have a problem with alcohol or other drug use?	PARTNER	<input type="checkbox"/> YES <input type="checkbox"/> NO
4. In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?	PAST	<input type="checkbox"/> YES <input type="checkbox"/> NO
5. Check YES if she agrees with any of these statements. - In the past month, have you drunk any alcohol or used other drugs? - How many days per month do you drink? _____ - How many drinks on any given day? _____ - How often did you have 4 or more drinks per day in the last month? _____	PRESENT	<input type="checkbox"/> YES <input type="checkbox"/> NO
6. Have you smoked any cigarettes or used any tobacco products in the past three months?	TOBACCO	<input type="checkbox"/> YES <input type="checkbox"/> NO
7. Over the last few weeks, has worry, anxiety, depression, or sadness made it difficult for you to do your work, get along with other people, or take care of things at home?	EMOTIONAL HEALTH	<input type="checkbox"/> YES <input type="checkbox"/> NO
8. Are you currently or have you ever been in a relationship where you were physically hurt, choked, threatened, controlled or made to feel afraid?	VIOLENCE	<input type="checkbox"/> YES <input type="checkbox"/> NO

PROVIDER USE ONLY

Brief Intervention/Brief Treatment	Y	N	NA
Did you State your medical concern?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Advise to abstain or reduce use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Check patient's reaction?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Refer for further assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Provide written information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Moderate drinking for non-pregnant women is one drink per day. Women who are pregnant or planning to become pregnant should not use alcohol, tobacco, illicit drugs or prescription medication other than as prescribed.

Developed by the Institute for Health and Recovery (IHR), Massachusetts, February, 2007. Adapted by the Southern Oregon Perinatal Task Force in partnership with AllCare Health Plan, Oregon, May 2013.

