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Smoking Cessation During Pregnancy: An Evidence Based Practice Protocol

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SMOKING CESSATION DURING PREGNANCY:
AN EVIDENCE BASED PRACTICE PROTOCOL

A project submitted in partial fulfillment
of the requirements for the degree of
Master of Science in Nursing

By

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Abstract

Intrauterine exposure to nicotine is one of the largest modifiable risk factors for infant morbidity and mortality. Previous progress toward decreasing the number impacted by intrauterine nicotine exposure has recently plateaued. While guidelines for assisting pregnant women to stop smoking are available, few providers have a formalized protocol in place. This project will evaluate most current research evidence regarding smoking cessation during pregnancy in order to develop a formalized protocol for implementation in an obstetric clinic in Southwest Ohio. Reviewed literature was summarized and level of evidence was established. Recommendations were made and categorized as strong, moderate, and weak. The information was compiled into a formalized protocol with hand outs and disseminated to select obstetric providers in Southwest Ohio.

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Smoking Cessation during Pregnancy: An Evidence Based Practice Protocol

Chapter 1: Introduction

Background

Smoking during pregnancy is one of the largest modifiable risk factors for infant morbidity and mortality (Smoking cessation during pregnancy, 2011; Tong et al, 2013). Rates of smoking during pregnancy have decreased due to public health education and campaigns within the United States (ACOG, 2010). However, rates have plateaued over recent years. In 2010, only 10.7 percent of women smoked during pregnancy (Tong et al, 2013) compared to nearly 42 percent in 1990 across the United States (ACOG, 2010). Many of these women also work hard to quit smoking during pregnancy. The Morbidity and Mortality Weekly Report published by the Center for Disease Control and Prevention (CDC) shows approximately 55 percent of U.S. pregnant smokers quit during pregnancy (Tong et al, 2013), however approximately 40 percent relapse within six months postpartum (Tobacco use and pregnancy, 2014; Tong et al, 2013). Within Ohio, 47.2 percent of pregnant smokers quit smoking during pregnancy in 2010, with 22 percent relapsing back to smoking after delivery (Tong et al, 2013). Both of these statistics show that a large number of women and babies are affected by smoking during pregnancy. Within Ohio, 16.5 – 21.6 percent of pregnant women smoked within the third trimester between 2000 and 2010 (Tong et al, 2013). The lowest percentage, 16.5 percent occurred in 2010. However, just one year prior 21 percent of pregnant women smoked during pregnancy. The second lowest year occurred in 2000 at 17.1 percent (Tong et al, 2013). These statistics show that the rates in smoking cessation during pregnancy have plateaued in recent years. Therefore, the current methods of assisting pregnant patients to stop smoking are not affective.

Significance

Smoking during pregnancy can cause unwanted effects to mother and fetus. During pregnancy, smoking causes decreased placental size and blood flow (Anblogan et al, 2013) which can cause placenta previa, abruptio placenta, and premature rupture of membranes (Castle et al, 1999; Shiozaki et al, 2011; Youngkin & Davis, 2013). Smoking any amount of cigarettes during pregnancy can lead to small for gestational age babies with decreases in birth weight, length, and head circumference (Batech et al, 2013; Gunnerbeck et al, 2011; Pickett et al, 2009; Roza, 2007; Ward, Lewis, & Coleman, 2007). Babies born to smoking mothers have an increased risk of low birth weight and preterm birth not only when compared to births of non-smoking mothers, but they are also at significantly increased risk when compared to babies born to mothers who quit smoking during pregnancy (Batech et al, 2013). Decreased organ size including brain, kidneys, and lungs in babies exposed to nicotine in utero has also been observed (Anblogan et al, 2013). These growing issues can continue after delivery as well. The newborn who was exposed to nicotine in utero continues to grow at decreased rates during through puberty (Fogelman & Manor, 1988). After delivery, newborns who were exposed to tobacco in utero suffered significantly more apnea episodes (Gunnerbeck et al, 2011). Adolescents born to mothers who smoked during pregnancy are more likely to have asthma (Shripak, 2014). As described above, smoking during pregnancy decreases health of baby and can negatively affect growth and development which leads to increased morbidity and mortality for infants exposed to smoke in utero.

Problem

Even with clear research evidence showing the damaging effects of smoking during pregnancy, many women's health providers lack an evidence based practice protocol to address

this issue. Oak Creek Ob/Gyn currently does not have a formal protocol in place. Among their practitioners, all survey respondents reported advising their smoking pregnant patients to quit. Half of the respondents reported following ACOG guidelines and half reported not following any set guidelines (K.R. Ruhlman, personal communication, November, 2014). In Ohio, nearly all providers recognize the damaging effects of smoking and ask their pregnant patients about smoking (Jordan et al, 2006). However, after the initial inquiry, many do not assist their patients in taking steps to quit. The American College of Obstetrics and Gynecology (ACOG, 2010) has outlined a five step program for women's health practitioners to assist their patients with smoking cessation. However, only six percent of Ohio obstetric providers actually use this protocol to its full extent (Jordan et at, 2006). Looking outside of Ohio this trend continues. Dr. Chang and associates (2013) monitored obstetrics offices within the United States for implementation of the smoking cessation program suggested by ACOG at first antepartum visits. Within their study no practitioners ever used all five of the steps recommended by ACOG and only 21 percent used three or more of the steps at the first antepartum visit (Chang et al, 2013). Studies show obstetric providers do not feel adequately prepared to successfully assist their patients to stop smoking early in pregnancy (Kim et al, 2009). This lack in preparation can be due to inadequate education, lack of appropriate resources, or time constraints. Without a quick and easy to use tool with clinic based interventions available at providers' finger tips, rates in smoking cessation are unlikely to change (Kim et al, 2009).

Purpose

Therefore, the purpose of this project is to evaluate research on smoking cessation during pregnancy and develop a quick, easy to use, evidence based practice protocol for implementation at Oak Creek OB/Gyn in southwest Ohio.

Chapter 2: Concept Analysis

In this section, the concept of smoking cessation assistance during pregnancy will be analyzed and operationally defined. The established operational definition for smoking cessation during pregnancy will help guide research on this topic and the development of an evidence based practice protocol.

Use of the Concept

The concept of smoking cessation assistance is a nursing intervention from the Nursing Intervention Classification (Mosby's dictionary of medicine, nursing, & health professions, 2006) and is defined as "helping a patient stop smoking through individual or group process" (Bluecheck, 2013). However, smoking cessation assistance during pregnancy is a combined term and is not formally defined in literature. For this reason, this concept will be broken down into defining attributes.

Defining Attributes

Smoking cessation assistance during pregnancy is made up of three defining attributes including 1) current smoker, 2) attempting to stop smoking, and 3) pregnancy.

Current smoker. Among current literature smoking status can be evaluated two ways including self-report (MMWR, 2011; Salmond et al, 2012; Dzibur, 2013; Patient Protection and Affordable Care Act, 2010) or biomedical testing (Melvin & Tucker, 2000). The CDC's National Health Interview Survey (2009) used a self-report questionnaire to categorize interviewed US citizens as current smokers, former smokers, or never smoked. Those interviewed were asked, "Have you smoked at least 100 cigarettes in your entire life? (NHIS, 2009)" Those who answered, "yes" were asked, "Do you now smoke cigarettes every day, some days, or not at all? (NHIS, 2009)" Those who answered every day were considered current smokers while those

who answered “some days” were considered current smokers attempting to quit. Salmond and associates (2012) also asked interviewees to self-report smoking status by answering the question, “Do you smoke regularly (that is one or more cigarettes a day)? (Salmond et al, 2012, p. 665)” Melvin and Tucker (2000) used the same question proposed by the CDC, however they also suggested verifying these answers via biochemical testing including cotinine levels in urine or saliva or verify by measuring expired carbon monoxide. Cotinine is the main metabolite of nicotine and stays in the body significantly longer than nicotine (Cotinine, 2013). Because of this, cotinine levels are the gold standard for biochemically verifying smoking status (Cotinine, 2013). Melvin and Tucker (2000) further clarify the CDC’s second question by asking whether the interviewee has smoked at least once in the last seven days. Those who have smoked even a puff in the last seven days are considered current smokers. The Patient Protection and Affordable Care Act (2010) defines current smokers as those who have smoked four or more times in a week within the previous six months. For the sake of this project, a current smoker is someone who self-reports smoking 100 cigarettes in their life and has smoked at least once in the last seven days.

