A Comparison of Self-Efficacy Between Pregnant Women Who Use Cigarettes Versus Electronic Nicotine Delivery Systems: A Cross-Sectional Study of Participants in the BC Healthy Connections Project

by

Tiffany Reeve

Bachelor of Arts, Western University, 2005

Graduate Diploma in Art Therapy, Toronto Art Therapy Institute, 2010

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Examining Committee:	**Chair:** Dr. Hui Xie Professor
	Dr. Charlotte Waddell Senior Supervisor Professor
	Dr. Kelley Lee Supervisor Professor
	Dr. Lawrence McCandless Supervisor Associate Professor
	Dr. Nicole Catherine Supervisor University Research Associate, Adjunct Professor
	Dr. Lenora Marcellus Supervisor Associate Professor
	Dr. John Calvert External Examiner Associate Professor
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Abstract

Self-efficacy (SE) has been regarded the strongest cognitive determinant of cigarette use during pregnancy, but has yet to be assessed in pregnant women who use alternative modes of nicotine, including electronic nicotine delivery systems (ENDS). Knowing that nicotine is harmful to the fetus, more research on SE in pregnant ENDS users is warranted. Using data from the BC Healthy Connections Project, the purpose of this research was to identify differences in SE between pregnant: *cigarette users; ENDS users*; *combination users (*ENDS and cigarettes); and *abstainers* (no tobacco or nicotine). The relationship between SE and mode of nicotine was examined using multiple linear regression. Due to small sample sizes, ENDS and combination users were collapsed (*ENDS/combination users).* SE was significantly higher in ENDS/combination users compared to abstainers. No other significant group differences emerged. Results from this research can be used to tailor interventions aimed at reducing fetal exposure to nicotine.

Keywords: self-efficacy; e-cigarettes, electronic nicotine delivery systems; BC Healthy Connections Project; pregnancy

I can't go back to yesterday because I was a different person then.
- Lewis Carroll

I dedicate this thesis work to my parents, for imparting the desire to strive for excellence, regardless of the challenges. Thank you for supporting me when I needed it the most.

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Chapter 1.

Introduction

It has been well established that cigarette use during pregnancy leads to a number of adverse outcomes including miscarriage, ectopic pregnancy, placental complications, fetal growth restriction, preterm birth, low birth weight, infant death, newborn self-regulation issues, and congenital malformations (Agrawal et al., 2010; Cnattingius, 2004; Stroud et al., 2009). According to the Maternity Experience and Canadian Community Health Surveys, risk factors for smoking cigarettes during pregnancy include: being under 25 years of age; experiencing socioeconomic disadvantage (including low income, less than a university degree, being unemployed, and not living as couple); having one or more mental illnesses; having no regular medical doctor; having at least one chronic physical illness; being a heavy cigarette smoker prior to becoming pregnant; consuming alcohol regularly; having poor self-perceived health; being born in Canada; not attending prenatal classes; and experiencing stressful events before/during pregnancy (Al-Sahab, Saqib, Hauser & Tamim, 2010; Cui, Shooshtari, Forget, Clara & Cheung, 2014).

1.1 Self-Efficacy

In addition to the risk factors above, self-efficacy (SE) has also been identified as a particularly important predictor of the use of cigarettes during pregnancy (Naughton, Prevost, Gilbert & Sutton, 2012; Maxson, Edwards, Ingram & Miranda, 2012). The construct is defined as the conviction one has to successfully execute a behaviour, in order to produce an outcome (Bandura, 1977). Importantly, SE is not considered a global personality trait that is independent of contextual factors. Instead, it represents the belief that one can perform specific behaviours in specific circumstances (Strecher, DeVellis, Becker, & Rosenstock, 1986). In his conceptual framework, Bandura (1977) stipulates that individuals may entertain the belief that a particular behaviour will lead to an outcome, but doubt in the ability to execute the necessary actions, will result in a lack of motivation to perform. In other words, SE is considered an important determinant of behaviour change because it influences the intention to engage, the effort expended,

and the persistence required to overcome barriers (Leganger, Kraft & Roysamb, 2000). Individuals with higher SE are therefore more likely to elicit the necessary actions to be able to successfully quit an unhealthy behaviour (Bandura, 1977).

SE has been linked to a number of socio-demographic constructs among the general public. For instance, in a study designed to identify correlates of SE, Leganger et al. (2000) found a gender-education interaction, wherein SE was positively correlated with education among women, but not men. An education-age interaction was also demonstrated by Leganger et al. (2000). That is, SE was negatively correlated with age among those with low levels of education. SE was also positively correlated with mastery, a construct that measures the extent to which one regards an outcome as being under their control (Pearlin and Schooler, 1978). In the Leganger et al. (2000) study, those with high scores on SE also had high scores on mastery. Finally, cross-cultural differences in SE were also reported (Leganger et al., 2000). For example, mean SE was lower in Norwegian and Chinese students compared to German and Costa Rican students. Being from a collectivist culture, Leganger et al. (2000) speculate that Chinese students may possess lower levels of personal SE, but higher levels of collective SE. The hypothesis, however, seems intuitively less likely to apply to Norwegian students. In addition to age, education, mastery, and ethnicity, previous research has also consistently found a relationship between SE and depression. For example, among pregnant cigarette smokers, Zhu and Valbø (2002) showed that those who were depressed were less confident in their ability to quit smoking than those who were not depressed.

SE has also been regarded as the strongest cognitive determinant of cigarette use during pregnancy (Naughton et al., 2012; Maxson et al., 2012). In fact, several studies have shown that the odds of prenatal cigarette use are reduced in women with higher levels of SE (Maxson et al., 2012; Morasco, Dornelas, Fischer, Oncken & Lando, 2006; Mullen, Pollak & Kok, 1999; Quinn, Mullen & Ershoff, 1991; Thyrian et al., 2006; Woodby, Windsor, Snyder, Kohler & Diclemente, 1999). However, little is known about SE in pregnant women who use alternative nicotine delivery systems. It is therefore unclear whether the inverse relationship between SE and prenatal cigarette use is also true for those who use these products.

1.1.1 Operational definition of “smoking”.

Adding to the problem, because the term *smoking* is rarely operationalized (i.e., specific information about the mode of nicotine delivery is seldom provided), the relationship between SE and smoking cannot be generalized to those who use alternative nicotine delivery systems (for more information, please see Appendix A and section 1.4 below). Neglecting to operationalize smoking is problematic because alternative nicotine delivery systems (e.g., the patch) are not actually smoked like combustible tobacco products (e.g., cigarettes). Besides not being smoked, many of these products are also meant to deliver nicotine without the harmful chemicals found in tobacco. For these reasons, those who use alternative modes of nicotine are less likely to self-report or categorize themselves as smokers (Studts et al., 2006). As a result, large national surveys, used to derive prevalence estimates of those at risk, may actually exclude alternative nicotine delivery users.

1.2 Fetal Exposure to Nicotine

Nicotine exposure has been directly linked to a number of adverse fetal and child health outcomes including preterm birth, low birth weight, newborn self-regulation issues, congenital malformations, and Sudden Infant Death Syndrome (Cope, 2014; England et al., 2015; Gaither et al., 2009; Lassen et al., 2010; Stroud et al., 2009). More specifically, nicotine crosses the placenta and binds to neuron receptor proteins called Nicotinic Acetylcholine Receptors or nAChRs (England et al., 2015). NAChRs are widely dispersed throughout the fetal nervous system. Non-neuronal nAChRs are also found in the respiratory tract, as well as endothelial and immune cells, and are elevated during critical periods of development. Consequently, fetal exposure to nicotine has also been linked to impaired brain and lung development (England et al., 2015). Further to this, research has shown that nicotine is actually metabolized faster during pregnancy. That is, plasma clearances of nicotine and cotinine (a biomarker for exposure to nicotine) are increased by 60% and 140% respectively (Dempsey, Jacob & Benowitz, 2002). As a result, pregnant women require stronger doses of nicotine for the effects to be noticed and sustained. Considering fetal concentrations of nicotine are generally higher than maternal concentrations, stronger doses may substantially compromise the health of the fetus (Lambers & Clark, 1996). In summary, although less harmful than tobacco,

alternative nicotine delivery during pregnancy is not without risk. Total abstinence from nicotine, rather than harm reduction, should therefore be the goal, especially during pregnancy.

1.3 Alternative Nicotine Delivery Systems

The only alternative nicotine delivery systems that are currently available in Canada are nicotine replacement therapy (NRT) and e-cigarettes or electronic nicotine delivery systems (ENDS). In addition to NRT and ENDS, although not yet in Canada, a device that is currently being developed and tested by Philip Morris (an American, global, cigarette and tobacco company) called iQOS (pronounced “eye-cos”) also delivers nicotine, in a tobacco-flavoured, aerosol format. Although controversial, like ENDS, Philip Morris has labelled iQOS a reduced risk product intended for harm reduction (Branswell, 2015; Health Canada, 2011; Rossel, 2016).

1.3.1 Nicotine replacement therapy.

Approved by Health Canada, NRT aids cessation by providing low doses of nicotine in an attempt to ease withdrawal symptoms, while gradually reducing nicotine doses over time. Currently, five types of NRT products that contain nicotine can legally be purchased over-the-counter and/or prescribed in Canada: nicotine gum, lozenges, inhalers, mouth sprays, and patches (Health Canada, 2011). Use of these products has been reported during pregnancy. For example, a Danish national study found that 2.5% of women reported using NRT at some point during the first 27 weeks gestation (Lassen et al., 2010). Further to this, should counseling fail, clinical practice guidelines produced by the Society of Obstetricians and Gynaecologists of Canada recommend the use of NRT during pregnancy as a means of harm reduction (Wong et al., 2011). Factors that contribute to the use of NRT during pregnancy include: being greater than 24 years of age; having a non-smoking partner; being primiparous; having a pre-pregnancy body mass index between 18.5 and 25 (i.e., within the normal range); consuming more than three alcoholic drinks per week pre-pregnancy; and experiencing low socioeconomic status (Gaither et al., 2009; Lassen et al., 2010).

Like cigarette users, users of NRT are also at risk for negative child health outcomes. For example, a systematic review revealed that compared to cigarette users,

birth outcomes were generally better for women using NRT, although findings did not reach statistical significance (Coleman, Chamberlain, Cooper & Leonardi-Bee, 2011). Conversely, Gaither et al. (2009) found that compared to cigarette users, women prescribed NRT during pregnancy had a statistically significant increased risk of low birth weight and preterm birth.

1.3.2 Electronic nicotine delivery systems.

In addition to NRT, ENDS have also been marketed as cessation aids. ENDS are battery powered devices that heat a liquid, often called “e-liquid” or “e-juice”, to create an aerosol (England et al., 2015). E-liquid contains either glycerin or propylene glycol, and is produced with or without nicotine. Although glycerin has a sweeter taste, both glycerin and propylene glycol are synthetic liquid substances that absorb water and are typically used as food additives. Propylene glycol and glycerin are generally regarded as safe when consumed orally, however it is not known whether the inhalation of these substances is also safe (England et al., 2015). E-liquid comes in a variety of fruit and candy flavourings, making ENDS particularly appealing to youth (Cobb, Byron, Abrams & Shields, 2010). In addition to e-liquid, ENDS are composed of three main components, a tank that holds the e-liquid, an atomizer, which turns the e-liquid into a vapour, and a battery. In Canada, companies like CanadaVapes.com charge between 25 and 100 dollars for an ENDS start-up package, which includes all three of the aforementioned components as well as the e-liquid. According to CanadaVapes.com, once purchased, e-liquid refills cost a fraction of the price of a pack of cigarettes (“How much will e-cigarette cost compared to cigarettes,” n.d.).