Fig. 3 5 Ps Screening Tool

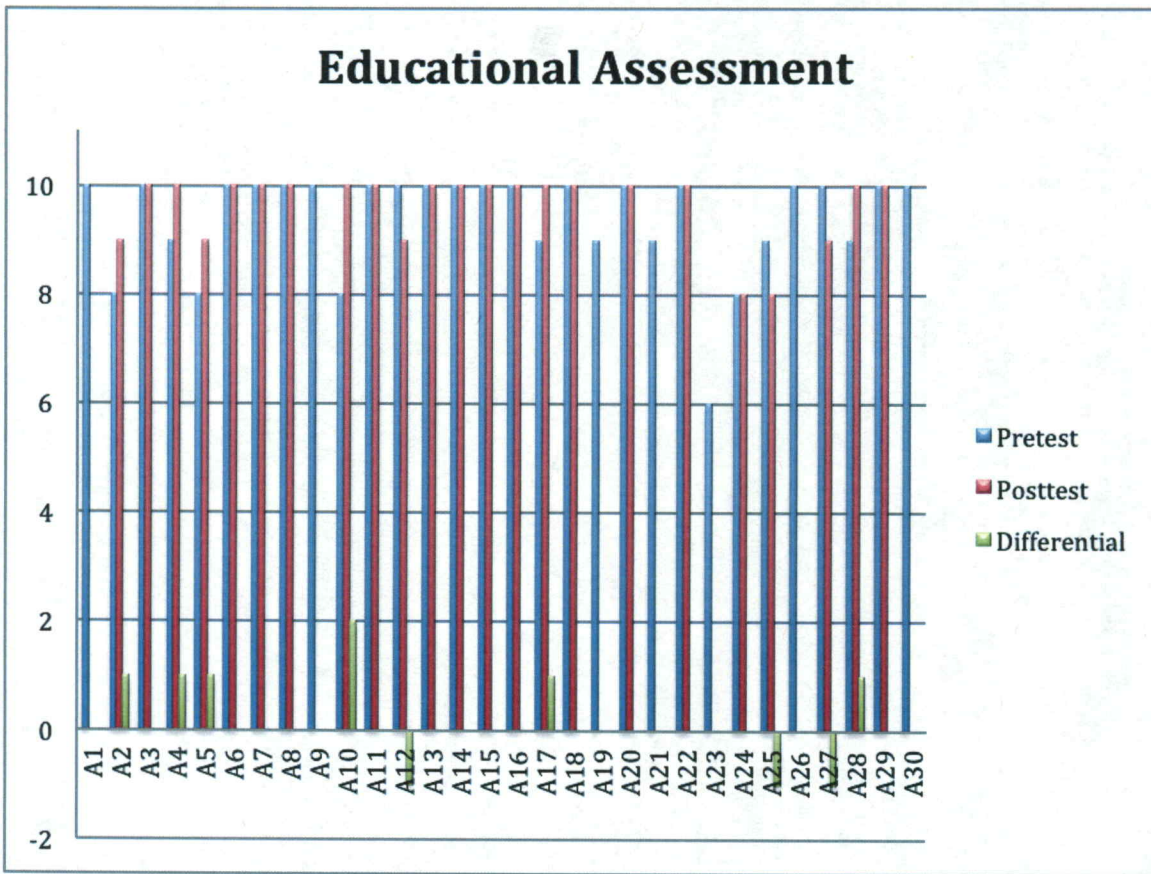


Fig 4. Evaluation of Patient Knowledge on Effects of Prenatal Substance Use

Similarities among the 6 patients with positive differentials: All patients were between ages of 24-30, were multigravida, denied histories of trauma/violence, and were established patients prior to this pregnancy. In contrast, the 3 patients with negative differentials also had a few similarities. 2 of the patients were under 24 years old and were primigravidas. 1 patient was in the 30-34 year age group and a multigravida. All three patients were new to the practice and admitted to using multiple substances. Two of the patients had histories of co-existing psychiatric disorders and had experienced trauma/violence. This seems to indicate that patients who are new to the practice, younger than 24 years old, and primigravidas may have a larger knowledge deficit regarding effects of prenatal substance use.

APPENDICES

Appendix A



April 25th 2019

Erin DeBruyn
Department of Nursing
University of Alabama in Huntsville

<input checked="" type="checkbox"/> Expedited (see pg 2)
<input type="checkbox"/> Exempted (see pg 3)
<input type="checkbox"/> Full Review
<input type="checkbox"/> Extension of Approval

Dear Mrs. DeBruyn,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Improving Prenatal Care: Implementing SBIRT Protocol to Screen Women for Substance Use During Pregnancy*, and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

A handwritten signature in black ink that reads 'Bruce Stallsmith'.

Bruce Stallsmith
IRB Chair
Professor, Biological Sciences

Appendix B

Jacqueline L. Rodier, M.D.

Obstetrics - Gynecology - Infertility

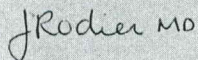
April 15, 2019

To Whom This May Concern,

Erin DeBruyn has my permission to complete her doctoral project at my practice.

If you have any questions or concerns, please contact me at (615) 301-9000.

Sincerely,



Jacqueline Rodier, M.D.

2201 Medical Plaza, Suite 302
2201 Murphy Avenue
Nashville, Tennessee 37203
Phone: 615-301-9000
Fax: 615-301-9006

1

Appendix C

BEHAVIORAL HEALTH RISKS SCREENING TOOL

For Pregnant Women

Patient/Client Name _____ DOB _____
 Is patient pregnant? YES NO Gestational Age _____ Date _____
 Provider Site _____ Screener Name _____

Women and their children's health can be affected by emotional problems, alcohol, tobacco, other drug use and violence. Women and their children's health are also affected when these same problems are present in people who are close to them. Alcohol includes beer, wine, wine coolers, liquor and spirits. Tobacco products include cigarettes, cigars, snuff and chewing tobacco.