Smoking cessation. Cessation of smoking means to temporarily or permanently stop smoking (Merriam-Webster, n.d.). Building off of the above definition of smoking, someone who has stopped smoking must not meet the definition of current smoker. Therefore they must have not smoked even once in the last seven days. Within currently literature there are two main ways to measure smoking cessation including 24 hour self-report (Catley et al, 2012; Etter 2009; Whitwell, 2011) or 7 days reported or verified smoke free (Catley et al, 2012; Chan et al, 2012; Winickoff et al, 2010) . Some studies use both of these measures with a higher percentage reporting smoke free for 24 hours compared to 7 days (Mason, Gilbert, & Sutton, 2012; Lycet,

Hajek, & Aveyard, 2010). One study suggested that any self-reported quit attempt, even less than 24 hours should be included in the definition of smoking cessation (Hughes et al, 2010). In non-pregnant adults, the reason for smoking cessation assistance is to recognize quit attempts in order to aid the patient in moving along stages of change to ultimately reach sustained cessation (Cabezas et al, 2011; Chan et al, 2012; Kim et al, 2013; Prochaska & Velicer, 1997). However, no amount of nicotine is safe in pregnancy and one puff can cause some extent of harm to the fetus (ACOG, 2010). Because of this effect, the premise for recognizing cessation attempts is to minimize or eliminate nicotine exposure to the fetus. Therefore, a full seven day cessation is used to define smoking cessation in pregnancy. For the purpose of this paper, smoking cessation means the patient has not taken even one puff of a cigarette in the previous seven days.

Pregnancy. Barnhart and associates (2010) published a review of literature for pregnancy definitions. They established formal operational definitions for intrauterine pregnancies, ectopic pregnancies, and pregnancies of undefined location. Since smoking cessation during pregnancy focuses on improving outcomes for both mother and unborn child, intrauterine pregnancies are of most interest. Barnhart and his associates (2010) define pregnancy based on transvaginal ultrasound. They identify intrauterine pregnancies as “intrauterine gestational sac with yolk sac and/or embryo (with or without cardiac activity). (Barhart et al, 2010, p 859)” While transvaginal ultrasound is the most sensitive way of positively diagnosing intrauterine pregnancy (Murray & McKinney, 2010; Youngkin & Davis, 2013), most uncomplicated pregnancies only receive an ultrasound at 18-22 weeks gestation (ACOG, 2013; Group health, 2013; United healthcare, n.d.; Youngkin et al, 2013). American College of Obstetricians and Gynecologists (ACOG,2013) calls for urine β -hcg level measurement to initially confirm pregnancy. Based off this standard established by ACOG, insurance companies will only pay for an ultrasound between 18-22

weeks unless signs of complications present prior (ACOG, 2013; Group health, 2013; United healthcare, n.d.). Another positive sign of pregnancy is auscultation of fetal heart tones through the abdomen (Murray & McKinney 2010; Youngkin et al, 2013). Fetal heart tones can initially be heard between eight and twelve weeks gestation (Murray & McKinney, 2010; Youngkin et al, 2013). Many women present to the clinic for pregnancy confirmation earlier than eight weeks. ACOG guidelines recommend always confirming pregnancy with urine β -hcg in the office setting and if beyond 8 weeks of gestation, auscultate fetal heart tones (ACOG, 2013). Since the standard care in the United States is to verify pregnancy only by positive urine β -hcg at initial conception visit (ACOG, 2013; Youngkin, et al, 2013; Group health, 2013; United healthcare, n.d.), this is the definition that will be used in this paper. Therefore pregnancy is defined as a positive urine β -hcg test confirmed in a healthcare setting.

Theoretical Definition

Combining the above definitions, smoking cessation during pregnancy occurs when a patient who has a healthcare confirmed positive urine β -hcg and was a current smoker at conception who self-reported smoking 100 cigarettes in their life and had smoked at least once in the seven days prior to conception, has not taken even one puff of a cigarette in the previous seven days.

Chapter 3: Methods and Framework

Iowa Model

Theories and models within nursing provide a framework for conducting research and developing evidence based protocols. The Iowa Model was developed in 1994 by Marita Titler as a model to guide evaluation of current nursing practices as well as develop and implement new practices grounded in best evidence (Titler, Kleiber, & Steelman, 2001). Since its

introduction, the Iowa Model has been utilized across the country to successfully guide development of evidence based practice standards and protocols (Bergstrom, 2011; Haxton, Doering, Gingras, & Kelly, 2012; Hermes, Deakin, Lee, & Robinson, 2009; Kowal, 2010). This project will follow the Iowa Model which has six steps: select a topic, form a team, retrieve evidence, develop an evidence based practice protocol, implement the new practice, and finally evaluate the outcome. However, this project is focused on developing an evidence based practice protocol, thus will only be using steps one through four.

Select a topic. As discussed above, this project will analyze research on assisting patients toward smoking cessation during pregnancy. The compilation of research will then be developed into an evidence based practice protocol. The topic of smoking cessation during pregnancy is explored and formally defined above.

Form a team. For this project a committee has been formed to guide research and development of the protocol. Dr. Angelia Mickle will chair the project committee and focus on overseeing and guiding project progression and implementation. Nurse Practitioner Carol Cooke has agreed to sit on this project committee and act as a liaison between research synthesis and practical implementation. She is a practitioner at Oak Creek OB/Gyn and will connect the academic research process to implementation where she practices.

Evidence retrieval. Evidence retrieval will begin January 5th, 2015 and will conclude February 8th, 2015. During this time Academic Search Complete, CINAHL, Cochrane, Healthsource: Nursing/Academic, and Medline databases will all be searched using the terms “smoking cessation” and “pregnancy” for articles published since 2009. Websites of applicable governing agencies such as ACOG, American Academy of Pediatrics, and the CDC will also be

searched for guidelines and research. Retrieved research will be stored and organized using Mendeley reference manager.

Developing an evidence based practice protocol. An evidence based practice protocol will be developed from the research and best evidence found during retrieval. This protocol will be developed for implementation at Oak Creek Ob/Gyn. Oak Creek is a primary care women's health practice made up of three office locations in which ten providers practice including seven Physicians and three Nurse Practitioners. Committee member Carol Cooke practices within this group as a Nurse Practitioner and will help guide implementation. In order for implementation of any new protocol it is vital that all participating members are on board and find value in the new implementation. Therefore, the remaining nine practitioners in this group also are key players for implementation of this protocol.

Chapter 4: Results

Databases and Key Terms

During the research process, five databases were searched as well as two governing agencies. The databases included Academic Search Complete, CINAHL, Cochrane, Healthsource: Nursing/Academic, and Medline. ACOG and the CDC online websites and databases were searched as well. The search terms "smoking cessation" and "pregnancy" were used and the search was limited to articles published since 2009.

Focus Areas

Inclusion criteria. Literature was searched for research regarding three main areas: (1) understanding quitting and its barriers, (2) effects of quitting and cutting down, (3) ways to assist the patient to stop smoking during pregnancy. Inclusion criteria were established using these three focus areas. Assisting the patient to stop smoking during pregnancy was further divided

into three categories including behavioral intervention, nicotine replacement therapy, and medications.