Although not yet regulated by the federal government, plans for new legislation were announced by Health Canada in November 2016. The proposed act will eventually allow Health Canada to regulate the manufacture, sale, promotion and labelling of ENDS. Despite the current lack of federal regulation, ENDS that contain nicotine are widely available through online retailers, such as CanadaVapes.com. As a result, ENDS have become increasingly popular, especially among youth and young adults, and those who are highly dependent on nicotine (Chapman & Wu, 2014; Ramo, Young-Wolff & Prochaska, 2015). For example, data from the 2015 Canadian Tobacco, Alcohol and Drugs Survey suggests that 26 percent of Canadian youth (aged 15 to 19) have tried ENDS (Health Canada, 2016). Also, a systematic review found that among adolescents

(grades 6 to 12), lifetime use of ENDS ranged from less than 1% to 3.3% in 2011. By 2012, however, lifetime use among adolescents had increased to 6.8% (Chapman & Wu, 2014). Another study conducted with young adults online throughout the US found that prevalence of "past month use" of ENDS was 6% between 2009 and 2010, 19% between 2010 and 2011, and 41% in 2013 (Ramo et al., 2015). Further to this, ENDS that contain nicotine are being used not only for cessation purposes, but to maintain and start new habits (Czoli, Hammond & White, 2014). In fact, in 2012, 16.1% of Canadians reported trying ENDS, and 5.2% of those who had tried them had not previously used tobacco or nicotine (Czoli et al., 2014).

In an attempt to stop the growing use of ENDS, several Canadian provinces and municipalities have passed their own legislation (Branswell, 2015). In British Columbia for example, the Ministry of Health amended the Tobacco Control Act, now called the Tobacco and Vapour Products Control Act. The new act, which came into effect on September 1, 2016, treats ENDS the same as cigarettes. For example, the act stipulates that ENDS can only be sold to adults aged 19 and above. Advertising ENDS to youth is also prohibited, as is the ability to use the product on public and private school grounds, indoor public spaces, workplaces, in vehicles carrying individuals younger than 16 years of age, and health authority property (Branswell, 2015; Harnett, 2016). Albeit progress has been made, no federal law requiring manufacturers to meet applicable health standards (e.g., legal levels of nicotine in e-liquids) is currently in effect. At present, health warning labels are also not required on ENDS products (Bill C-145, 2016).

Little research exists on the prevalence of the use of ENDS during pregnancy. One recent study in the United States (US) found that 0.6% of pregnant women used ENDS daily; the sample, however, was limited to women who presented to a prenatal care center in a University and may therefore not be representative of all ENDS users (Mark, Farquhar, Chisolm, Coleman-Cowger & Terplan, 2015). Factors that contribute to the use of ENDS among the general population include: being between the ages of 11 and 28; being male; being white in ethnicity; having a higher income; and a high level of nicotine dependence (Chapman & Wu, 2014; Pokhrel, Fagan, Little, Kawamoto, & Herzog, 2013; Ramo et al., 2015).

Particularly relevant to pregnant women, a lack of mandatory manufacturing standards for ENDS has resulted in e-liquid cartridges containing either more or less

nicotine than levels declared on product packaging (Goniewicz et al., 2015; Pokhrel et al., 2013). Concentrated solutions in e-liquid may therefore deliver levels of nicotine that are comparable to a typical cigarette (Goniewicz et al., 2015). Goniewicz et al. (2015) also found that products labeled “nicotine-free” still had detectable levels of nicotine in their e-liquid solutions. Further to this, some of the chemical flavourings found in ENDS (e.g. diacetyl), have recently been linked to lung disease (Allen et al., 2016). Even more troubling, many women are unaware of the risks. For example, women in the Baeza-Loya et al. (2014) study perceived ENDS to be much less harmful during pregnancy than cigarettes. Moreover, those who had tried ENDS were more likely to hold the belief that they do not lead to lung cancer (Baeza-Loya et al., 2014).

1.3.3 Heated nicotine delivery systems.

Despite being unavailable in Canada, results obtained from test markets in Italy and Japan suggest that Philip Morris, will likely expand the iQOS to other markets in the near future. The iQOS looks similar to ENDS in that it resembles a pen-like device. However, iQOS differs from ENDS in several ways. Rather than using e-liquid, the iQOS uses actual tobacco in the form of miniature cigarettes, called HeatSticks. The HeatSticks are heated to a temperature of less than 350 degrees Celsius, but not burned like a traditional cigarette, which is heated to approximately 800 degrees Celsius. As a result, iQOS delivers a tobacco-flavoured aerosol, which Philip Morris claims to be much less harmful than cigarette smoking. However, the product in not yet approved by the US Food and Drug Administration or Health Canada (Rossel, 2016). The safety of iQOS, and the claim that it reduces exposure to harmful chemicals, therefore remains unclear.

1.4 Self-Efficacy and Alternative Nicotine Delivery During Pregnancy

In an attempt to evaluate whether an inverse relationship exists between SE and the use of alternative nicotine delivery systems during pregnancy, a review using systematic methods was conducted between September 2015 and October 2015 (See Appendix A for more information). The Cochrane Database of Systematic Reviews, MEDLINE, and PsycINFO were searched with the goal of identifying differences in SE between pregnant women who use: 1) combustible tobacco products, 2) NRT, and 3) ENDS with or without nicotine. Since iQOS was not available in Canada, it was excluded

from the review. Search terms that were used include “Self-Efficacy”, “Confidence”, “Pregnancy”, “Smoking”, “Cigarettes”, “Nicotine Replacement Therapy”, “E-Cigarettes”, “Electronic Nicotine Delivery Systems”, “Systematic Review”, “Stages of Change”, and “Transtheoretical Model”. To be screened, studies were required to meet all four of the following inclusion criteria: 1) published between 1990 and 2015 (inclusive); 2) use of systematic review, cross-sectional, cohort, or randomized controlled trial (RCT) methodology; 3) have a sample consisting of pregnant women; and 4) have SE mentioned in either the title or the abstract. Studies were then disqualified from the review if they met either one of the following two exclusion criteria: 1) completed as part of a dissertation, and 2) SE measured in the postpartum. Of the 2814 hits, 11 met inclusion criteria. A duplicate hit (i.e., a study that was identified twice through various search strategies) occurred for 10 of the 11 studies. Of the 11 that met inclusion criteria, two measured SE in the postpartum and were disqualified (for a summary of studies meeting exclusion criteria, please see Appendix A). A total of nine studies were therefore included in the review (for a summary of the studies reviewed, please see Table 1.1 below). A flow chart illustrating the studies assessed in the systematic review is provided in Figure 1.1 below.

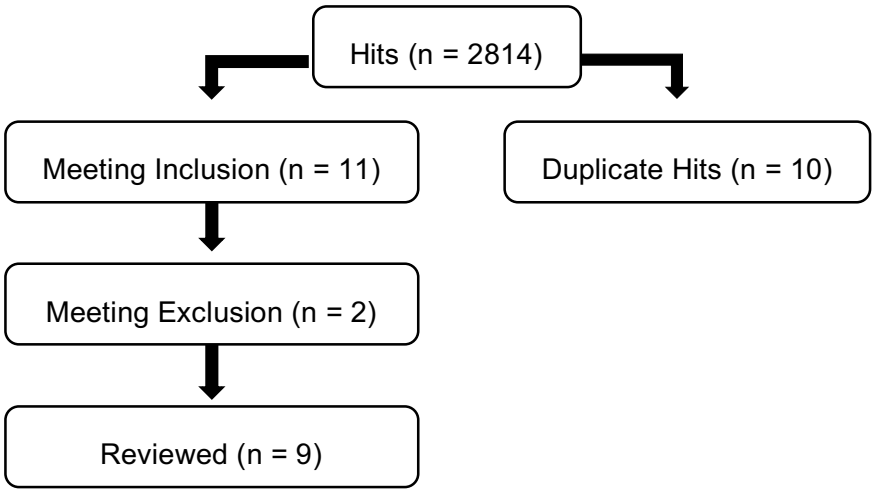

Figure 1-1 Flow Chart of Review

Although the objective of the review was to evaluate whether an inverse relationship exists between SE and the use of alternative nicotine delivery systems during pregnancy, none of the studies identified specifically focused on the use of NRT or ENDS. In fact, the majority of the studies reviewed neglected to specify the mode of tobacco/nicotine under investigation.

Among the nine studies reviewed, three used a cohort design, four used a cross-sectional design, and two were RCTs. More than half of the studies reviewed neglected to operationalize the term smoking (n = 5). The four remaining articles operationalized smoking as the use of cigarettes. All of the cross-sectional and cohort studies uncovered a significant negative relationship between SE and smoking, or cigarette use, during pregnancy, such that higher levels of SE were associated with a greater likelihood of abstinence. One RCT, conducted by Naughton et al. (2012), evaluated a tailored intervention called MiQuit, and operationalized smoking as the use of cigarettes. Conversely, the Stotts, DeLaune, Schmitz, and Grabowski (2004) RCT examined treatment mechanisms affected by a motivational interviewing intervention and did not operationalize smoking. In both RCTs, SE was higher in the treatment group, but neither significantly reduced smoking/cigarette use. It is important to note that, although non-significant, the abstinence rates in the Naughton et al. (2012) trial were higher in the intervention arm. Similarly, the intervention participants in the Stotts et al. (2004) trial were more likely to set a quit date, suggesting that in addition to improving SE, both interventions had a trend towards improving abstinence rates.

To summarize, the review revealed no literature on SE in pregnant women who use ENDS or NRT. The relationship between SE and the use of alternative nicotine delivery during pregnancy remains unclear. More research is therefore needed to determine whether an inverse relationship exists between the use of alternative nicotine delivery systems and SE during pregnancy.

Table 1-1 Studies Meeting Inclusion Criteria For Review

Reference	Database	Search Terms	Mode of Nicotine Investigated	Results
Cross-Sectional Designs				
devries, H., & Backbier, E. (1994). Self-efficacy as an important determinant of quitting among pregnant women who smoke: The ø-pattern. *Preventive Medicine, 23*(2), 167-174. doi:10.1006/pmed.1994.1023	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	Significant negative relationship between SE and smoking/cigarettes during pregnancy
Morasco, B. J., Dornelas, E. A., Fischer, E. H., Oncken, C., & Lando, H. A. (2006). Spontaneous smoking cessation during pregnancy among ethnic minority women: A preliminary investigation. Addictive Behaviors, 31(2), 203-210.	MEDLINE	Self-efficacy + Pregnancy + Cigarettes	Cigarettes	
Slade, P., Laxton-Kane, M., & Spiby, H. (2006). Smoking in pregnancy: The role of the transtheoretical model and the mother's attachment to the fetus. Addictive Behaviors, 31(5), 743-757.	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	
Stotts, A. L., Diclemente, C. C., Carbonari, J. P., & Mullen, P. D. (1996). Pregnancy smoking cessation: A case of mistaken identity. Addictive Behaviors, 21(4), 459-471. doi:10.1016/0306-4603(95)00082-8	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	
Cohort Designs				
Maxson, P. J., Edwards, S. E., Ingram, A., & Miranda, M. L. (2012). Psychosocial differences between smokers and non-smokers during pregnancy. Addictive Behaviors, 37(2), 153-159.	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	Significant negative relationship between SE and smoking/cigarettes during pregnancy
Quinn, V. P., Mullen, P. D., & Ershoff, D. H. (1991). Women who stop smoking spontaneously prior to prenatal care and predictors of relapse before delivery. Addictive Behaviors, 16(1-2), 29-40. doi:10.1016/0306-4603(91)90037-I	PsycINFO	Self-efficacy + Pregnancy + Smoking	Cigarettes	
Woodby, L. L., Windsor, R. A., Snyder, S. W., Kohler, C. L., & Diclemente, C. C. (1999). Predictors of smoking cessation during pregnancy. Addiction, 94(2), 283-292. doi:10.1046/j.1360-0443.1999.94228311.x	PsycINFO	Self-efficacy + Pregnancy + Smoking	Cigarettes	

Randomized Controlled Trials				
Naughton, F., Prevost, A. T., Gilbert, H., & Sutton, S. (2012). Randomized controlled trial evaluation of a tailored leaflet and SMS text message self-help intervention for pregnant smokers (MiQuit). Nicotine & Tobacco Research, 14(5), 569-577. doi:10.1093/ntr/ntr254	PsycINFO	Self-efficacy + Pregnancy + Smoking	Cigarettes	Treatment improved SE, but had no significant effect on abstinence
Stotts, A. L., DeLaune, K. A., Schmitz, J. M., & Grabowski, J. (2004). Impact of a motivational intervention on mechanisms of change in low-income pregnant smokers. Addictive Behaviors, 29(8), 1649-1657.	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	

1.5 The Transtheoretical Model of Change

The Transtheoretical Model of Change (TTM), a biopsychosocial model used to conceptualize changes to health-related behaviour, has provided a theoretical basis for the inverse relationship that exists between SE and prenatal cigarette use (Prochaska & DiClemente, 1982). The underlying assumptions of the model may contribute to our understanding of the relationship between SE and the use of alternative nicotine delivery during pregnancy, even though this population has been overlooked in the SE literature.