1. Did any of your parents have a problem with alcohol or other drug use?	PARENTS	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
2. Do any of your friends have a problem with alcohol or other drug use?	PEERS	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
3. Does your partner have a problem with alcohol or other drug use?	PARTNER	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
4. In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?	PAST	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
5. Check YES if she agrees with any of these statements. - In the past month, have you drunk any alcohol or used other drugs? - How many days per month do you drink? _____ - How many drinks on any given day? _____ - How often did you have 4 or more drinks per day in the last month? _____	PRESENT	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
6. Have you smoked any cigarettes or used any tobacco products in the past three months?	TOBACCO	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
7. Over the last few weeks, has worry, anxiety, depression, or sadness made it difficult for you to do your work, get along with other people, or take care of things at home?	EMOTIONAL HEALTH	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
8. Are you currently or have you ever been in a relationship where you were physically hurt, choked, threatened, controlled or made to feel afraid?	VIOLENCE	<input type="checkbox"/> YES	<input type="checkbox"/> NO	

PROVIDER USE ONLY

Brief Intervention/Brief Treatment	Y	N	NA
Did you State your medical concern?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Advise to abstain or reduce use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Check patient's reaction?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Refer for further assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Did you Provide written information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Moderate drinking for non-pregnant women is one drink per day. Women who are pregnant or planning to become pregnant should not use alcohol, tobacco, illicit drugs or prescription medication other than as prescribed.

Developed by the Institute for Health and Recovery (IHR), Massachusetts, February, 2007. Adapted by the Southern Oregon Perinatal Task Force in partnership with AllCare Health Plan, Oregon, May 2013.

Appendix D

Alcohol and drug use during pregnancy

When a pregnant woman drinks alcohol or uses drugs during her pregnancy, so does her baby. These substances can pass through the placenta and to the baby through the umbilical cord.

When a baby is exposed to substances, a number of things can go wrong. Below is a list of problems more likely to happen to babies exposed to alcohol, tobacco, and drugs:

Premature birth is a birth that takes place more than three weeks before the baby is due. Premature babies, especially those born earliest, often have medical problems.

Birth defects are problems with how a baby's organs and body parts form, how they work, or how their bodies turn food into energy. Some birth defects need no treatment and others cause disabilities or require medical or surgical treatment.

Low birth weight is when a baby is born weighing less than 5 pounds, 8 ounces. Some low birthweight babies are healthy, even though they're small. But being low birthweight can cause serious health problems for some babies.

Placental abruption is a serious condition in which the placenta separates from the wall of the uterus before birth. The placenta supplies the baby with food and oxygen through the umbilical cord. Placental abruption can cause very heavy bleeding and can be deadly for both mother and baby.

Fetal alcohol spectrum disorders are health problems that can happen to babies when their mothers drink alcohol during pregnancy. The most serious of these is fetal alcohol syndrome. Fetal alcohol syndrome can seriously harm your baby's brain and body.

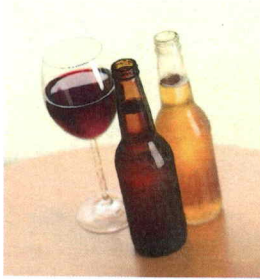
Miscarriage is when a baby dies in the womb before 20 weeks of pregnancy. **Stillbirth** is when a baby dies in the womb after 20 weeks of pregnancy.

Development and behavior problems may not show up for several years after a baby is exposed to substances during pregnancy. These problems make it harder for a child to learn, communicate and get along with others, take care of her/himself, and can include attention deficit hyperactivity disorder (also called ADHD).



Neonatal abstinence syndrome (NAS) is a group of conditions a newborn can have if his/her mother is addicted to drugs during pregnancy. NAS happens when a baby gets addicted to a drug before birth and then goes through drug withdrawal after birth. What type and how serious an infant's withdrawal symptoms depend on the drug(s) used, how long and how often the birth mother used, how her body breaks the drug down, and whether the infant was born full term or premature.

Alcohol



There is no amount of alcohol that is proven to be safe during pregnancy. Alcohol includes wine, wine coolers, beer and liquor. You may know some women who drank regularly during pregnancy and had seemingly healthy babies. You may know some women who had very little alcohol during pregnancy and had babies with serious health conditions. Every pregnancy is different. Drinking alcohol may hurt one baby more than another. The best way to ensure a healthy baby is to stay away from alcohol altogether.