Exclusion criteria. Articles excluded from evaluation were articles evaluating relapse post-partum, smoking with psychiatric disorders, and smoking with other drug addictions. Anxiety and depression handled by primary care providers was not considered a psychiatric disorder and was evaluated in this study. Some descriptive research articles included other drug use as a descriptive variable while evaluating many variables. These studies were not specifically evaluating drugs during pregnancy and were included in the evaluation of literature.

Findings

Research was grouped by above listed themes and formatted into a table for each theme. Findings in each of these core areas were summarized for discussion in this section. Each article was also summarized in tables below and level of evidence was identified. The level of evidence rating system used seven levels with level one being the strongest made up of systematic review (SR) of randomized controlled trials (RCT), level two includes articles from atleast one RCT, level three includes controlled trials without randomization, level four includes case control and cohort studies, level five includes SR of descriptive or qualitative studies, level six is made up of descriptive or qualitative studies, and level seven is expert opinion. This rating system has been used to develop nursing evidence based practice protocols and extensively in nursing literature (Melnik & Fineout-Overholt, 2005; Dearholt & Dang, 2012).

Understanding. After reviewing the literature, risk factors for smoking while pregnant included age (Masho et al, 2013), less than a high school education (Masho et al, 2013; Alford, Lappin, Peterson, & Johnson, 2009), unemployed, criminal history, social services involved, ETOH and drugs (Masho et al, 2013), smoking partner, high rate of tobacco consumption,

decreased or no pre-natal care, multiparous (Alford, Lappin, Peterson, & Johnson, 2009; Schneider, Huy, Schultz, & Diehl, 2010). Risk factors for prohibiting smoking cessation while pregnant were living with smoking partner, emotional distress (Hauge, Aarø, Torgersen, & Vollrath, 2013) anxiety, depression, relationship discord, negative life events (Hauge, Torgersen, & Vollrath, 2012; Massey & Compton, 2013), and stress (Haskins et al, 2010; Holtrop, Meghea, Raffo, Biery, Chartkoff, & Roman, 2010), increased number of years between pregnancies (Hauge, Aarø, Torgersen, & Vollrath, 2013), and heavy smoking/increased tobacco usage (20+/d) (Hauge, Aarø, Torgersen, & Vollrath, 2013; Haskins et al, 2010). Barriers cessation while pregnant included weight control, mood stabilization (Davies, 2012; Varescon, Leignel, Poulain, & Gerard, 2011), and prenatal depression (Orr, Blazer, & Orr, 2012). Factors that play a role in achieving cessation included being in an advanced stage of change due to pregnancy (Buja et al, 2011). Table 1 summarizes the findings of each research article in this category.

Table 1: Understanding

	Citation	Title	Level of Evidence		Summary
1 U	(Flemming, Graham, Heirs, Fox, & Sowden, 2013)	Smoking in Pregnancy: a Systematic Review of Qualitative Research of Women who Commence Pregnancy as Smokers	V	SR of qualitative research	Four main themes emerged regarding women's experiences of smoking during pregnancy. (1) Smoking was very embedded in women's lives. (2) Women felt like they were questioned about smoking only because they were pregnant. (3) Many viewed cessation as quitting for pregnancy rather than for good. (4) Quitting had significant costs for the woman and cutting down was a positive alternative.
2 U	(Hauge, Aarø, Torgersen, & Vollrath, 2013)	Smoking During Consecutive Pregnancies among Primiparous Women in the Population-Based Norwegian Mother and Child Cohort Study	IV	cohort study	Risk factors preventing smoking cessation included living with smoking partner, emotional distress, increased number of years between pregnancies, heavy smoking
3 U	(Davies, 2012)	The Effect of Body Image and Mood on Smoking Cessation in Women.	V	SR of qualitative and quantitative research	Many women use smoking as a way to control weight and stabilize their mood.

4 U	(Buja et al, 2011)	Socio-Demographic Factors and Processes Associated with Stages of Change for Smoking Cessation in Pregnant Versus Non-pregnant Women.	IV	descriptive study	Pregnancy causes women to be at a more advanced stage of change and thus more open to smoking cessation counseling.
5 U	(Masho et al, 2013)	Least Explored Factors Associated with Prenatal Smoking	I V	cohort study	Risk factors for smoking during pregnancy include age, less than a high school education, unemployed, criminal history, social services, alcohol or drug use.
6 U	(Hauge, Torgersen, & Vollrath, 2012)	Associations Between Maternal Stress and Smoking: Findings from a Population-Based Prospective Cohort Study	IV	cohort study	Anxiety, depression, relationship discord, and negative life events can decrease likelihood of smoking cessation.
7 U	(Ferguson & Hansen, 2012)	A Preliminary Examination of Cognitive Factors that Influence Interest in Quitting During Pregnancy	VI	descriptive	Women are less likely to recognize risks to the fetus as a risk of smoking compared to risks to other body systems.
8 U	(Schneider, Huy, Schultz, & Diehl, 2010)	Smoking Cessation During Pregnancy: A Systematic Literature Review	II	SR of RCT	A smoking partner, a large number of children, a high rate of tobacco consumption, as well as deficiencies in prenatal care were predictors of smoking during pregnancy.
9 U	(Holtrap, Meghea, Raffo, Biery, Chartkoff, & Roman, 2010)	Smoking Among Pregnant Women with Medicaid Insurance: Are Mental Health Factors Related?	VI	descriptive	"Mental health history, stress, demographics, current alcohol and past drug use are all strongly related to continued smoking during pregnancy".
10 U	(Massey & Compton, 2013)	Psychological Differences Between Smokers Who Spontaneously Quit During Pregnancy and Those Who Do Not: A Review of Observational Studies and Directions for Future Research	II	SR of RCT	Those with mental health histories are less likely to spontaneously quit smoking during pregnancy.
11 U	(Alford, Lappin, Peterson, & Johnson 2009)	Pregnancy Associated Smoking Behavior and Six Year Postpartum Recall.	VI	descriptive	"Mother's education, asthma status, amount of pre-pregnancy smoking, gravidity, and father's smoking status were important in the prediction of pregnancy associated smoking."
12 U	(Varesco, Leignel, Poulain, & Gerard, 2011)	Coping Strategies and Perceived Stress in Pregnant Smokers Seeking Help for Cessation	IV	case control	Pregnant smokers attempting to quit report a higher level of anxiety and lower coping strategies.

13 U	(Wigginton & Lee, 2013)	Stigma and Hostility Towards Pregnant Smokers: Does Individuating Information Reduce the Effect?	VI	descriptive	Perceptions of college students were more negative of smoking mothers.
14 U	(Tombor, Urban, Berkes, & Demetrovics, 2010)	Denial of Smoking-Related Risk among Pregnant Smokers.	IV	cohort	A higher level of risk denial seems to be one of the major determinants of women's smoking status during pregnancy.
15 U	(Haskins et al, 2010)	Correlates of Smoking Cessation at Pregnancy onset among Hispanic Women in Massachusetts	IV	cohort	Women born outside the United States, a family history of diabetes, and non-Puerto Rican Hispanics were more likely to quit smoking. Women with high stress, marijuana use, and parous women were less likely to quit. Women who smoked 20+ cigarettes/d in pre-pregnancy were less likely to quit smoking compared with light smokers. Age, income, body mass index, language preference, pre-pregnancy exercise, and alcohol consumption were not associated with quitting.
16 U	(Orr, Blazer, & Orr, 2012)	Maternal Prenatal Depressive Symptoms, Nicotine Addiction, and Smoking-Related Knowledge, Attitudes, Beliefs, and Behaviors.	VI	descriptive	Prenatal depressive symptoms may be a barrier to smoking cessation.