Essentially, the TTM posits that behaviour change occurs when individuals pass through a series of stages: precontemplation (no intention to quit); contemplation (considering quitting within the next six months); preparation (considering quitting within the next 30 days with recent quit attempts); action (continuously quitting for the last six months); and maintenance (continuously quitting for more than six months). Relapse, may occur at any time and is said to operate in a circular fashion. That is, individuals may go through the aforementioned stages several times before staying in maintenance (Slade, Laxton-Kane, & Spiby, 2006).

According to the TTM, SE competes with temptation, or the desire to relapse. As individuals progress through the stages of change, SE is said to increase whereas temptation is said to decrease. As SE increases, the tendency to smoke cigarettes diminishes (Prochaska & Velicer, 1997; Ruggiero, Tsoh, Everett, Fava, & Guise, 2000; Slade et al., 2006).

Empirical evidence has reinforced the assumptions underlying the TTM. For example, among pregnant women, those who continue to smoke cigarettes (precontemplators, contemplators, and preparers) have been shown to exhibit lower SE than those who quit (actors and maintainers) (deVries & Backbier, 1994). More recent research has also supported the hypothesis that SE increases as an individual progresses through the stages of change. For example, Slade et al. (2006) found higher levels of SE in maintainers compared to actors. Slade et al. (2006) also found that actors demonstrated higher levels of SE compared to precontemplators, contemplators, and preparers. The TTM has therefore proven useful in explaining the inverse relationship that exists between SE and the use of cigarettes during pregnancy – namely, as

individuals progress through the stages of change, SE increases, and cigarette smoking decreases.

To summarize, previous research has regarded SE as the strongest cognitive determinant of cigarette use during pregnancy (Naughton et al., 2012; Maxson et al., 2012). In fact, several studies have found an inverse relationship between SE and prenatal cigarette use (Maxson et al., 2012; Morasco et al., 2006; Mullen et al., 1999; Quinn et al., 1991; Thyrian et al., 2006; Woodby et al., 1999). The TTM offers a theoretical justification for this relationship, namely, as individuals progress through the stages of change, SE increases, whereas cigarette smoking decreases. SE, however, has not yet been assessed in pregnant women who use alternative nicotine delivery systems. Given that SE is associated with prenatal cigarette use, and that nicotine has been directly linked to harmful fetal and child health outcomes, more research on SE in pregnant women who use alternative modes of nicotine is needed (Cope, 2014; Gaither et al., 2009; Lassen et al., 2010).

1.6 Aims and Objectives

Accordingly, this research aimed to determine whether the inverse relationship that exists between SE and prenatal cigarette use was also true for pregnant women who used alternative nicotine delivery systems. More specifically, the main objective of this research was to address the question, “Is there a difference in SE between pregnant women who use cigarettes versus ENDS?” A second, broader objective was to identify differences in SE between pregnant women who use: cigarettes (*cigarette users*), a combination of cigarettes and ENDS (*combination users),* ENDS exclusively *(ENDS users)*, and no tobacco or nicotine *(abstainers)*.

This study was the first to evaluate SE in pregnant women who use ENDS. It was also the first to report the prevalence of ENDS use among pregnant women enrolled in the BC Healthy Connections Project (BCHCP) (for more information about the BCHCP please refer to section 2.3 below).

1.7 Rationale

Although SE has not yet been assessed in pregnant women who use any of the aforementioned nicotine products (NRT, ENDS, and iQOS), the current study focused exclusively on the use of ENDS during pregnancy for several reasons. First, the current emphasis on harm reduction by tobacco and ENDS manufacturers may result in a diminished concern for the effects of nicotine on the developing fetus. Indeed, many women are unaware of the risks (Baeza-Loya et al., 2014) Second, the use of unregulated ENDS is steadily increasing in Canada, especially among youth and young adults. (Coleman et al., 2010; Gaither et al., 2009; Ramo et al., 2015). Third, although it has been estimated that 89.5% of Canadian women do not smoke during pregnancy, those who claim to be non-smokers may still use ENDS and are therefore exposed to the harmful effects of nicotine (Al-Sahab et al., 2010). For instance, because ENDS have been marketed as non-combustible, smoking cessation aids (like NRT), when asked if they smoke, women who use ENDS may categorize themselves as non-smokers (Studts et al., 2006). Finally, very little research on the use of ENDS during pregnancy currently exists. With the exception of the Mark et al. (2015) study, which was conducted in the US, Canadian prevalence estimates for the use of ENDS during pregnancy are virtually unavailable. Taken together, these issues suggest that more research on SE among pregnant ENDS users is required.

Knowing that tailored interventions are generally more effective, characteristics that are unique to ENDS users may in turn be used to inform the development of intervention strategies that are specific to the mode of tobacco/nicotine that is actually being used (Naughton et al., 2012). For example, women who use ENDS during pregnancy may be in a later stage of change (action and maintenance) with higher levels of SE, than women who use cigarettes (precontemplation, contemplation, and preparation). Should SE be higher among ENDS users compared to cigarette users, interventions for ENDS users could be tailored to focus less on SE. Alternatively, no observed differences in SE would suggest that ENDS users are similar to cigarette users in relation to SE (both in precontemplation, contemplation, and/or preparation). ENDS users may therefore require similar interventions.

Chapter 2. Methods

2.1 Hypothesis

According to the TTM, SE increases as individuals progress through the stages of change and the ability to successfully quit smoking cigarettes improves. Given that ENDS have been marketed as cessation devices, and are often perceived to be a healthier alternative to cigarettes, women who use these products during pregnancy may be doing so to reduce harm (Baeza-Loya et al., 2014). It was therefore hypothesized that pregnant ENDS users are in a later stage of change, with higher levels of SE, than pregnant women using cigarettes. A gradient in SE was therefore expected wherein, SE was lowest in cigarette users, followed by combination users, then ENDS users, and finally abstainers. We therefore tested the null hypothesis that SE was equal among pregnant cigarette users, combination users, ENDS users, and abstainers.

2.2 The BC Healthy Connections Project

Funded by the BC Ministry of Health, with support from the BC Ministry of Children and Family Development and four regional Health Authorities, the BCHCP RCT involves a scientific evaluation of the Nurse-Family Partnership (NFP) in BC (Catherine et al., 2016). NFP is a targeted nurse home-visitation program that aims to improve the health and wellbeing of young, first-time mothers (and their children) who are experiencing socioeconomic disadvantage. Although successful in the US and the Netherlands, NFP has never been evaluated in Canada (Mejdoubi et al., 2011; Mejdoubi et al., 2013; Mejdoubi et al., 2014; Mejdoubi et al., 2015; Olds, 2006). With a sample goal of n = 1040, the BCHCP therefore aims to evaluate the effectiveness of NFP compared to existing health and social services in BC. Women are eligible to participate if they meet the criteria presented in Table 2.1 below (Catherine et al., 2016).

Table 2-1. BC Healthy Connections Project Eligibility Criteria

Women are eligible to participate if they meet *all* inclusion criteria at time of baseline interviews
1. Age 24 years or younger 2. First birth 3. Less than 28 weeks gestation 4. Competent to provide informed consent, including conversational competence in English 5. Experiencing socioeconomic disadvantage • Age 19 or younger • Age 20–24: Meets 2 of 3 indicators: Lone parent; less than grade 12; or low income which requires one or more of: i. Receiving Medical Services Plan Premium Assistance, disability assistance or other income assistance; ii. Finding it very difficult to live on total household income with respect to food or rent; or iii. Homeless, defined as living on the streets, living in a place not meant as a long-term dwelling (e.g., car or tent), staying in a shelter, or staying somewhere temporarily with no permanent address (e.g., "couch surfing")
Women are ineligible to participate if they meet *any* exclusion criteria at time of baseline interviews
1. Planning to have the child adopted 2. Planning to leave the BCHCP catchment area for three months or longer

Self-report data on pregnancy and maternal and child health outcomes, including the maternal use of ENDS during pregnancy, are being collected by Scientific Field Interviewers (SFIs). Data on maternal SE are also being collected using the General Self-Efficacy Scale (Schwarzer & Jerusalem, 2010). Data collection for the BCHCP takes place prior to randomization, at less than 28 weeks gestation (baseline), and then after randomization at 34 weeks gestation, as well as at two, 10, 18, and 24 months postpartum.

2.3 Study Participants

The sample for this research was n = 631 participants from the BCHCP RCT at baseline, pre-randomization. Participants were therefore young BC women who were preparing to parent for the first time, and who were experiencing socioeconomic disadvantage, according to the BCHCP eligibility criteria presented in Table 2.1 above. As previously mentioned, being under 25 years of age and experiencing socioeconomic disadvantage puts women at an increased risk of smoking cigarettes during pregnancy (Cui et al., 2014). The use of ENDS is also greater among youth and young adults (Chapman & Wu, 2014; Lassen et al., 2010; Ramo et al., 2015). Since being less than

25 years of age and experiencing socioeconomic disadvantage were also BCHCP inclusion criteria, compared to the general population, it was predicted that the current study sample would have a higher proportion of cigarette and ENDS use. Consequently, the results of this research may be particularly helpful in designing intervention strategies for young, pregnant women experiencing socioeconomic disadvantage.

2.4 Research Ethics and Data Access

Research ethics board (REB) approval for the BCHCP was acquired through the BC Ethics Harmonization Initiative. Approvals were obtained from: 1) Fraser Health REB; 2) Vancouver Coastal Health Research Institute; 3) Island Health REB; 4) Interior Health REB; 5) Simon Fraser University Office of Research Ethics (SFU ORE); 6) The University of British Columbia Clinical REB; 7) The University of Victoria Human REB; 8) McMaster University REB; and 9) Health Canada and The Public Health Agency of Canada REB. With confirmation from the SFU ORE, the SFU REB approval obtained for the purposes of the BCHCP was also assigned to the current study. Participant written informed consent was obtained in-person, prior to randomization, and was also attributed to the current study.