Your liver works hard to break down the alcohol in your blood. But your baby's liver is too small to do the same and alcohol can hurt your baby's development. That's why alcohol is much more harmful to your baby than to you during pregnancy.

Drinking alcohol during pregnancy can cause **birth defects, miscarriage, premature birth, stillbirth, development and behavior problems, low birth weight, and fetal alcohol spectrum disorders.**

Marijuana

No amount of marijuana has been proven safe to use during pregnancy. Using marijuana over a long time may raise the risk of **premature birth**. Some children born to women who used marijuana during their pregnancies are more likely to have certain **development and behavior problems**. More research is needed, however, to know if these effects come from marijuana use or related her factors, like a poor home environment or the mother's use of other drugs.

Some women use marijuana to treat nausea (sick stomach) during their pregnancy. Women thinking about using medical marijuana while pregnant should check with a health care provider first.

Nursing mothers are advised not to use marijuana. THC (the main chemical in marijuana) can gather in breast milk in high amounts if a pregnant mother uses marijuana often. Some studies show that exposure to THC through breast milk could result in less ability to control body movement at 1 year of age. Because a baby's brain is still forming, THC could affect how the brain grows. New mothers using medical marijuana should talk about their use with the doctor caring for their baby.



Cocaine (coke) and Methamphetamine (meth)



Both cocaine and meth are white powders that are eaten, snorted or mixed with liquid and injected with a needle. Sometimes meth comes as a pill or is made into a clear or white shiny rock (called crystal meth) that can be smoked.

Cocaine use during pregnancy makes **premature birth, low birthweight, miscarriage and placental abruption** more likely to happen.

One study found that babies of women who used meth were more than three times as likely to grow poorly before birth. Even when born at term, these affected babies tend to be born with **low birthweight** and have a smaller-than-normal head circumference.

Use of meth during pregnancy also increases the risk of **premature birth** and **placental abruption**. There also have been cases of **birth defects**, including heart defects and cleft lip/palate, in exposed babies, but researchers do not yet know whether the drug contributed to these defects.

After delivery, some babies who were exposed to meth before birth appear to undergo withdrawal-like symptoms, including jitteriness, drowsiness and breathing problems.

Heroin (smack, junk)

Heroin is a street drug made from poppy plant seeds. It can be a white or brown powder, or it can be a black, sticky goo. Heroin usually is injected with a needle, but it can be smoked or snorted.



Using heroin during pregnancy can be dangerous, even deadly. It may cause serious problems, including: **birth defects, placental abruption, premature birth, low birthweight** and **stillbirth**.

If you're pregnant and using heroin, don't stop taking it without getting treatment from your health care provider first. Quitting suddenly (sometimes called cold turkey) can cause severe problems for your baby, including death. Your health care provider or a drug-treatment center can treat you with drugs like methadone or buprenorphine. These drugs can help you gradually reduce your dependence on heroin in a way that's safe for your baby.

MDMA (ecstasy, molly)



MDMA comes as a pill. It's sometimes called the "love drug" because it makes some people feel very friendly and touchy-feely. It also can make people feel depressed or confused and have a hard time remembering things.

What little research exists on the effects of MDMA use in pregnancy suggests that prenatal MDMA exposure may cause learning, memory, and motor problems in the baby. More research is needed on this topic.

This document is available at www.sbirtoregon.org. Information used with permission from the March of Dimes and compiled from the National Institute on Drug Abuse; National Institutes of Health; U.S. Department of Health and Human Services. All images licensed for use.

Appendix E

Pre-Test and Post-Test

What Do You Know About Taking Drugs and Drinking Alcohol During Pregnancy?

Smoking, drinking alcohol, and using illegal drugs can have serious consequences for a pregnant woman and her baby. Knowing what these dangers are, and how to avoid them, can help you have a healthy pregnancy and baby. To assess how much you know about using drugs during pregnancy, just circle true or false.