(*SR* = systematic review; *RCT* = randomized controlled trial; *U* = category of understanding)

Effects of stopping and cutting down on smoking. Literature consistently reported smoking cessation is the gold standard and first priority regarding tobacco exposure during pregnancy. Smoking cessation reduces chance of low birth weight and prematurity (Flower, Shawe, Stephenson, & Doyal, 2013). Cessation early in pregnancy is best. The literature supports the third trimester as the cutoff point for benefit. Cessation prior to third trimester increases weight, head circumference, and length (Bailey, McCook, Clements, & McGrady, 2011; Vardavas, 2010). One of the only negative effects of smoking cessation during pregnancy is it can cause pregnant women to gain more weight during pregnancy (Restall et al, 2014).

Reducing smoking as a secondary option for those who fail complete cessation during pregnancy received mixed reviews. Reducing nicotine exposure during pregnancy can decrease preterm delivery (Bailey, McCook, Hodge, & McGrady, 2012) and increases birth weight (Flower, Shawe, Stephenson, & Doyal, 2013). However, Bengamin-Garner & Stotts (2013)

found although there was an increase in raw birth weight, differences were not statistically significant. Consensus throughout all of these articles remains the same. Smoking cessation should still be the gold standard. However, cutting down should be recognized as a second line alternative measure (Graham, Flemming, Fox, Heirs, & Sowden, 2014). Table two summarizes findings of each individual research article examining understanding quitting and cutting down.

Table 2: Effects of Quitting and Cutting Down

	Citation	Title	Level of Evidence		Summary
17 E	(Amash & Jaradeh, 2012)	Effect of Active and Passive smoking during Pregnancy on its Outcomes	IV	cohort study	Statistically significant lower birth weight and lower apgar scores of those who smoked.
18 E	(Flower, Shawe, Stephenson, & Doyal, 2013)	Pregnancy Planning, Smoking Behaviour during Pregnancy, and Neonatal Outcome: UK Millennium Cohort Study	IV	cohort study	This study grouped those who stopped smoking and those who reduced number of cigarettes together and was still significant that it reduced low birth weight and prematurity.
19 E	(Bailey, McCook, Clements, & McGrady, 2011)	Quitting Smoking During Pregnancy and Birth Outcomes: Evidence of Gains Following Cessation by Third Trimester	IV	cohort study	There is a significant improvement in weight and head circumference if quit prior to third trimester.
20 E	(Restall et al, 2014)	Risk Factors for Excessive Gestational Weight Gain in a Healthy, Nulliparous Cohort	IV	cohort study	Women gain more weight when stop smoking during pregnancy which can act as a barrier to smoking cessation.
21 E	(Vardavas, 2010)	Smoking and Smoking Cessation During Early Pregnancy and its Effect on Adverse Pregnancy Outcomes and Fetal Growth	IV	cohort study	Smoking cessation during early pregnancy significantly increases birth weight, length, and head circumference.
22 E	(Bengamin-Garner & Stotts, 2013)	Impact of Smoking Exposure Change on Infant Birth Weight Among a Cohort of Women in Prenatal Smoking Cessation Study	IV	cohort study	Although not statistically significant, the increase in infant birth weight associated with reduction from heavy to light exposure suggests potential for benefit. The only statistically significant comparison was between quitters and sustained heavy smokers, confirming that smoking cessation should remain the goal for pregnant women.
23 E	(Bailey, McCook, Hodge, & McGrady, 2012)	Infant Birth Outcomes Among Substance Using Women: Why Quitting Smoking During Pregnancy is Just as Important as Illicit Drugs	IV	case control	Smoking during pregnancy caused lower birth weight than illicit drug use.

24 E	(Seybold et al, 2012)	Smoking in Pregnancy in West Virginia: Does Cessation/Reduction Improve Perinatal Outcomes?	IV	cohort study	Decreasing smoking reduces preterm deliveries
25 E	(Graham, Flemming, Fox, Heirs, & Sowden, 2014)	Cutting Down: Insights from Qualitative Studies of Smoking in Pregnancy	V	SR of qualitative research	"Our findings suggest that cutting down in pregnancy, as an aid and an alternative to quitting require greater recognition of healthcare and tobacco control policies are to be sensitive to the perspectives and circumstances of smokers."

Behavioral interventions.

Theories. Two theories and one model were displayed in multiple studies throughout literature. The theory of planned behavior helps guide intervention development (Ben Natan, Golubev, & Shamrai, 2010). Using the transtheoretical model to guide intervention was more likely to assist patients to stop smoking (Aveyard et al, 2006). The model of the 5 A’s was widely supported throughout literature. ACOG uses this model to guide recommendations for smoking cessation during pregnancy. The 5 A’s include asking about smoking status, assess readiness to change, advise the pregnant patient about risks with smoking, assist her to stop smoking, and arrange follow up. Using the 5 A’s has shown improvement in quit rates during pregnancy (Kim, England, Kendrick, Dietz, & Callaghan, 2009). However, as discussed above, usage of the 5 A’s is suboptimal. Because of this, current literature mostly examined how to increase utilization of the 5 A’s. Having an established office intervention improved the “assist” stage of the 5A’s (Moss, Cluss, Watt-Morse, & Pike, 2009). Educating providers also improves utilization of 5A’s (Bowden, Oag, Smith, & Miller, 2010).

Financial incentives. Throughout literature there was a high number of articles examining financial incentives role and efficacy in smoking cessation during pregnancy. Financial incentives were found to increase and prolong cessation rates (Ierfino et al, 2015; Donatell, 2000) They also increase program involvement and program success (Mantzari, Vogt, &

Marteau, 2012). A voucher system was shown to have improved birth outcomes (Higgins et al, 2010). However, financial incentives had low acceptance rates among pregnant women (Lynagh, Bonevski, Symonds, & Sanson-Fisher, 2011). This was in part due to beliefs it would create inequalities, enhance or decrease motivation, and add stress to relationships (Thomson, Morgan, Crossland, Bauld, Dykes, & Hoddinot, 2014).

Increasing access. Another common theme throughout literature regarding behavioral interventions for smoking cessation during pregnancy was increasing access to obstetric providers. This was hypothesized to help because there were many pregnant women who reported low to moderate awareness of effects of smoking during pregnancy (Levis et al, 2014). Many different programs were trialed in attempt to address this issue, however minimal success was documented. Phone calls weekly from the providers' office did not increase cessation rates compared to receiving a handout (Bullock, Everett, Mullen, Geden, Longo, & Madsen; 2009). Motivational interviewing did not increase cessation rates (Hayes et al, 2013). Counseling did not provide large gains in cessation (Filion et al, 2011). Ultrasound feedback did not increase quit rates (Stotts et al, 2009). While many attempts were unsuccessful, there were a few programs able to successfully help pregnant smokers to quit. Community based pregnancy resource centers were found to successfully educate low income and help with successful quitting (Cluss, Levine, & Landsittel, 2011). Home visits were found to increase successful quit rates (Karatay, Kublay, & Emiroğlu, 2010; Fedall et al, 2012; Matone, O'Reilly, Xianqun, Localio, & Rubin, 2012) Video Doctor access which “delivered interactive tailored messages, an educational worksheet for participants, and a cuing sheet for providers at next visit” at baseline, 1 month, and each prenatal care visit after one month did increase cessation rates (Tsoh, Kohn, & Gerbert, 2010).

Coping mechanisms. There were three main coping mechanisms found to increase smoking cessation during pregnancy. Yoga helped manage stress while quitting (Bock et al, 2012). Exercise decreased craving and withdrawal symptoms (Harper, Fitzgeorge, Tritter, & Prapavessis, 2012). Partner support was found to have mixed reviews; two articles found it did not impact quit rates (Koshy, Mackenzie, Tappin, & Bauld, 2010; Hemsing, Greaves, O'Leary, Chan, & Okoli, 2012), while another article found it significantly increased quit rates (Donatell, 2000). Table three summarizes the findings of individual research articles in the focus area of behavioral interventions.