2.5 Data Collection

Consent to access de-identified BCHCP data was obtained through the BCHCP Scientific Team. With approval from the SFU ORE, data for this cross-sectional study came from the BCHCP baseline questionnaire, which was administered, by SFIs, in-person, and prior to the participant's 28th week of gestation. Consent and data collection took approximately two hours. SFIs interviewed participants, however all measures with the potential to elicit a social desirability (e.g., questions related to substance use during pregnancy) were administered in a private, participant-driven format. That is, participants listened to an audio recording of a series of personal questions, whilst privately responding on a hard copy answer sheet (i.e., with no SFI involvement). The answer sheet was then put into a sealed envelope and handed back to the SFI to be delivered to the study team. Data collection occurred in a hardcopy format from participant one to 494, and through an electronic REDCap survey thereafter (Harris et al., 2009). All hardcopy data was entered into SPSS and then merged with REDCap data, however all

analyses for the current study were conducted in R, a programming language and software environment for statistical computing and graphics (Harris et al., 2009; IBM Corp, 2013; R Core Team, 2016).

2.6 Measures

The BCHCP baseline questionnaire contains a number of previously validated instruments as well as a series of self-report questions adapted for the RCT. For this study, the variables/scales of interest are identified and expanded upon below.

Demographic information. Participants were asked to report their: 1) current gestational age in weeks; 2) current age in years; 3) range of income; 4) relationship status; 5) ethnicity; and 6) current level of education (for more information on each of these variables, please see Appendix C).

Mode of tobacco/nicotine use. Participants were classified according to mode of tobacco/nicotine (i.e., the independent variable): *cigarette users, combination users, ENDS users,* and *abstainers*. Women who reported using at least one cigarette (or any combustible tobacco product as well as tobacco that is chewed), within the last 48 hours, were categorized as *cigarette users*. Since some ENDS products that claim to be nicotine free still contain traces of nicotine, women who reported the exclusive use of ENDS, with or without nicotine, within the last 48-hours, were categorized as *ENDS users* (Goniewicz et al., 2015). In addition to the exclusive use of ENDS, women who reported the dual use of cigarettes (or any combustible tobacco product as well as tobacco that is chewed) and ENDS, within the last 48 hours, were categorized as combination *users.* Finally, women who reported no use of any tobacco or nicotine product, within the last 48 hours, were categorized as *abstainers*.

Self-efficacy. SE (i.e., the dependent variable) was measured using the General Self-Efficacy Scale, which includes a series of ten items. Each item provides likert-type response options ranging from 1 = Not at all true to 4 = Exactly true. Responses are then summed to create a composite score that ranges between 10 and 40, with higher scores indicating greater levels of self-efficacy (Schwarzer & Jerusalem, 2010). Cronbach's alpha for the scale ranges from 0.76 to 0.90 (Maxson et al., 2012; Luszczynska, Scholz, & Schwarzer, 2005). For more information, please see Appendix B.

Mastery. The Pearlin Mastery Scale measures the extent to which one regards being in control over the forces that affect one's life, in contrast to being ruled by fate or some outside source. The seven item scale provides the following response options: 1 = Strongly agree, 2 = Agree, 3 = Disagree, 4 = Strongly disagree. Items four and six were reverse coded, then all seven answers were summed to create a composite score between seven and 28, with higher scores indicating greater levels of mastery (Pearlin and Schooler, 1978).

Age of onset (ever use of cigarettes). Age of onset (ever use of cigarettes) was measured using the following item "How old were you when you tried your first cigarette in years?" Based on findings from Chen, Stanton, Shankaran, & Li, (2006), a categorical variable was created wherein responses were coded as 1 = Never used cigarettes, 2 = Initiation occurred at less than 16 years of age, 3 = Initiation occurred at 16 years of age or greater.

Age of onset (daily use of cigarettes). Age of onset (daily use of cigarettes) was measured using the following item "How old were you when you first started smoking cigarettes daily in years?" A categorical variable was again created wherein responses were coded as 1 = Never used cigarettes daily, 2 = Initiation of daily use occurred at less than 16 years of age, 3 = Initiation of daily use occurred at 16 years of age or greater.

Diagnosis of depression/anxiety. Participants were asked to indicate a diagnosis of depression or anxiety from a healthcare professional. Responses were dichotomized to represent diagnosed versus undiagnosed.

Pregnancy programs. Participants were asked to indicate their use of prenatal services within the last four weeks, including prenatal classes and various forms of telephone healthcare. The data provided were dichotomized to indicate the use of at least one pregnancy program or none.

Community healthcare services. Participants were asked to indicate the use of community healthcare services within the last four weeks, including family doctor, nurse, midwife, walk-in clinic, emergency room with no overnight stay, obstetrician/gynecologist, and various forms of telephone healthcare. The data provided

were dichotomized to indicate the use of at least one community healthcare service or none.

Alcohol. Prenatal alcohol consumption was measured using the following item "In the last month how often did you drink beer, wine, liquor or any other alcoholic beverage?" Response options ranged from 0 = Not applicable (I have never had any alcoholic beverage) to 8 = Every day. The data provided were dichotomized to indicate consumption versus abstinence in the last month.

Marijuana. Prenatal marijuana use was measured using the following item "In the last month, how often did you use marijuana or hash?" Response options ranged from 1 = Not applicable (I have never used marijuana or hash) to 7 = Every day. The data provided were dichotomized to indicate consumption versus abstinence in the last month.

Other drugs. Other prenatal drug use was measured using the following item "In the last month, how often did you use or try other drugs, such as LSD or mushrooms, ecstasy, cocaine, speed, heroin or crystal meth?" Response options ranged from 1 = Not applicable (I have never used drugs such as hallucinogens, ecstasy, cocaine, or speed) to 7 = Every day. The data provided were dichotomized to indicate consumption versus abstinence in the last month.

Perceived general health status. Perceived general health status was measured using the following item "In general would you say your health is…" Response options ranged from 1 = Excellent to 5 = Poor. The data provided were dichotomized to represent a perceived health status of either good or poor.

2.7 Statistical Analysis

2.7.1 Independent variables.

Three types of variables were included in the model building process: 1) previously identified covariates or variables that had already been identified through previous research as related to the dependent variable (SE); 2) previously identified confounders or variables that had already been identified through previous research as related to the variable of interest (mode of tobacco/nicotine); 3) and potential

confounders or variables that could theoretically be related to the predictor of interest, but had not been identified through a review of the literature. Previously identified covariates were age, education, ethnicity, mastery, and depression/anxiety (for more information please refer to section 1.1). Previously identified confounders were nicotine dependence (measured by age of onset), income, relationship status, drug and alcohol use, perceived general health status, and use of pregnancy programs. Accordingly, these variables were all included in the model building process. Finally, gestational age and use of community healthcare services were also included in the model building process as potential confounders (i.e., to see if they were related to the variable of interest).

2.7.2 Missing data.

Prior to testing, each variable was evaluated for missing data. The evaluation revealed that missing data comprised only 0.28% of the entire dataset. Bennett (2001) maintains that results may be biased when missing data is greater than 10%. Although missing data in the current study accounted for less than 10%, multiple imputation methods were used to create a *complete dataset.* The decision to use multiple imputation was based on the fact that the data was either missing at random (MAR) (i.e., missing data was conditional on another variable), or missing completely at random (MCAR) (i.e., missing data were a random subset of the dataset). According to Bennett (2001), multiple imputation will be unbiased for data that is either MAR or MCAR. Thus, using the multiple imputation by chained equations (MICE) package in R, missing data was imputed with predictive mean matching for continuous variables, logistic regression for dichotomous variables, and polytomous logistic regression for unordered categorical variables (van Buuren & Groothuis-Oudshoorn, 2011). More specifically, missing data was imputed on the stratified data (i.e. according to mode of tobacco/nicotine) for continuous, dichotomous, and categorical variables respectively.

2.7.3 Descriptive statistics.

The sample was first stratified by mode of tobacco/nicotine (abstainers, cigarette users, combination users, and ENDS users) so that a descriptive analysis could be conducted on each of the groups, as well as the entire sample. Categorical variables

were reported as a percentage, whereas continuous variables were reported as a mean and standard deviation.

2.7.4 Bivariate analyses.

To determine the relationship between each independent variable and the dependent variable (SE), a series of bivariate analyses were conducted using Pearson correlations and a one-way analysis of variance (ANOVA). Among the variables that had a significant relationship with SE (i.e., $p \leq 0.05$), collinearity was investigated by evaluating the relationship between each independent variable and the predictor of interest (mode of tobacco/nicotine). Collinearity was investigated using a series of Pearson chi-square tests and a one-way ANOVA.

2.7.5 Multivariate analyses.

The primary hypothesis that SE would differ according to mode of tobacco/nicotine was examined using multiple linear regression with backward selection. First, a full model (Model A), containing each of the independent variables, was created, followed by two more models (Model B and Model C). In Model B, SE was regressed on the predictor of interest (mode of tobacco/nicotine), as well as the variables that were significant in the bivariate analyses (income, perceived general health status, diagnosis of depression/anxiety, education and mastery). Variables that also emerged in Model A as significant predictors of SE were included in Model B (pregnancy programs). Backward selection was then used to refit Model B. In Model C, SE was regressed on the same variables used to construct Model B, however, mastery was removed from Model C because of it's theoretical and statistical similarity with the dependent variable. Backward selection was also used to refit Model C. The assumptions of normality, and homogeneity of variance were investigated on the final model by visually inspecting residual plots. Multicollinearity was investigated on each of the regression coefficients in the final model using a variance inflation factor (VIF) with a cutoff score of 10 (O'brien, 2007). Finally, post hoc comparisons to evaluate specific group differences were conducted using Tukey's HSD.

Chapter 3. Results

3.1 Univariate Outliers

Univariate outliers within SE were identified by visually inspecting a boxplot (See Figure 3.1). Six scores appeared to be deviant (two abstainers scored 22, which is represented by two overlapping dots in Figure 3.1). Although women with low levels of SE are more likely to smoke cigarettes during pregnancy, five of the six deviant scores were abstainers (Naughton et al., 2012). After carefully inspecting each of the deviant scores, no pattern of careless responding or any type of response bias emerged. Outlying participants simply scored between 14 and 22 on SE. The deviant scores were therefore considered meaningful and the decision was made to include all outliers in future calculations and hypothesis tests.

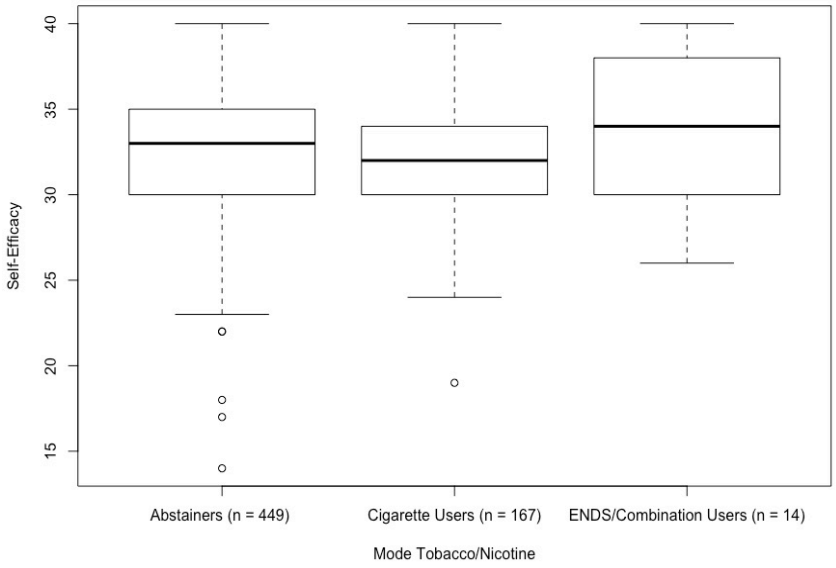

Figure 3-1 Distribution of Self-Efficacy by Mode of Tobacco/Nicotine (n = 630)

3.2 Descriptive Statistics

The sample was first stratified according to mode of tobacco/nicotine (abstainers, cigarette users, combination users, and ENDS users). Information on mode of

tobacco/nicotine was unavailable for one participant (n = 1) who was ultimately excluded from the sample, making the total sample size for the current study n = 630. 164 participants (n = 164) indicated that they had smoked at least one cigarette within the last 48 hours and were therefore classified as cigarette users. In addition, two participants (n = 2) reported smoking Primetime Cigars, and one participant (n = 1) reported smoking pipe tobacco. These participants were also classified as cigarette users making the total sample size for cigarette users n = 167. Six participants (n = 6) reported exclusive use of ENDS and eight participants (n = 8) reported dual use of cigarettes and ENDS. Due to small samples, to increase power, the decision was made to collapse ENDS users with combination users (*ENDS/combination users*). Although combining ENDS users with combination users could dilute the effect of exclusive ENDS use on SE, the conservative nature of this approach (i.e., making it harder to demonstrate group differences) made it the most appealing. The total sample size for ENDS/combination users was therefore n = 14. Next, n = 449 participants reported no use of any tobacco/nicotine products within the last 48 hours and were therefore classified as abstainers.