Please answer the following questions:

1. Pregnant women who smoke are less likely to have miscarriages and deliver low birth weight infants.
A. True B. False
2. Studies have shown that infants of women who smoke have an increased risk of sudden infant death syndrome (SIDS) and of developing asthma.
A. True B. False
3. Smoking after your baby is born won't harm the child.
A. True B. False
4. It's safe to drink alcohol during pregnancy as long as you don't drink a lot or every day.
A. True B. False
5. A woman who drinks alcohol while pregnant puts her baby at risk for physical or behavioral problems.
A. True B. False
6. Aspirin and ibuprofen are not safe to take while pregnant.
A. True B. False
7. Babies born to women who used narcotics while they were pregnant can have withdrawal symptoms.
a. A. True B. False

8. Women who inject drugs intravenously while pregnant risk becoming infected with hepatitis B or HIV, which can be passed on to their babies.

A. True B. False

9. Babies born to women who used heroin during pregnancy can have mental and behavioral problems, low-birth weight, and an addiction to the drug.

A. True B. False

10. It's safe for a pregnant woman to take tranquilizers, sleeping pills, or amphetamines.

A. True B. False

Appendix F

Patient Satisfaction Evaluation

Did you find this educational program helpful?

Do you feel satisfied with the program?

Is there anything that we could have done differently to make this program more satisfying?

Do you think this intervention should be used to help pregnant women with quitting substance abuse during pregnancy?

Which part did you like most?

Which part did you like least?

Use of 5Ps screening tool for my doctoral project



DNP Project x



Erin DeBruyn <ed0027@uah.edu>
to muenchj ▾

Tue, Feb 26, 9:12 PM (2 days ago)



To whom this may concern,

I am a doctoral nursing student at University of Alabama-Huntsville and am doing my doctoral project on integrating the use of 5Ps screening tool into routine prenatal practices. I am reaching out to get permission to use this tool. Thanks!

...



John Muench
to me ▾

Feb 27, 2019, 10:27 AM (1 day ago)



Hi Erin,

Yes, feel free to use the 5P form on the SBIRT Oregon website.
Good luck with your project.

John

John Muench, MD, MPH
Professor of Family Medicine
Oregon Health & Science University

...

Appendix H



Guidelines for Authors

Women's Healthcare: A Clinical Journal for NPs is the official journal of the National Association of Nurse Practitioners in Women's Health (NPWH). This peer-reviewed journal, published quarterly, focuses on clinical topics of interest and importance to NPs and other advanced practice nurses who attend to women's healthcare needs. **Women's Healthcare (WH)** is indexed in CINAHL.

Authors who wish to submit manuscripts to **WH** must adhere to these guidelines; otherwise, manuscripts will be returned and you will be asked to correct and resubmit them. Manuscripts should have a clinical focus, providing NPs with up-to-date information that is useful in everyday practice. In addition, research studies with clinical implications are eligible for consideration. Before submitting manuscripts, you may send a brief email query to managing editor Dory Greene (dgreene@npwomenshealthcare.com) and/or Editor-in-Chief Beth Kelsey (bkelsey@npwomenshealthcare.com) to determine whether the chosen topic is likely to be of interest to **WH** readers.

Publication ethics

Women's Healthcare: A Clinical Journal for NPs adheres to the principles stated on the International Committee of Medical Journal Editors (ICMJE) website [Recommendations page](#). In particular, authors are directed to read the Roles and Responsibilities information on this website page, specifically with regard to Defining the Role of Authors and Contributors and Author Responsibilities—Conflicts of Interest. Authors submitting research manuscripts should also read the section on Protection of Research Participants. This section addresses patients' right to privacy, informed consent, and human and animal rights as research participants.

All authors are asked to address these concerns and others in the [Manuscript Submission Cover Letter](#). In addition, each author must complete the ICMJE [Disclosure of Conflicts of Interest form](#).

Therefore, in order to ensure that ethical principles in publication are addressed, the **author(s)** must submit to **WH**, along with the manuscript itself, the Manuscript Submission Cover Letter. In addition, **each author** must submit her or his own ICMJE Disclosure of Conflicts of Interest form to **WH**.