Table 3: Behavioral Interventions

	Citation	Title	Level of Evidence		Summary
28 B	(Ben Natan, Golubev, & Shamrai, 2010)	Smoking During Pregnancy: Analysis of Influencing Factors Using the Theory of Planned Behaviour	VI	descriptive	Nursing interventions guided by the TPB constructs may help Israeli women quit smoking during pregnancy and reduce prevalence of smoking during pregnancy.
29 B	(Levis et al, 2014)	Women's Perspectives on Smoking and Pregnancy and Graphic Warning Labels	VI	descriptive	Participants had low to moderate awareness of effects of smoking during pregnancy. Many believed it was okay to smoke during 1st trimester. Motivations to quit included risk-focused info especially about risk to baby and graphic warning labels with pictures.
30 B	(Stotts et al, 2009)	Ultrasound Feedback and Motivational Interviewing Targeting Smoking Cessation in the Second and Third Trimesters of Pregnancy.	II	RCT	Ultrasound feedback with smoking effects on baby yielded no significant difference in quit rates.
31 B	(Aveyard et al, 2006)	A Randomized Controlled Trial of Smoking Cessation for Pregnant Women to Test the Effect of a Transtheoretical Model-Based Intervention on Movement in Stage and Interaction with Baseline Stage.	II	RCT	Transtheoretical model based interventions are statistically more likely to assist patients to stop smoking.
32 B	(Ierfino et al, 2015)	Financial Incentives for Smoking Cessation in Pregnancy: a Single Arm Intervention Study Assessing Cessation and Gaming	IV	cohort study	This study found there were higher prolonged cessation rates with financial incentives

33 B	(Tsoh, Kohn, & Gerbert, 2010)	Promoting Smoking Cessation in Pregnancy with Video Doctor Plus Provider Cueing: a Randomized trial	II	RCT	The Video Doctor plus provider cueing is an efficacious adjunct to routine prenatal care by promoting provider advice and smoking reduction among pregnant smokers.
34 B	(Moss, Cluss, Watt-Morse, & Pike, 2009)	Targeting Pregnant and Parental smokers: Long-term Outcomes of a Practice-Based Intervention	IV	cohort study	Office interventions improved obstetric providers' rates of "assist".
35 B	(Kim, England, Kendrick, Dietz, & Callaghan, 2009)	The Contribution of Clinic-Based Interventions to Reduce Prenatal Smoking Prevalence among US Women	IV	cohort study	5 A's with 5-15 min of provider counseling and a self-help handout decreased the smoking prevalence in late pregnancy from 16.4% to 15.6%
36 B	(Mantzari, Vogt, & Marteau, 2012)	The Effectiveness of Financial Incentives for Smoking Cessation During Pregnancy: is it from Being paid or from the Extra Aid?	III	controlled trial without randomization	Woman receiving incentive for involvement perceive significantly higher involvement and program success.
37 B	(Harper, Fitzgeorge, Tritter, & Prapavessis, 2012)	Acute Exercise Effects on Craving and Withdrawal Symptoms among Women Attempting to Quit Smoking Using Nicotine Replacement Therapy	IV	case control	An acute bout of moderate intensity exercise can alleviate cravings as well as psychological and sedation withdrawal symptoms in quitters using NRT.
38 B	(Lynagh, Bonevski, Symonds, & Sanson-Fisher, 2011)	Paying Women to Quit Smoking During Pregnancy? Acceptability Among Pregnant Women.	VI	descriptive	Acceptability for the use of financial incentives in reducing antenatal smoking is low among pregnant women.
39 B	(Bullock, Everett, Mullen, Geden, Longo, & Madsen; 2009)	Baby BEEP: a Randomized Controlled Trial of Nurses' Individualized Social Support for Poor Rural Pregnant Smokers.	II	RCT	No significant difference between women who received weekly phone calls and those who received pamphlets
40 B	(Thomson, Morgan, Crossland, Bauld, Dykes, & Hoddinot, 2014)	Unintended Consequences of Incentive Provision for Behavior Change and Maintenance around Childbirth	VI	descriptive	"Financial incentives are controversial and generated emotive and oppositional responses." "Four key themes emerged: how incentives can address or create inequalities; enhance or diminish intrinsic motivation and wellbeing; have a positive or negative effect on relationships"
41 B	(Tappin et al, 2015)	Financial Incentives for Smoking Cessation in Pregnancy: RCT	II	RCT	Significantly more women who received financial incentives stopped smoking.
42 B	(Bowden, Oag, Smith, & Miller, 2010)	An Integrated Brief Intervention to Address Smoking in Pregnancy	IV	cohort	Educating providers about 5A's and how to utilize increases their rate of 5A utilization

43 B	(Filion et al, 2011)	The effect of Smoking Cessation Counselling in Pregnant Women: a Meta-Analysis of Randomized Controlled Trials.	I	SR of RCT	"Available data from RCTs examining the isolated effect of smoking cessation counseling in pregnant woman are limited but sufficient to rule out large treatment effects. Future RCTs should examine pharmacological therapies in this population."
44 B	(Koshy, Mackenzie, Tappin, & Bauld, 2010)	Smoking Cessation During Pregnancy: the Influence of Partners, Family and Friends on Quitters and Non-Quitters	VI I	qualitative	Close associates such as partners and support people vary in their support for the smoking woman attempting to quit. Future research needs to evaluate their role further.
45 B	(Hemsing, Greaves, O'Leary, Chan, & Okoli, 2012)	Partner Support for Smoking Cessation During Pregnancy: a Systematic Review	I	SR of RCT	Partner support was not found to have a significant impact on pregnant smoker quit rates.
46 B	(Higgins et al, 2010)	Effects of Smoking Cessation with Voucher-Based Contingency Management on Birth Outcomes	II	RCT	These results provide evidence that smoking-cessation treatment with voucher-based CM may improve important birth outcomes.
47 B	(Bock et al, 2012)	Yoga as a Complementary Treatment for Smoking Cessation in Women	II	RCT	At 8 weeks, more women had stopped smoking in yoga group. It is thought to be because of stress control.
48 B	(Hayes et al, 2013)	Effectiveness of Motivational Interviewing in Influencing Smoking Cessation in Pregnant and Post-partum Disadvantaged Women	IV	cohort	No significant difference between those who received motivational interviewing and those who did not.
49 B	(Chang et al, 2013)	Smoking Is Bad for Babies: Obstetric Care Providers' Use of Best Practice Smoking Cessation Counseling Techniques	VI	qualitative	5A's: 98% of providers asked, 21% performed at least the first three A's, no providers did all 5
50 B	(Naughton, Prevost, Gilbert, & Sutton, 2012)	Randomized Controlled Trial Evaluation of a Tailored Leaflet and SMS Text Message Self-help Intervention for Pregnant Smokers (MiQuit)	II	RCT	MiQuit intervention group received a tailored handout and 11 week program of tailored text messages. Significantly more women stopped smoking in the control group and significantly more women had cognitive determinants to quit in the future.
51 B	(Windsor et al, 2014)	Effectiveness of the Smoking Cessation and Reduction in Pregnancy Treatment (SCRIPT) Dissemination Project: A Science to Prenatal Care Practice Partnership.	III	case control	SCRIPT program included home visits and was significantly more likely to quit.
52 B	(Naughton, Jamison, & Sutton, 2013)	Attitudes Towards SMS text Message Smoking Cessation Support: a Qualitative Study of Pregnant Smokers	VI	qualitative	Text messaging helped most when it was personalized and convenient real-time intervention.
53 B	(Hill et al, 2013)	Baby Be Smoke Free: Teenage Smoking Cessation Pilot.	IV	cohort study	Technology may be best way to help pregnant teens stop smoking because they prefer to keep their smoking status a secret (stage of development?)