As predicted, the proportion of cigarette use in the current sample (26.51%, n = 167) was more than double the proportion of use in the general population of pregnant women in Canada (10.5%) (Al-Sahab et al., 2010). Similarly, the proportion of ENDS use in the current study was 2.22% (n = 14), whereas the proportion of use reported by Mark et al. (2015), in a sample of pregnant women who presented to a university clinic, was only 0.60%.

Table 3.1 provides descriptive statistics for the entire sample as well as each of the stratified subsets (i.e., cigarette users, ENDS/combination users, and abstainers). Categorical variables were reported as a percentage, whereas continuous variables were reported as a mean and standard deviation. With respect to the demographic composition of the entire sample, the average age was 19.67 (SD = 2.40) years. The average gestational age was 19.97 (SD = 5.12) weeks. The majority of the sample (56.35%) reported being white in ethnicity. Moreover, a substantial proportion of the sample were in a relationship (76.03%), had a highschool diploma or less (66.98%), and an annual income of less than 10,000 dollars (72.06%). As the composition of the sample demonstrates, BCHCP participants are highly representative of women who are experiencing socioeconomic disadvantage. In addition to assessing the composition of

the entire sample, sample characteristics by mode of tobacco/nicotine are also presented in Table 3.1 below. Both Table 3.1 and Figure 3.1 (above) illustrate differences in average levels of SE across mode of tobacco/nicotine, with cigarette users scoring 31.85 (SD = 3.96), abstainers scoring 32.46 (SD = 3.83), and ENDS/combination users scoring 34.07 (SD = 4.39).

Table 3-1. Descriptive Statistics Stratified by Mode of Tobacco/Nicotine for n = 630 Participants in the BC Healthy Connections Project

Variable		Entire Sample (n = 630) n (%)	Abstainers (n = 449) n (%)	Cigarette Users (n = 167) n (%)	ENDS/Combination Users (n = 14) n (%)
Age (Years)	Mean (SD)	19.67 (2.40)	19.67 (2.43)	19.69 (2.32)	19.29 (2.43)
Gestational Age (Weeks)	Mean (SD)	19.97 (5.12)	19.94 (5.18)	20.23 (4.94)	17.64 (5.23)
Ethnicity	White	355.00 (56.35)	245.00 (54.44)	102.00 (61.08)	8.00 (57.14)
	Non-white	275.00 (43.65)	204.00 (45.33)	65.00 (38.92)	6.00 (42.89)
Education	≤ highschool	422.00 (66.98)	290.00 (64.59)	125.00 (74.85)	9.00 (64.29)
	> highschool	208.00 (33.02)	159.00 (35.41)	42.00 (25.15)	5.00 (35.71)
Income	< 10, 000	454.00 (72.06)	319.00 (71.05)	127.00 (76.05)	11.00 (78.57)
	≥ 10, 000	176.00 (27.94)	130.00 (28.95)	40.00 (23.95)	3.00 (21.43)
Relationship Status	Single	151.00 (23.97)	97.00 (21.60)	51.00 (30.54)	3.00 (21.43)
	In a relationship	479.00 (76.03)	352.00 (78.40)	116.00 (69.46)	11.00 (78.57)
Self-Efficacy	Mean (SD)	32.33 (3.89)	32.46 (3.83)	31.85 (3.96)	34.07 (4.39)
Perceived General Health Status	Good	569.00 (90.32)	414.00 (92.20)	144.00 (86.23)	11.00 (78.57)
	Poor	61.00 (9.68)	35.00 (7.80)	23.00 (13.77)	3.00 (21.43)
Diagnosis Depression/Anxiety	Diagnosed	287.00 (45.56)	184.00 (40.98)	95.00 (56.89)	8.00 (57.14)
	Undiagnosed	343.00 (54.44)	265.00 (59.02)	72.00 (43.11)	6.00 (42.86)
Mastery	Mean (SD)	21.41 (3.07)	21.57 (2.92)	20.85 (3.33)	22.71 (3.75)
Alcohol	Use During Pregnancy	36.00 (5.71)	23.00 (5.12)	13.00 (7.78)	-
	Abstinence	594.00 (94.29)	426.00 (94.88)	154.00 (92.22)	14.00 (100.00)

Marijuana	Use During Pregnancy	157.00 (24.92)	85.00 (18.93)	67.00 (40.12)	5.00 (35.71)
	Abstinence	473.00 (75.08)	364.00 (81.07)	100.00 (59.88)	9.00 (64.29)
Other Drugs	Use During Pregnancy	13.00 (2.06)	3.00 (0.67)	9.00 (5.39)	-
	No Use	617.00 (97.94)	446.00 (99.33)	158.00 (94.61)	14.00 (100.00)
Age of Onset (Ever Use of Cigarettes)	Never Smoked	93.00 (14.76)	92.00 (20.49)	1.00 (0.01)*	-
	< 16 years of age	408.00 (75.98)	258.00 (57.46)	140.00 (84.34)	10.00 (71.43)
	≥ 16 years of age	129.00 (24.02)	99.00 (22.05)	26.00 (15.66)	4.00 (28.57)
Age of Onset (Daily Use of Cigarettes)	Never Smoked Daily	186.00 (29.52)	184.00 (40.98)	1.00(0.01)	1.00 (0.07)
	< 16 years of age	282.00 (44.76)	154.00 (34.30)	120.00 (71.86)	8.00 (57.14)
	≥ 16 years of age	162.00 (25.71)	111.00 (24.72)	46.00 (27.54)	5.00 (35.71)
Pregnancy Programs	Accessed	227.00 (36.03)	153.00 (34.08)	68.00 (40.72)	6.00 (42.86)
	Not Accessed	403.00 (63.97)	296.00 (65.92)	99.00 (59.28)	8.00 (57.14)
Community Healthcare Services	Accessed	612.00 (97.14)	434.00 (96.66)	164.00 (98.20)	14.00 (100.00)
	Not Accessed	18.00 (2.86)	15.00 (3.34)	3.00 (1.80)	-

* One cigarette user did not report age of onset (ever use of cigarettes)

3.3 Bivariate Analyses

The results of the bivariate analyses are presented in Table 3.2 and Table 3.3 below. The Pearson correlations revealed a significant positive relationship between SE and mastery ($p < 0.001$). In addition to mastery, the one-way ANOVA revealed a significant effect of: 1) income ($p = 0.01$); 2) perceived general health status ($p < 0.001$); 3) diagnosis of depression/anxiety ($p < 0.01$); and 4) education ($p = 0.05$), on SE. Mode of tobacco/nicotine, however, did not have a significant effect on SE in the presence of the other independent variables ($p = 0.08$).

Of the variables significantly related to SE, collinearity was evaluated by looking at the relationship between each independent variable and the predictor of interest (mode of tobacco/nicotine). The results are presented in Table 3.4 and Table 3.5 below. Significant relationships were uncovered between mode of tobacco/nicotine and: 1) mastery ($p < 0.01$); 2) diagnosis of depression/anxiety ($p < 0.001$); 3) education; ($p = 0.04$); and 4) perceived general health status ($p = 0.03$).

Importantly, the bivariate analyses revealed that mastery was significantly correlated with both the dependent variable (SE) ($p < 0.001$), and the predictor of interest (mode of tobacco/nicotine) ($p < 0.01$).

Table 3-2 Pearson Product Moment Correlations Between Self-Efficacy and All Continuous Independent Variables (n = 630)

Independent Variables	*r*	*P* *
Gestational Age	-0.01	0.88
Age	0.07	0.10
Mastery	0.52	0.00 ***

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Table 3-3 One-Way Analysis of Variance Between Self-Efficacy and All Categorical Independent Variables (n = 630)

Variable	Degrees of Freedom	Sum Square	Mean Square	*F*	*P* *
Income	1.00	86.00	86.02	6.07	0.01 *
Perceived General Health Status	1.00	292.00	291.58	20.57	0.00 ***
Alcohol	1.00	0.00	0.01	0.00	0.98
Marijuana	1.00	7.00	7.33	0.52	0.47
Other Drugs	1.00	42.00	42.43	2.99	0.08
Mode Tobacco/Nicotine	2.00	71.00	35.66	2.51	0.08
Ethnicity	1.00	8.00	7.57	0.53	0.47
Relationship Status	1.00	30.00	29.62	2.09	0.15
Diagnosis Depression/Anxiety	1.00	134.00	133.51	9.42	0.00 **
Pregnancy Programs	1.00	32.00	31.75	2.24	0.14
Community Healthcare Services	1.00	9.00	8.66	0.61	0.44
Education	1.00	55.00	55.09	3.89	0.05 .
Age Onset Ever Use Cigarettes	2.00	53.00	26.31	1.86	0.16
Age Onset Daily Use Cigarettes	2.00	59.00	19.59	1.38	0.25
Residuals	616	8768	14.23	-	-

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Table 3-4 One-Way Analysis of Variance Between Mode of Tobacco/Nicotine and Mastery (n = 630)

Variable	Degrees of Freedom	Sum Square	Mean Square	*F*	*P* *
Mastery	2.00	88.00	44.48	4.77	0.00 **
Residuals	627	5846.00	9.33		

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Table 3-5 Pearson Chi-Square Tests Between Mode of Tobacco/Nicotine and Independent Variables Significantly Correlated with Self-Efficacy (n = 630)

Variable	X^2	P *
Education	6.36	0.04 .
Diagnosis Depression/Anxiety	13.19	0.00 ***
Perceived General Health Status	7.23	0.03 .
Income	2.25	0.33

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

3.4 Multivariate Analyses

As mentioned above, the hypothesis that SE would differ according to mode of tobacco/nicotine was examined using multiple linear regression. A summary of the regression coefficients and p-values from each model are provided in Table 3.6 below.

3.4.1 Model A.

To start, SE was regressed on a full model containing each of the variables that were measured. The entire output for Model A is presented in Appendix D. Importantly, mode of tobacco/nicotine was not a significant predictor of SE (p = 0.90 and p = 0.21 for cigarette users and ENDS/combination users respectively). Also, the direction of the regression coefficient for cigarette users was incongruent with the mean differences observed in Table 3.1 ($ß$ = 0.04). Given that cigarette users had lower average SE compared to abstainers, a negative regression coefficient would have been expected. With the exception of income and diagnosis of depression/anxiety, all of the variables identified in the bivariate analyses above (mastery, perceived general health status, and education) were significant predictors of SE. Also, a significant positive relationship emerged between SE and the use of pregnancy programs (p = 0.03). Pregnancy programs were therefore included in the construction of each subsequent model (Model B and Model C below). Model A accounted for 28.88% of the variance in SE (F[20, 609] = 13.77, p < 0.001, $R^{2adjusted}$ = 0.29).