Manuscripts submitted to **WH** must not have been previously published or be under consideration for publication in another journal. In accordance with the ICMJE, each listed author must have made a substantive intellectual contribution without which the manuscript could not have been written. Authors assume responsibility for all content. Once a manuscript is published in **WH**, it becomes the joint property of HealthCom Media and NPWH.

Text format

The **title page** must contain, in the following order, the paper's full title; each author's first name, middle initial, last name, credentials (eg, DNP, WHNP-BC), position, and affiliation; any source(s) of financial support (if none, please state so); and disclaimers, if any. The title page must also include the name, address, phone numbers, fax number, and email address of the corresponding author.

The next page must contain a single-spaced **abstract** of 3-4 sentences summarizing the purpose/content of the article. If the article is a clinical study, you need not describe the findings or conclusion in the abstract. Please include six **key words** for database searching.

The **manuscript** is to be double-spaced, in 12-point Times New Roman font (MS Word only), using 1-inch margins (maximum, 3,500 words, including references and graphics). Do *not* add headers or footers. In the text of the manuscript, use one character space, not two spaces, between sentences. Keep abbreviations to a minimum and define each abbreviation at first use. Units of measure are abbreviated only when used with numbers. Refer to the *American Medical Association Manual of Style: A Guide for Authors and Editors (10th ed.)* for standard scientific abbreviations. Cite references (no older than 5 years if possible) using a superscript¹ in the text and then list them in the reference section in the order cited in the text. Internet websites, if cited, must be reliable resources; original articles are strongly preferred. References are styled in AMA format. You are responsible for the accuracy of all information, including references.

Short-form article options

As an alternative to submitting feature-length papers or research studies, authors may submit shorter articles for any of the departments listed here. Authors of short-form articles still need to heed the guidelines listed in the Text format section—minus the need for an abstract or key words.

- **"DNP projects: Spotlight on practice"** (600-1,300 words, including references and graphics): *WH* invites students or recent graduates to submit reports on their DNP projects in abstract form for publication consideration. The project should focus on quality improvement in an aspect of women's healthcare relevant to NPs providing this care. The project must include implementation of an evidence-based intervention for change and an evaluative component to determine the impact of the intervention. Preferred projects for consideration will have an innovative approach to addressing a clinical problem or improving health outcomes. The content of the abstract should include the purpose of the project with brief literature support; description of the setting/population for the project, intervention, methods used for evaluation of outcomes, outcomes, limitations, and implications for women's health; and references. In addition, authors must submit documentation of institutional review board status, including if deemed exempt or not human research status. The student's faculty advisor must approve the abstract for submission.
- **"On the case"** (2,000-2,500 words, including references and graphics): The case study addresses complex women's health situations, and is presented in a way that challenges readers, as led by the author, to work through each step from making the diagnosis to the planning of care. The particular challenge may

involve co-morbidities and/or psychosocial, cultural, or ethical dimensions that complicate the situation. Authors should first provide background information about the patient and the health situation, which will help readers understand the complexity of the case. The case study itself should reflect an evidence-based approach to assessment, diagnosis, development of desired outcomes, plan and implementation of care, and evaluation of outcomes. Readers are led through this process as the case unfolds. Authors can pose decision-point questions, and then use these questions to address the rationale for each step in the clinical decision-making process. Use of decision-making algorithms, charts, or tables is encouraged. Last, authors should provide a lessons-learned component with take-home messages that readers can apply to the management of cases similar to the one described.

- **"Assessment and management"** (1,300-2,000 words, including references and graphics): This short piece provides readers with up-to-date, evidence-based information on screening, diagnosis, pharmacologic/nonpharmacologic treatment, patient counseling/education, and/or referral resources for a specific health condition important to women and relevant to NPs providing care for women with this condition.
- **"Commentary"** (1,300-2,000 words, including references and graphics): In this unique *WH* forum, authors can share their perspective on a topic of importance to women's healthcare and relevance to NPs providing this care. The commentary may challenge current practice, reflect on the author's real-world experience in providing services not widely considered part of NP practice, propose thought-provoking ideas concerning practice, and/or provide a viewpoint on the implications of expanding some aspect of clinical practice. Authors need cite only references deemed essential to support their viewpoint.
- **"Clinical resources"** (600-2,000 words, including references and graphics): This department focuses on new or updated practice guidelines, screening and diagnostic tests, and technology for high-quality, evidence-based patient care.
- **Professional development** (600-2,000 words, including references and graphics): This department focuses on processes that foster learning or quality improvement in clinical practice or that promote the business aspect of being an NP.