54 B	(Bombard et al, 2013)	Telephone Smoking Cessation Quitline Use Among Pregnant and Non-pregnant Women	IV	cohort study	Quitlines improved cessation rates.
55 B	(Baxter, Everson-Hock, Messina, Guillaume, Burrows, & Goyder; 2010)	Factors Relating to the Uptake of Interventions for Smoking Cessation among Pregnant Women: A Systematic Review and Qualitative Synthesis.	I	SR of qualitative and quantitative literature	"The review suggests a need for greater training in this area and the greater use of protocols. (p 685)"
56 B	(Cluss, Levine, & Landsittel, 2011)	The Pittsburgh STOP Program: Disseminating an Evidence-Informed Intervention for Low-Income Pregnant Smokers.	IV	cohort study	Community based pregnancy resource centers can successfully educate low income pregnant smokers on smoking risks during pregnancy. This can lead to smoking cessation.
57 B	(Albrecht, Kelly-Thomas, Osborne, & Ogbagabar, 2011)	The SUCCESS Program for Smoking Cessation for Pregnant Women	IV	cohort study	Setting Universal Cessation Counseling Education and Screening Standards (SUCCESS) was developed as an evidence-based practice program which established a protocol for office use with intervention guides and successful increased quit rates.
58 B	(Fujioka, Kobayashi & Turale, 2012)	Short-Term Behavioral Changes in Pregnant Women after a Quit-Smoking Program via E-Learning	IV	case control	E-learning program using cell phone internet connection to give support and advise to pregnant smokers successfully increased quit rates.
59 B	(Karatay, Kublay, & Emiroğlu, 2010)	Effect of motivational interviewing on smoking cessation in pregnant women	IV	case control	This is an example of a successful stop smoking program which included 8 home visits, 5 interventions based of transtheoretical model, and 3 follow up appointments.
60 B	(Fedall et al, 2012)	Integrating a Clinical Model of Smoking Cessation into Antenatal Care.	IV	cohort study	Midwife home visits and enlisting in formal smoking cessation program increased quit rates.
61 B	(Tappin et al, 2010)	Smoking Prevalence and Smoking Cessation Services for Pregnant Women in Scotland	IV	cohort study	The US problem of poorly implemented plan is happening in other countries too (Scotland).
62 B	(Donatell, 2000)	Randomized Controlled Trial Using Social Support and Financial Incentives for High Risk Pregnant Smokers: Significant Other Support (SOS) Program	II	RCT	Monetary incentive and personal support person significantly increased quit rates.
63 B	(Matone, O'Reilly, Xianqun, Localio, & Rubin, 2012)	Home Visitation Program Effectiveness and the Influence of Community Behavioral Norms: a Propensity Score Matched Analysis of Prenatal Smoking Cessation	IV	cohort study	Home visits increased rates of smoking cessation.

Nicotine replacement therapy. The United States Food and Drug Administration (FDA) has determined nicotine replacement therapy (NRT) to be category D (Nicotin, 2015). Because of this, providers within the United States do not generally prescribe NRT. However, European countries have approved NRT's use in pregnancy; effectiveness and consequences of NRT have been extensively studied. Throughout literature, NRT has been found to decrease nicotine cravings and decrease fetal exposure to nicotine (Oncken, Campbell, Chan, Hatsukami, & Kranzler, 2009). NRT has also been found to decrease low birth weight compared to smokers (Oncken & Kranzler, 2009; Lancaster, 2014; Forinash, Pitlick, Clark, & Alstat, 2010) and when studied there was no difference compared to active smokers (Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2012). NRT also decreased prematurity compared to smokers (Forinash, Pitlick, Clark, & Alstat, 2010), and there was no difference compared to non-smokers (Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2012). However, both of these results are only true if the mother stops smoking with NRT use. One study found that if the mother uses NRT and continues to smoke the risk of preterm delivery and small for gestational age double compared to non-smokers, whereas those who smoke without NRT use is only 1.31 times more likely to experience these effects as non-smokers (Gaither, Brunner Huber, Thompson, & Huet-Hudson; 2009). There were three studies that evaluated NRT's correlation with birth defects. All three studies found that NRT did not cause birth defects (Oncken & Kranzler, 2009; Coleman et al, 2012; Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2012). However, of the five studies that evaluated NRT usage and quit rates, none of the five studies found a significant difference in quit rates when NRT was used at standard dosing (standard dosing means the same dosing used on non-pregnant adults). It is hypothesized that this is because maternal nicotine absorption decreases since some of the nicotine is transferred to the fetus. If this is true,

increased doses of nicotine replacement may lead to higher cessation rates. However, high dose NRT has not been studied for efficacy or safety profile. Table four summarizes the findings of individual research articles focusing on NRT.

Table 4: NRT

64 N	(Coleman, Chamberlain Cooper, & Leonardi-Bee, 2011)	Efficacy and Safety of Nicotine Replacement Therapy for Smoking Cessation in Pregnancy: Systematic Review and Meta-Analysis	I	SR of RCT	No statistical significance that NRT is any more or less safe nor is it more or less effective than standard practice.
65 N	(Coleman et al, 2014)	The SNAP Trial: A Randomized Placebo-Controlled Trial of Nicotine Replacement Therapy in Pregnancy -- Clinical Effectiveness and Safety Until 2 years After Delivery, with Economic Evaluation	II	RCT	NRT use at standard dosing yielded no significant difference in smoking cessation rates. 2-year-olds born to women who used NRT were more likely to have survived without any developmental impairment. More research needed to evaluate higher doses
66 N	(Gaither, Brunner Huber, Thompson, & Huet-Hudson; 2009)	Does the Use of Nicotine Replacement Therapy During Pregnancy Affect Pregnancy Outcomes?	I V	cohort study	Women who use NRT and continue to smoke are at twice the risk of preterm delivery and small for gestational age as non-smokers. Those who smoke without NRT use are 1.31 times more likely to deliver early and have babies small for gestational age. Thus, if NRT is used, the women must stop smoking.
67 N	(Strandberg-Larsen et al, 2008)	Use of Nicotine Replacement Therapy During Pregnancy and Stillbirth: A Cohort Study	I V	cohort study	NRT not associated with still births. Smoking during pregnancy has higher rate of still births.
68 N	(Brose, McEwen, & West, 2013)	Association Between Nicotine Replacement Therapy Use in Pregnancy and Smoking Cessation	I V	cohort study	"Combination NRT was associated with higher odds of quitting compared with no medication, whereas single NRT showed no benefit."
69 N	(El-Mohandes, 2013)	A Randomized Clinical Trial of Trans-Dermal Nicotine Replacement in Pregnant African-American Smokers.	II	RCT	No significant difference between those who received NRT and cognitive behavioral therapy (CBT) and those who received CBT alone.
70 N	(Oncken & Kranzler, 2009)	What do We Know about the Role of Pharmacotherapy for Smoking Cessation Before or During Pregnancy?	I	SR RCT	NRT does not improve quit rates, but does increase birth weight and did not adversely affect birth outcomes.
71 N	(Lancaster, 2014)	In Pregnant Smokers, the Nicotine Patch did not Increase Abstinence or Birthweight More than Placebo.	II	RCT	In pregnant women who smoked, the 16-hour nicotine patch did not increase smoking abstinence or infant birthweight more than placebo.
72 N	(Coleman et al, 2012)	A Randomized Trial of Nicotine-Replacement Therapy Patches in Pregnancy	II	RCT	No significant difference in smoking cessation or birth defects between those who received NRT patches and the control group.
73 N	(Forinash, Pitlick, Clark, & Alstat, 2010)	Nicotine Replacement Therapy Effect on Pregnancy Outcomes	I	SR	NRT use significantly decreased the risk of preterm delivery and low birth weight compared to that of smokers.