3.4.2 Model B.

Next, in addition to the predictor of interest (mode of tobacco/nicotine), Model B was fit using variables that were significantly related to the dependent variable (SE) in

the bivariate analyses (i.e., income, perceived general health status, diagnosis of depression/anxiety, education and mastery). As a significant predictor of SE in Model A, pregnancy programs were also included in the construction of Model B. Through backwards selection, mode of tobacco/nicotine and diagnosis of depression/anxiety were removed from the final model and the *AIC* was reduced from 1504.43 to 1501.39. The output generated, after backward selection, is presented in Appendix E. With the exception of income ($p = 0.13$), each of the variables in the model significantly predicted SE; 1) mastery ($p \leq 0.001$); 2) perceived general health status ($p = 0.02$); 3) education ($p = 0.01$); and 4) pregnancy programs ($p = 0.02$). Furthermore, Model B accounted for 29.15% of the variance in SE ($F[5, 624] = 52.77$ $p = < 0.001$, $R^{2adjusted} = 0.29$).

3.4.3 Model C (final model).

The same variables used to construct Model B were used to construct Model C (i.e., mode of tobacco/nicotine, income, perceived general health status, diagnosis of depression/anxiety, education, and pregnancy programs) However, due to the fact that mastery was significantly related to both the dependent variable (SE) ($p < 0.001$) and the predictor of interest (mode of tobacco/nicotine) ($p < 0.01$), it was removed from Model C. No variables were removed from the model during the backward selection process (*AIC* = 1680.43). The output generated from Model C is presented in Table 3.7 below. Interestingly, with mastery excluded, mode of tobacco/nicotine emerged as a significant predictor of SE. More specifically, SE in ENDS/combination users was 2.07 units greater than abstainers ($p = 0.04$). The direction of the regression coefficient for cigarette users also became congruent with the mean differences observed in Table 3.1 ($ß = -0.24$). Model C accounted for 6.16% of the variance in SE ($F[7, 622] = 6.90$, $p < 0.001$, $R^{2adjusted} = 0.06$).

Taken together, results from Model A, Model B, and Model C suggest that mode of tobacco/nicotine could not be modeled independent of mastery. In other words, mastery was too theoretically and statistically similar to SE. Three findings support this notion. First, the expected direction of the regression coefficient for cigarette users was reversed in the presence of mastery (Model A). Next, in the presence of mastery, mode of tobacco/nicotine was not a significant predictor of SE (Model A) and was removed through backward selection (Model B). Finally, with mastery removed, a significant relationship between mode of tobacco/nicotine and SE was observed. Conceptually,

these variables also measure very similar constructs (for more information about mastery, please see section 1.1 above). For these reasons, although the adjusted r-squared was lower in Model C ($R^{2adjusted}$ = 0.06) compared to Model B ($R^{2adjusted}$ = 0.29), Model C was chosen as the final model. Also, given that the focus of the current study was to examine the relationship between SE and mode of tobacco/nicotine, a model that contained the predictor of interest was essential. If the focus of the current study had been to examine predictors of SE, then due to the higher adjusted r-squared, Model B would have been evaluated further.

Table 3-6 Summary of Multivariate Analyses Predicting Self-Efficacy in n = 630 Participants from the BC Healthy Connections Project

Variable	Model A		Model B		Model C	
	ß	P*	ß	P*	ß	P*
Intercept	15.69	0.00 ***	16.95	0.00 ***	30.28	0.00 ***
Cigarette Users	0.04	0.90	-	-	-0.24	0.49
ENDS/Combination Users	1.13	0.21	-	-	2.07	0.04 .
Age	0.05	0.41	-	-	-	-
Gestational Age	0.01	0.76	-	-	-	-
Income	0.41	0.20	0.47	0.13	0.62	0.08
Ethnicity	-0.08	0.78	-	-	-	-
Education	0.65	0.04 *	0.75	0.01 *	0.73	0.03 .
Relationship Status	-0.05	0.87	-	-	-	-
Perceived General Health Status	1.05	0.02 *	1.08	0.02 *	2.12	0.00 ***
Mastery	0.64	0.00 ***	0.64	0.00 ***	-	-
Diagnosis Depression/Anxiety	-0.32	0.26	-	-	-0.97	0.00 **
Age Onset Ever Use Cigarettes (<16 years of age)	0.66	0.21	-	-	-	-
Age Onset Ever Use Cigarettes (≥16 years of age)	-0.25	0.63	-	-	-	-
Age Onset Daily Use Cigarettes (<16 years of age)	-0.69	0.15	-	-	-	-
Age Onset Daily Use Cigarettes (≥16 years of age)	0.18	0.69	-	-	-	-
Alcohol	0.31	0.59	-	-	-	-
Marijuana	0.28	0.40	-	-	-	-
Other Drugs	-0.53	0.58	-	-	-	-
Pregnancy Programs	0.62	0.03 *	0.68	0.02 *	0.50	0.12
Community Healthcare Services	0.34	0.69	-	-	-	-

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Table 3-7 Multivariate Analysis Predicting Self-Efficacy in n = 630 Participants from the BC Healthy Connections Project (Final Model – Model C)

Coefficients	Estimate	Standard Error	*T*	*P* *
Intercept	30.28	0.57	52.68	0.00 ***
Cigarette users	-0.24	0.35	-0.69	0.49
ENDS/combination users	2.07	1.03	2.02	0.04 .
Income	0.62	0.35	1.74	0.08
Perceived General Health Status	2.12	0.52	4.10	0.00 ***
Diagnosis Depression/Anxiety	-0.97	0.31	-3.13	0.00 **
Education	0.73	0.33	2.17	0.03 .
Pregnancy Programs	0.50	0.32	1.57	0.12

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

3.5 Multicollinearity

Due to the fact that diagnosis of depression/anxiety, education, and perceived general health status were all significantly correlated with the predictor of interest, a VIF was calculated for each of the regression coefficients in Model C (see Table 3.8 below). The VIF did not exceed the suggested cut-off of 10 for any of the variables in Model C (O'brien, 2007). Thus, the variance of the regression coefficients was not exceedingly inflated. Simply put, there was no indication of multicollinearity in the final model (Model C).

Table 3-8 Variance Inflation Factor For Model C (n = 630)

Variable	Generalized Variance Inflation Factor	Degrees of Freedom	GVIF = VIF^[1/(2*df)]
Mode of Tobacco/Nicotine	1.04	2	1.01
Income	1.11	1	1.06
Perceived General Health Status	1.03	1	1.02
Diagnosis Depression/Anxiety	1.05	1	1.03
Education	1.10	1	1.05
Pregnancy Programs	1.04	1	1.02

3.6 Assumptions

In addition to meeting the assumption of independence of observations, and to addressing multicollinearity, residual plots were created for Model C in order to visually inspect the assumptions of normality and homogeneity of variance. The plots are presented in Figure 3.2 below. The residual versus fitted plot suggests constant variance

across x-values and therefore a linear relationship between the predictors and SE. The normal Q-Q plot, however, suggests that the data came from a distribution that was negatively skewed. However, as a consequence of the central limit theorem, the sampling distribution of the sample means will always approach normality regardless of the shape of the underlying distribution. Due to the central limit theorem, and to allow for ease of interpretation of the regression coefficients, SE was not transformed (i.e., left in it's original units). Finally, none of the observations had a Cook's distance value of greater than one. Thus, none of the outliers that were previously identified had high leverage (i.e., none were influencing the slope of the regression line).

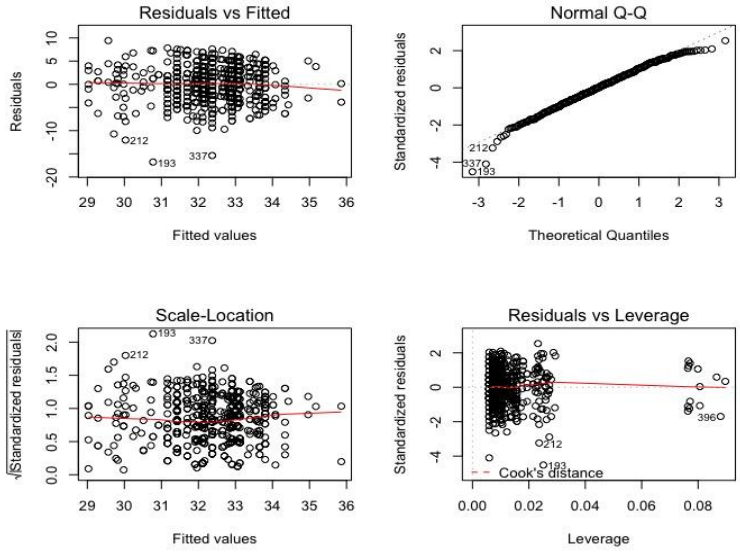

Figure 3-2 Residual versus Fitted, Normal Q-Q, Scale-Location, and Resdiuals versus Leverage Plots for Model C

3.7 Post Hoc Tests

With the assumptions of Model C satisfied, a one-way ANOVA was conducted and the significant main effect of mode of tobacco/nicotine on SE was evaluated using Tukey's HSD (See Table 3.9 below). Although a significant difference in average SE between abstainers and ENDS/combination users was established in Model C, post hoc comparisons revealed no significant differences between any levels of the predictor of interest. Compared to the one-way ANOVA, the Tukey procedure controls the type I error rate and limits false-positive results. It therefore requires a larger sample size and effect in order to identify significance. The main effect (mode of tobacco/nicotine on SE)

that was established was likely due to the fact that the one-way ANOVA and multiple linear regression were better able to detect lower variability around the mean. Overall, the results from the Tukey analysis are congruent with the previous analyses given that the effect measures are in the same direction and the p-values are almost significant. The results demonstrate that there is some arbitrariness in the convention that p-values less than 0.05 are considered significant.

Table 3-9 Tukey's HSD for Main Effect of Mode of Tobacco/Nicotine on Self-Efficacy

Mode Tobacco/Nicotine	Difference	Lower	Upper	*P**
Cigarette Users Versus Abstainers	- 0.60	- 1.40	0.20	0.19
ENDS/Combination Users Versus Abstainers	1.62	- 0.78	4.03	0.25
ENDS/Combination Users Versus Cigarette Users	2.22	- 0.24	4.69	0.09

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

3.8 Summary of Findings

The results generated from Model C suggest that the null hypothesis (mean levels of SE are equal among pregnant cigarette users, ENDS/combination users, and abstainers) can be rejected with $\alpha \leq 0.05$. More specifically, SE was found to be significantly higher in ENDS/combination users compared to abstainers ($p = 0.04$). Due to the small sample size, further research is needed to definitively confirm this result. Furthermore, although non-significant, results from Model C suggest that SE may be somewhat lower in cigarette users compared to abstainers ($p = 0.49$). Finally, although non-significant, results generated from the Tukey procedure suggest that SE may also be somewhat lower in cigarette users compared to ENDS/combination users ($p = 0.09$). SE was therefore found to be highest in ENDS/combination users, followed by abstainers, then cigarette users, with a significant difference between ENDS/combination users and abstainers.