Student authors

We accept manuscript submissions from master's-prepared APNs enrolled in a doctoral-degree program. Students who have previously authored an article in a peer-reviewed journal may submit a manuscript as a solo author (documentation of this previously published work must be provided at the time of manuscript submission). Otherwise, the student's faculty advisor or another faculty member must serve as second author on the manuscript.

Graphics

Manuscripts may be accompanied by tables, figures, photographs, illustrations, and/or video links. In the body of the manuscript, indicate where the graphic should be placed (e.g., Insert Figure 1 here). Tables are designed on the Word document and placed in numerical order after the reference section. Other graphics are submitted in a *separate electronic file* titled "Figure 1," "illustration of digestive system," and the like. Figure titles and associated captions, legends, and sources are placed in numerical order following the reference section.

If you did not create or if you do not own the graphic image presented for publication, you must obtain written permission to reproduce the image from the creator/owner of the image and give proper credit. In addition, any person whose image is shown in a photograph must sign a consent form giving permission to publish it.

Preferred graphics: TIFF, EPS, or JPG formats are preferred. Do not embed figures, photos, or illustrations in the Word document. Line art must have a minimum resolution of 600 dpi, halftone art (photos) a minimum of 300 dpi, and combination art (line/tone) a minimum of 500 dpi. Color figures should be submitted actual size. Multiple figure files can be compressed into a Stuffit or Zip file.

Alternatives:

Photos and slides:

- *Physical photos, preferably in color, are acceptable.* Glossy black and white photographs are submitted unmounted. You must obtain written permission from photographers and from all persons identifiable in photographs.
- *Digital photos:* Images are prepared so that they may be printed at 4 x 6 with a resolution of 300 dpi. They must be at least 200 KB in size. File sizes >10 MB must be submitted on a CD (they cannot be emailed).

PowerPoint images: All logos and images must be embedded in the PowerPoint file, and photographic images must be saved at 300 dpi at 4 x 6. Low-resolution (<300 dpi) PowerPoint charts cannot be reproduced; they will be redrawn by our art director.

More information:

- *Tables:* Articles may contain up to four tables containing actual tabular material (simple lists should be incorporated into the text). Tables are cited in the text in numerical order, but they are physically placed in numerical order after the reference section. You must obtain permission to reproduce a previously published table, which must also include a credit line stating the original source.
- *Figures, graphs, and illustrations:* These should be professionally prepared in color or produced on a high-quality laser printer. As mentioned previously, they are cited in the text in numerical order but are physically submitted in separate files. Figure titles, captions, legends, and sources are listed in numerical order after the reference section.
- *Video links:* Links to videos from professional organizations, as well as from academic and government sources, are encouraged.

Manuscript submission process

After you submit a manuscript to the managing editor Dory Greene (dgreene@npwomenshealthcare.com), you will receive an email confirmation. The editor-in-chief will determine whether the manuscript is ready for peer review, needs minor or major revision, or is not suitable for *WH*. This determination is then communicated to the

corresponding author by the managing editor. If the manuscript is sent directly for blind peer review, a process that can take 4-6 weeks, the managing editor, upon hearing from the peer reviewers, will advise the corresponding author whether the manuscript has been accepted for publication, accepted pending revision, or rejected. If the manuscript is accepted for publication, authors are asked to sign an agreement giving HealthCom Media and NPWH the rights to the article. Next, the article will undergo standard in-house editing to ensure consistency with *WH* editorial style. The corresponding author may be asked to address outstanding queries and concerns at this time. Before the article is published, the corresponding author will be asked to review and approve the page proofs.