74 N	(Dornelas, Oncken, Greene, Sankey, & Kranzler, 2013)	Major Depression and PTSD in Pregnant Smokers Enrolled in Nicotine Gum Treatment Trial.	II	RCT	"Pregnant women with a history of MDD and PTSD appear to be as likely to benefit from smoking cessation treatment as those without such a history."
75 N	(Oncken, Campbell, Chan, Hatsukami, & Kranzler, 2009)	Effects of Nicotine Patch or Nasal Spray on Nicotine and Cotinine Concentrations in Pregnant Smokers.	II	RCT	Daily, cigarette craving decreased more in the patch verses other groups. Nicotine patch and nasal spray reduce maternal nicotine exposure compared with smoking and may be effective for smoking cessation.
76 N	(Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2012)	Pharmacological Interventions for Promoting Smoking Cessation during Pregnancy	I	SR of RCT	This SR found no studies examining bupropion or varenicline. No statistically significant difference was seen for smoking cessation in later pregnancy after using NRT as compared to control. There were no statistically significant differences in rates of miscarriage, stillbirth, premature birth, birthweight, low birthweight, admissions to neonatal intensive care or neonatal death between NRT or control groups.

Medications. Outside of NRT there are two main pharmacologic therapies offered to non-pregnant adults that have been documented throughout literature as effective for smoking cessation assistance. Bupropion and varenicline are relied on extensively to successfully assist smokers to stop smoking. However, neither of these medications are approved by the FDA for use in pregnancy. Very few studies have evaluated their safety and effectiveness.

Bupropion. Bupropion was originally developed for depression. It works to inhibit uptake of norepinephrine and dopamine by the neurons (Bupropion hydrochloride, 2015). Its mechanism of action for smoking cessation assistance is unknown, but is used widely within the United States and is approved by the FDA. However, it is pregnancy category C (Bupropion hydrochloride, 2015). One study evaluated Bupropion's effects on the fetus (Chun-Fai-Chan et al, 2005). It found that no major malformations occurred. Babies were delivered at normal gestational age and normal birth weights (Chun-Fai-Chan et al, 2005). However, spontaneous abortions increased (20 spontaneous abortions in 136 live births). A study looking at bupropion effects on placentas after birth observed that bupropion did in fact cross the placenta, but

appeared to not impair placental functioning (Earhart, Patrikeeva, Wang, Reda Abdelrahman, Hankins, Ahmed, & Nanovskaya, 2010).

Varenicline. The other drug widely used by non-pregnant smokers wishing to stop smoking is varenicline which works by both agonizing and blocking nicotine receptors (Varenicline, 2015). There is only one observational study of a mother who used varenicline for four weeks while pregnant. Her baby was born at 38 weeks with no abnormalities (Kaplan, Dündar, Kasap, & Karadas; 2014). Even though varenicline has hardly been studied, it is estimated that one percent of women are exposed to varenicline during pregnancy accidentally. Because of this, Harrison-Woolrych, Paterson, and Tan, (2013), call for a registry of women exposed to varenicline during pregnancy to track drug efficacy and pregnancy outcomes. Table five outlines the articles covering medications for smoking cessation during pregnancy.

Table 5: Medications

79 M	(Chun-Fai-Chan et al, 2005).	Pregnancy Outcome of Women Exposed to Bupropion during Pregnancy: A Perspective Comparative Study	I	SR of RCT	Bupropion exposure during pregnancy did not increase preterm delivery, small for gestational age, or malformations. It raised the rates of spontaneous abortion. Rates of spontaneous abortions are similar to the safety of antidepressants during pregnancy."
80 M	(Harrison-Woolrych, Paterson, & Tan, 2013)	Exposure to the Smoking Cessation Medicine Varenicline During Pregnancy: A Prospective Nationwide Cohort Study	IV	cohort study	Approximately 1% of women of reproductive age prescribed varenicline may be exposed to this medicine during pregnancy. "This could result in significant fetal exposure worldwide and indicates the need for a global pregnancy register for varenicline."
81 M	(Kaplan, Dündar, Kasap, & Karadas; 2014)	Pregnancy Outcome after Varenicline Exposure in the First Trimester	VI I	case report	Mother used varenicline for 4 weeks and baby was born at 38 weeks with no anomalies.
82 M	(Earhart, Patrikeeva, Wang, Reda Abdelrahman, Hankins, Ahmed, & Nanovskaya, 2010)	Transplacental Transfer and Metabolism of Bupropion	IV	case control	Bupropion crosses the placenta, however does not affect placental functioning. These data suggest that bupropion has the potential of being used for smoking cessation during pregnancy and should be further investigated for its safety and efficacy.

Recommendations

Four key recommendations with four sub-recommendations emerged from reviewed literature. Table six summarizes these recommendations. NRT therapy at standard doses did not yield cessation improvements. However, since nicotine crosses the placenta, a smaller percent is available to the mother. Therefore further research needs to evaluate higher doses of NRT for safety and efficacy. A varenicline registrar could benefit the progression of research in understanding the safety and efficacy of varenicline. Monetary incentives were the most effective non-pharmacologic intervention. This could be utilized by insurance companies to incentivize women to stop smoking while pregnant.

Table 6: Recommendations

Recommendation	Strength	Corresponding Studies and Level of Evidence	
1) Future research studying high dose NRT	Strong	43 (Filion et al, 2011)	I
		65 (Coleman et al, 2014)	II
		75 (Oncken, Campbell, Chan, Hatsukami, & Kransler, 2009)	II
2) Establish a varenicline registrar	Strong	43 (Filion et al, 2011)	I
		80 (Harrison-Woolrych, Paterson, & Tan, 2013)	IV
		81 (Kaplan, DüNDAR, Kasap, & Karadas; 2014)	VII
3) Monetary incentives	Strong	41 (Tappin et al, 2015)	II
		46 (Higgins et al, 2010)	II
		62 (Donatelle, 2000)	II
4) Development and utilization of clinic based practice protocols	Strong	39 (Bullock, Everett, Mullen, Geden, Longo, & Madsen; 2009)	II
		55 (Baxter, Everson-Hock, Messina, Guillaume, Burrows, & Goyder; 2010)	I
		57 (Albrecht, Kelly-Thomas, Osborne, & Ogbagabar, 2011)	IV
		59 (Karatay, Kublay, & Emiroğlu, 2010)	IV
		61 (Tappin et al, 2010)	IV
4. a) Use the 5 A's to the full extent	Moderate	33 (Tsoh, Kohn, & Gerbert, 2010)	II
		34 (Moss, Cluss, Watt-Morse, & Pike, 2009)	IV
		35 (Kim, England, Kendrick, Dietz, & Callaghan, 2009)	IV
		42 (Bowden, Oag, Smith, & Miller, 2010)	IV
		49 (Chang et al, 2013)	VI
4. b) Target pre-conception visits	Moderate	76 (Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2012)	I
4. c) Recognize cutting down as 2 nd line	Moderate	23 (Bailey, McCook, Hodge, & McGrady, 2012)	IV
		24 (Seybold et al, 2012)	IV
		25 (Graham, Flemming, Fox, Heirs, & Sowden, 2014)	V
4. d) Cessation before 3 rd trimester	Weak	19 (Bailey, McCook, Clements, & McGrady, 2011)	IV

Evidence based practice protocol. In order to address the need for established protocols and interventions, an evidence based practice protocol was developed for implementation at an obstetric office in Southwest Ohio. This protocol uses the 5 A's and starts with asking every gynecologic patient, regardless of pregnancy status, if they smoke. This allows for providers to target pre-conception patients for smoking cessation (recommendation 4b) From this question, providers follow the protocol algorithm (image 1) which leads to a provider hand out (image 2) which prompts the provider regarding what to discuss and key points to highlight. The protocol also utilizes a patient hand out (image 3). This handout is to be sent home with the pregnant smoking patient at every visit as a reminder of the goal and provides tips when they are no longer at the providers' office. Both the provider hand out and patient hand out highlight recommendations 4c and 4d.