Chapter 4. Discussion

While identified as the strongest cognitive determinant of cigarette use during pregnancy, prior to this study, SE had not yet been evaluated in pregnant ENDS users. (please see section 1.4 and Appendix A) (Naughton et al., 2012; Maxson et al., 2012). It was therefore unclear whether the inverse relationship between SE and prenatal cigarette use was also true for prenatal ENDS users. Examining SE in pregnant ENDS users is important given: 1) the recent surge in unregulated ENDS use among youth and young adults; 2) the associated health risks; and 3) a lack of research on the prevalence of the use of ENDS during pregnancy (Gaither et al., 2009; Ramo et al., 2015). This study was the first to evaluate SE in pregnant ENDS users. Consequently, the results may be used to tailor intervention strategies according to the mode of tobacco/nicotine being used, thereby improving effectiveness. This study was also the first to report prevalence rates for the use of ENDS among participants in the BCHCP. Knowing the proportion of pregnant women who use ENDS in the BCHCP will help to inform which populations are most at risk and therefore in need of tailored interventions. That said, the current study aimed to uncover differences in SE according to mode of tobacco/nicotine. Of particular interest was how cigarette users differed from ENDS users. It was hypothesized that group differences in average SE would be observed. More specifically, a gradient in SE was expected wherein abstainers demonstrated the highest levels, followed by ENDS users, then combination users, and finally cigarette users.

4.1 Pairwise Comparisons

4.1.1 ENDS/combination users versus cigarette users.

The main objective of this study was to answer the question “Is there a difference in SE between pregnant women who use cigarettes versus ENDS?” Unfortunately, small samples motivated the decision to increase power by collapsing ENDS with combination users. In doing so, the main objective of this study could not be fully achieved. However, the results suggest that no statistically significant difference in SE exists between pregnant cigarette users and ENDS/combination users. It is important to note that although the results did not reach statistical significance, a trend in the expected direction was present. That is, ENDS/combination users had higher average SE

compared to cigarette users. With a larger sample size, the results may have reached significance, with $\alpha \leq 0.05$. Also, combination users may have diluted the effect, making it harder to detect a difference between the groups. This trend implies that women who use ENDS, or a combination of ENDS and cigarettes, may be more confident in their ability to quit an unhealthy behaviour compared to cigarette users. Although inconclusive, this suggests that pregnant women may not be using ENDS recreationally or in the same fashion as cigarettes. Instead, they may be using ENDS for the purposes of either harm reduction or cessation. More qualitative research is needed to determine whether this is accurate. Nevertheless, these findings suggest that intervention strategies for cigarette users may be less effective for exclusive ENDS users, as well as dual users of both cigarettes and ENDS.

4.1.2 ENDS/combination users versus abstainers.

The second, broader objective of this study was to identify group differences in SE between pregnant: 1) cigarette users; 2) ENDS/combination users*;* and 4) abstainers. The null hypothesis was rejected; however, the only observed difference in SE that reached statistical significance was between abstainers and ENDS/combination users. Surprisingly, ENDS/combination users demonstrated higher average SE compared to abstainers, when the opposite was predicted to be true. The expectation that SE would be higher in abstainers was based on previous research that found higher SE in quitters compared to cigarette users (deVries & Backbier, 1994; de Vries, Dijkstra & Kuhlman, 1988; Slade at al., 2006). The current findings are especially surprising given that cigarette users were included in the combination user group. Also, having the power to detect an effect such as this was unanticipated given the notably low sample size in the ENDS/combination user group (n = 14). For this reason, these results should be interpreted with caution. Unlike the results that were generated from the multiple linear regression and one-way ANOVA, stricter post hoc comparisons revealed no statistically significant differences between any of the groups. Also, wide confidence intervals for the observed difference in mean SE suggest that these results lack precision. Although large confidence intervals undermine the reliability of these results, findings from Stotts, DiClemente, Carbonari, and Mullen (1996) provide a possible interpretation. By comparing pregnant quitters to non-pregnant quitters, Stotts et al. (1996) found that SE was significantly higher during pregnancy. Although both

populations quit smoking and were found to be in the action stage of change, the pregnant women in their study demonstrated higher SE. Stotts et al. (1996) concluded that pregnancy represents an exceptional time when external factors, such as the baby's health, contribute to one's motivation to quit an unhealthy behaviour, such as smoking cigarettes. Thus increased motivation to quit smoking cigarettes while pregnant (i.e., for the baby's health) may explain higher average SE in ENDS/combination users compared to abstainers.

4.1.3 Cigarette users versus abstainers.

Findings from the current study may also be used to validate previous research that has shown that SE is typically lower in pregnant cigarette smokers compared to those who quit (deVries & Backbier, 1994). For example, though non-significant, the current study found that SE was lower in pregnant cigarette users compared to abstainers. However, caution should also be taken when interpreting and comparing these results. Another considerable limitation to the methodology of the current study was the potential for group contamination and the inability to distinguish between quitters (i.e., women who smoked previously) or those who had never used (i.e., women who never smoked). For example, women were categorized according to mode of tobacco/nicotine, based on use *within the last 48 hours*. This time frame may have been too short to accurately categorize participants. For instance, participants who smoked cigarettes outside of the aforementioned timeframe may have reported no use of tobacco/nicotine in the last 48 hours. These participants would have incorrectly been categorized as abstainers. Similarly, it is unclear whether abstainers were actually quitters or had never used.

To summarize the current findings, first, no significant difference in SE between cigarette users and ENDS/combination users was observed. However, there was a clear trend in the expected direction, such that ENDS/combination users had higher SE compared to cigarette users. That is, women who use ENDS during pregnancy, or a combination of ENDS and cigarettes, may be more confident in their ability to quit an unhealthy behaviour compared to cigarette users. Although inconclusive, pregnant women may therefore be using ENDS for the purposes of either harm reduction or cessation. However, more research is needed to confidently make this interpretation. This finding also suggests that tailored intervention strategies may be necessary for

these particular modes of tobacco/nicotine. Next, ENDS/combination users also had significantly higher SE compared to abstainers. This finding was particularly surprising and should be evaluated with caution. Nonetheless, increased motivation to quit for the baby's health, may explain higher SE in ENDS/combination users compared to abstainers. Finally, despite being non-significant, SE was lower in pregnant cigarette users compared to abstainers. Although it is unclear whether abstainers are actually never users or quitters, these results appear to validate previous research that has shown that SE is typically lower in pregnant cigarette smokers compared to those who quit.

4.2 The Transtheoretical Model of Change

Results from the current study do not necessarily endorse the notions declared by the TTM. Namely, as individuals progress through the stages of change, SE is said to increase, and the unhealthy behaviour is said to decrease (Prochaska & Velicer, 1997). Surprisingly, this study found the opposite to be true. That is, compared to abstainers, those who were still using tobacco/nicotine had significantly higher SE. More specifically, ENDS/combination users had significantly higher SE compared to abstainers. Although stage classifications were not explicitly carried out in this study, higher average SE suggests that women using ENDS, or a combination of ENDS and cigarettes, were in a later stage of change (e.g., action and maintenance), compared to abstainers (e.g., precontemplation, contemplation, and preparation). Although causation cannot be inferred from these results, one could speculate that lower levels of SE, observed in abstainers, were the result of being in an earlier stage of change, whereas higher levels of SE, observed in ENDS/combination users, were the result of being in a later stage of change. By conducting stage classifications on pregnant women prior to measuring SE, future research (i.e., a prospective cohort study) would facilitate the clarification of this notion.

4.3 Limitations

Results from the current study should be interpreted with caution. First, a considerable limitation was the small sample in the ENDS/combination user group. Although a significant difference between ENDS/combination users and abstainers was

obtained using multiple linear regression and a one-way ANOVA, the stricter post hoc comparisons revealed no statistically significant differences between any of the groups. Also, wide confidence intervals for the observed difference in mean SE suggest that these results lack precision. A type I error, or false positive, may be responsible for the significant difference. Further follow-up studies are therefore needed to confirm this study's findings.

Next, due to a methodological limitation, the proportion of ENDS use reported in this study was somewhat conservative in nature. To clarify, mode of tobacco/nicotine use was derived from two questions that asked about the use of cigarettes and ENDS, within the last 48 hours. Unlike the question regarding cigarettes, the question regarding ENDS was included in the BCHCP baseline questionnaire part way through the RCT. When it became apparent that ENDS were increasing in popularity among BCHCP participants, the decision was made to capture this information. Questions regarding the use of ENDS were first administered to participant 293. Since ENDS use was only captured in the last 338 participants, the reported proportion of use of these products, albeit conservative, was also a substantial underestimate. The proportion of ENDS/combination use in the entire sample was 2.22%, however a more accurate estimate, using only participants who were actually questioned about the use of ENDS, would be 4.14%.

Group contamination should also be acknowledged as a considerable drawback to this research. For example, women in this study were categorized according to mode of tobacco/nicotine, based on use *within the last 48 hours*. The time frame that was used may have been too short to accurately represent the use of various modes of tobacco/nicotine, resulting in group contamination and a reduced ability to demonstrate an effect. Another consequence of adding questions about the use of ENDS part way through the RCT is that women who reported using cigarettes within the last 48 hours were coded as cigarette users, whereas women who reported no use of cigarettes were coded as abstainers. These women may have actually been ENDS/combination users. Similarly, determining whether abstainers are actually quitters (i.e., women who smoked previously) or never users (i.e., women who never smoked) cannot be established from this study's methodology.

Finally, a distinction should be made between general SE and SE as it relates to quitting smoking. Whereas general SE refers more globally to the conviction one has to successfully execute a behaviour, SE for quitting smoking refers more specifically to the conviction one has for successful cessation (Luszczynska et al., 2005). Although it has been shown that the General Self-Efficacy Scale is sensitive to some specific health-related behaviours, research has found that it does not consistently capture SE as it relates to quitting smoking (Luszczynska et al., 2005). A smoking-specific SE scale may have been more sensitive to subtle group differences.

4.4 Implications for Public Health

Significantly higher SE in ENDS/combination users compared to abstainers, and a trend towards higher SE in ENDS/combination users compared to cigarette users, suggests that ENDS/combination users are more confident in their ability to perform the actions required to quit an unhealthy behaviour. In addition, more than half of the ENDS/combination users were combination users, or dual users of cigarettes and ENDS (n = 8). Taken together, these findings raise the question “Are ENDS/combination users using ENDS for harm reduction, rather than recreation, at least during pregnancy?” Although there is a lack of qualitative data in the current study to directly answer such a question, the possibility that ENDS are being used in this manner has substantial implications for public health.

Given that e-liquid may contain either more or less nicotine than levels declared on product packaging, that nicotine is harmful to the fetus, and that many women are unaware of the harmful effects of ENDS, greater efforts are required to prevent the use of ENDS during pregnancy (Baeza-Loya, 2014; Coleman et al., 2011; Goniewicz et al., 2015). Compared to the Mark et al. (2015) study, a greater proportion of women in this sample used ENDS during pregnancy (2.22% or 4.14% of those who were questioned about ENDS). The women in the current study were less than 25 years of age and experiencing socioeconomic disadvantage (e.g., low education, low income, or lone parenting). The use of ENDS during pregnancy may therefore be overrepresented among youth and young adults as well as women who are experiencing socioeconomic disadvantage. This finding should be taken into account when determining the conditions under which ENDS should be sold. For example, low-literacy health warning labels should be attached to ENDS products, especially those that are known to contain

nicotine. Given that nicotine-free ENDS may still contain traces of nicotine, until they are more strictly regulated by Health Canada, low-literacy health warning labels should also be attached to these products. Also, despite the initial cost for an ENDS start-up kit, many companies that sell ENDS claim that e-liquid refills, in the long run, are actually cheaper than cigarettes, which may appeal to women experiencing low income ("How much will e-cigarette cost compared to cigarettes," n.d.). Increasing the cost of e-liquid refills may therefore prevent, or at least deter, women from using these products during pregnancy. Finally, greater efforts are needed to prevent youth and young adults from experimenting with ENDS and ultimately developing new habits (Chapman & Wu, 2014). BC's Tobacco and Vapour Products Control Act now prevents anyone under the age of 19 from legally purchasing ENDS or ENDS-related products (Bill C-145, 2016). However, fruit and candy-flavoured e-liquid may be particularly enticing to youth. For example, according to the 2010/2011 Youth Smoking Survey, 52% of Canadian youth smokers used some form of flavoured tobacco within the last 30 days (Minaker, 2014). Therefore, to prevent youth and young adults from initiating new habits, fruit and candy-flavoured ENDS products should be prohibited.