Chapter 5: Discussion

After a thorough search of the literature, there was no clearly effective and safe option for smoking cessation during pregnancy. Home visits were consistently effective at increasing smoking cessation rates, however, most of these studies utilized the Midwife system set up in Europe. Home visits may not be feasible in the current US healthcare system. Incentives such as monetary or voucher systems showed success. One drawback to these is perceived stress on relationships and emotional status that women reported (Thomson, Morgan, Crossland, Bauld, Dykes, & Hoddinott, 2014). Utilization of the 5A's framework leads to increased cessation rates if fully utilized. At this time, no pharmacologic options including NRT, Bupropion, and varenicline have been found both safe and effective. For these reasons it is best to target smoking women before they are pregnant in order to attain highest smoke free pregnancy rates. As the protocol shows, pre-family planning visits are key visits for providers to emphasize that stopping

smoking is a must prior to pregnancy. At this stage, medications can be used safely with greater efficacy. If a woman is already pregnant and still smoking the priority should be to stop before reaching the third trimester. Complete cessation of smoking early in pregnancy is the gold standard and best goal. However, for woman who cannot stop, decreasing nicotine exposure should be recognized as second line. The goal of cutting down on cigarettes early in pregnancy is to ultimately stop smoking by the third trimester. However, even if smoking is never completely stopped, research has shown that cutting down improves fetal outcomes. To continue addressing this problem, more clinics need to implement evidence based practice protocols.

Figure 1: Evidence Based Practice Protocol

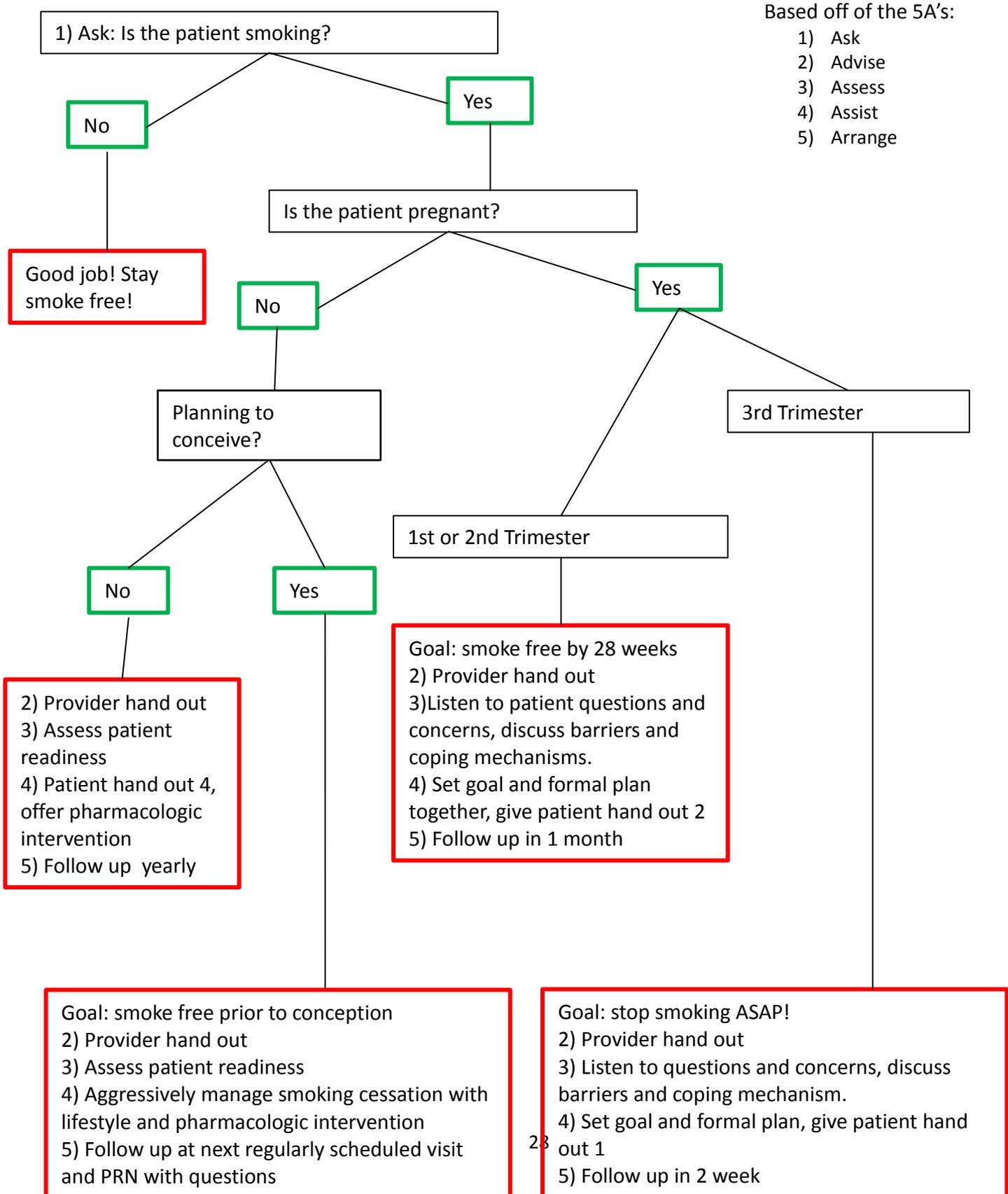


Figure 2: Provider Handout

What to Tell Your Patients About Smoking and Pregnancy



Complications during Pregnancy

Smoking during pregnancy can cause intrauterine growth restriction leading to small for gestational age. It can also cause pre-term delivery.



Complications after Delivery

Smoking during pregnancy can cause your baby to have more apnea episodes immediately after delivery, can cause asthma as a child and into adulthood, and can decrease growth from delivery through puberty.

Goals of Quitting

Quitting *before the third trimester* significantly decreases damage to the placenta and fetus. No nicotine during pregnancy is the goal, but cutting down can also reduce the damage to placenta and fetus. Before the third trimester, discuss importance of 100% cessation prior to 28 weeks. If in 3rd trimester stress importance of minimizing exposure starting now!



Coping Mechanisms

Stress/emotions and habit are two of the hardest parts of stopping smoking. Remove cigarettes and ash trays from view. Remove triggers and stay away from situations that make you want to smoke. Think through relaxation techniques that you can use as coping mechanisms. Many find benefit from yoga, exercise, and talking with supportive people in your life.



Resources for Quitting:

ACOG: *A Clinician's Guide to Helping Pregnant Women Quit Smoking*

<http://www.acog.org/-/media/Departments/Tobacco-Alcohol-and-Substance-Abuse/SCDP.pdf>

Figure 3: Patient Handout

Stopping Smoking can Help Your Baby be Healthy!

Smoking during pregnancy can cause preterm delivery, decreased weight and size, new born apnea episodes, childhood asthma, and many other complications.



Coping Mechanisms

Coping mechanisms can make your stopping smoking journey a little easier

Yoga, Exercise, Talking with a close friend or partner, Getting outside, message.

Ready to Quit? These tips can help!

- 1) Make a plan
- 2) Tell family and friends your plan
- 3) Plan for challenges and prepare coping skills
- 4) Remove and avoid triggers
- 5) Talk to your obstetric provider

Resources to help you stay smoke free: smokefree.gov, women.smokefree.gov and the smoke free women app, 1-800-QUIT-NOW

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