In addition to increasing awareness of the risks that are known, more data are needed to determine the effect of ENDS on respiratory health. In particular, more research is needed to determine whether the compounds in e-liquid are safe when inhaled. More data are also needed to determine whether these compounds could effect a developing fetus when inhaled. Many argue that there is a pressing need to quickly regulate ENDS in Canada (Branswell, 2015). At the vey least, heightened control over manufacturing standards would provide pregnant women with an accurate estimate of the amount of nicotine they are consuming via ENDS. However, more research is needed in order to justify the regulation of these products. For example, a recent study conducted by Allen et al. (2016) revealed that diacetyl, a chemical linked to lung disease when inhaled, was detected in 39 of 51 types of the flavoured ENDS products that were tested. Knowing how diacetyl effects fetal health through the maternal use of ENDS is an important question that still needs to be addressed. Thus, more research on maternal and fetal health outcomes, associated with ENDS, should be conducted prior to allowing these products to be made available on the market for public consumption.

4.5 Conclusions

First, this research was unable to comment on exclusive ENDS use or combination use independently due to small sample sizes. A larger sample would allow ENDS/combination users to be broken down into their respective modes of use, without compromising statistical power. In doing so, SE could be evaluated, as this study intended, among pregnant cigarette users, exclusive ENDS users, combination users, and abstainers. Future research should therefore consider replicating this study with a much larger group of both exclusive ENDS users and combination users. Given that ENDS/combination users had only slightly higher SE compared to cigarette users, it would be interesting to see if group differences reached significance with a larger sample. This would, in turn, provide a stronger justification for the need to tailor intervention strategies according to ENDS versus cigarette use. Larger samples may also facilitate the ability to distinguish between pregnant women who use ENDS with nicotine versus ENDS that claim to be nicotine-free.

Preventing group contamination, by using a wider time frame to capture mode of tobacco/nicotine use would also elicit more accurate results and a greater chance of finding an effect. Likewise, being able to distinguish quitters from never users would support the ability to validate and extend previous research in a more precise fashion. For example, deVries and Backbier (1994) found lower SE in pregnant cigarette smokers compared to those who quit. Similarly, the current study found that SE was lower in cigarette users compared to abstainers. Although these results appear to validate the deVries and Backbier (1994) findings, quitters would provide a more accurate comparison. By asking more extensive questions about ‘ever use’ of various modes of tobacco/nicotine, and by extending the time frame used to capture this information, future research could prevent group contamination and ultimately improve upon this study’s methodology.

Given that this study only focused on the relationship between SE and ENDS, and that nicotine is harmful to the fetus, more research is needed to evaluate SE in other products that contain nicotine, such as NRT (Agrawal et al., 2010; Cnattingius, 2004). Intervention strategies would benefit from the identification of characteristics that are also unique to women who use various types of NRT during pregnancy.

Finally, knowing that ENDS/combination users differ from cigarette users on SE means that ENDS/combination users should not be treated the same as women who exclusively use cigarettes. By providing an operational definition for the term *smoking*, future research would allow more accurate generalizations to be made. By commenting more specifically on the mode of tobacco/nicotine being used, researchers will be better able to highlight differences between users, thereby enhancing intervention strategies, increasing cessation rates, and ultimately improving maternal and child health.

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Appendix A – Self-Efficacy and Alternative Nicotine Delivery During Pregnancy

Background

Regarding the use of nicotine during pregnancy, contributing factors have been identified in an attempt to develop effective prevention strategies. Among these factors, self-efficacy (SE), the confidence one has in their ability to perform a task, has been described as the strongest cognitive determinant of cigarette use during pregnancy (Naughton, Prevost, Gilbert & Sutton, 2012; Maxson, Edwards, Ingram & Miranda, 2012). In fact, the odds of prenatal cigarette use are reduced in women with higher levels of SE (Maxson et al., 2012; Morasco et al., 2006; Mullen, Pollak & Gerjo, 1999; Quinn, Mullen & Ershoff, 1991; Thyrian et al., 2006; Woodby et al., 1999). However, research on SE rarely provides an operational definition for the term *smoking*. In other words, research on SE rarely distinguishes among women who use different forms of nicotine (i.e., smoked tobacco products versus nicotine replacement therapy [NRT] versus e-cigarettes or electronic nicotine delivery systems [ENDS]).

Objective

Thus, the purpose of this review was to identify differences in SE between pregnant women who use: 1) combustible tobacco products; 2) NRT; and 3) ENDS (with or without nicotine)

Methods

Databases Searched

Cochrane Database of Systematic Reviews, MEDLINE, and PsycINFO

Search Topics

Topic 1. SE and the use of combustible tobacco products during pregnancy
Topic 2. SE and the use of NRT during pregnancy
Topic 3. SE and the use of ENDS (with or without nicotine) during pregnancy

Search Terms Used for Topic 1

Self-Efficacy/Confidence + Pregnancy + Smoking/Cigarettes
Systematic Review + Self-Efficacy + Pregnancy + Smoking
Stages of Change + Pregnancy + Smoking
Transtheoretical Model + Pregnancy + Smoking

Search Terms Used for Topic 2

Self-Efficacy + Pregnancy + Nicotine Replacement Therapy

Search Terms Used for Topic 3

Self-Efficacy + Pregnancy + E-Cigarettes/Electronic Nicotine Delivery Systems

Inclusion Criteria

1. Articles published between 1990 and 2015 (inclusive)
2. Use of systematic reviews, cross-sectional designs, cohort design, randomized-controlled trials (RCTs) methodology
3. Sample consists of pregnant women
4. SE mentioned in title or abstract

Exclusion Criteria

1. Dissertations
2. SE measured during the postpartum or later

Results

The purpose of this review was to evaluate whether an inverse relationship exists between SE and the use of alternative nicotine delivery systems during pregnancy, including NRT and ENDS (with or without nicotine). This review was conducted between September 2015 and October 2015. The Cochrane Database of Systematic Reviews, MEDLINE, and PsycINFO were searched with the goal of identifying differences in SE between pregnant women who use: 1) combustible tobacco products (topic one), 2) NRT

(topic two), and 3) ENDS with or without nicotine (topic three). To be screened, studies were required to meet all four of the inclusion criteria (presented above). Studies were then disqualified from the review if they met either one of the two exclusion criteria (also presented above). Of the 2814 hits, 11 met inclusion criteria. A duplicate hit (i.e., a study that was identified twice through various search strategies) occurred for 10 of the 11 studies. Of the 11 studies that met inclusion criteria, two measured SE in the postpartum and were disqualified (for a summary of the studies meeting exclusion criteria, please see Table A.2 below). A total of nine studies were therefore included in the review (for a summary of the studies reviewed, please see Table A-3 below). A hit summary is presented in Figure A-1 and Table A-1 below.

Although the objective of the review was to evaluate whether an inverse relationship exists between SE and the use of alternative nicotine delivery systems during pregnancy, none of the studies identified specifically focused on the use of NRT or ENDS. In fact, the majority of the studies reviewed neglected to specify the mode of tobacco/nicotine under investigation.

Among the nine studies reviewed, three used a cohort design, four used a cross-sectional design, and two were RCTs. More than half of the studies reviewed neglected to operationalize the term smoking (n = 5). The four remaining articles operationalized smoking as the use of cigarettes. All of the cross-sectional and cohort studies uncovered a significant negative relationship between SE and smoking or cigarette use during pregnancy, such that higher levels of SE were associated with a greater likelihood of abstinence. One RCT, conducted by Naughton et al. (2012), evaluated a tailored intervention called MiQuit, and operationalized smoking as the use of cigarettes. Conversely, Stotts, DeLaune, Schmitz, and Grabowski (2004) RCT examined treatment mechanisms affected by a motivational interviewing intervention and did not operationalize SE. In both RCTs, SE was higher in the treatment group, but neither significantly reduced smoking/cigarette use. It is important to note that, although non-significant, the abstinence rates in the Naughton et al. (2012) trial were higher in the intervention arm. Similarly, the intervention participants in the Stotts et al. (2004) trial were more likely to set a quit date, suggesting that in addition to improving SE, both interventions had a minor effect on abstinence rates.

To summarize, the review revealed no literature on SE in pregnant women who use ENDS or NRT. The relationship between SE and the use of alternative nicotine delivery during pregnancy remains unclear. More research is therefore needed to determine whether an inverse relationship exists between the use of alternative nicotine delivery systems and SE, during pregnancy.

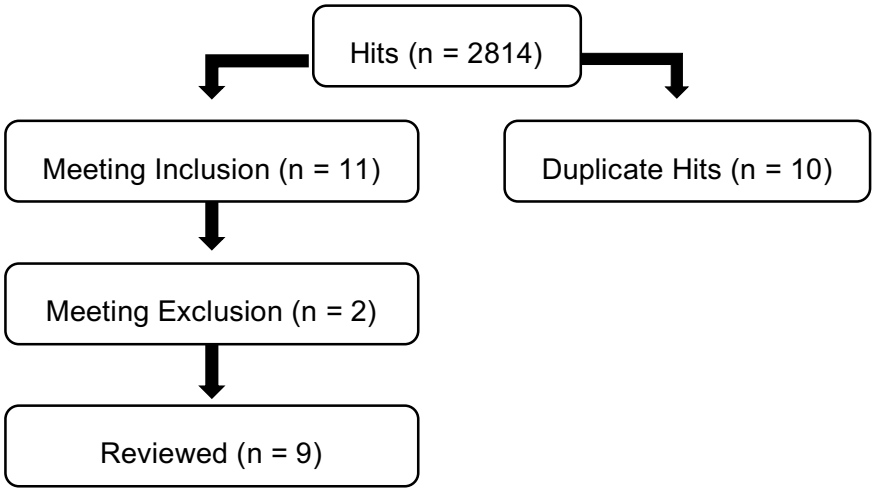

Figure A-1 Flow Chart of Review

Table A-1 Hit Summary

Database	Search Terms	Total Number of Hits	Number of Hits Meeting Inclusion Criteria		Number of Studies Meeting Exclusion Criteria
			Duplicate Hit **	Novel	
Cochrane DSR *	Self-Efficacy + Pregnancy + Smoking	0	N/A	0	0
	Confidence + Pregnancy + Smoking	0	N/A	0	0
	Self-Efficacy + Pregnancy + Cigarettes	0	N/A	0	0
	Self-Efficacy + Pregnancy + E-Cigarettes	0	N/A	0	0
	Self-Efficacy + Pregnancy + Electronic Nicotine Delivery Systems	0	N/A	0	0
	Self-Efficacy + Pregnancy + Nicotine Replacement Therapy	0	N/A	0	0
	Stages of Change + Pregnancy + Smoking	0	N/A	0	0
	Transtheoretical Model + Pregnancy + Smoking	0	N/A	0	0
PsycINFO	Self-Efficacy + Pregnancy + Smoking	54	N/A	9	1
	Confidence + Pregnancy + Smoking	236	0	0	0
	Confidence (title) + Pregnancy (title) + Smoking (title)	0	0	0	0
	Self-Efficacy + Pregnancy + Cigarettes	11	0	0	0
	Systematic Review + Self-Efficacy + Pregnancy + Smoking	1	0	0	0
	Self-Efficacy + Pregnancy + E-Cigarettes	0	0	0	0
	Self-Efficacy + Pregnancy + Electronic Nicotine Delivery Systems	0	0	0	0
	Self-Efficacy + Pregnancy + Nicotine Replacement Therapy	4	0	0	0
	Stages of Change + Pregnancy + Smoking	40	3	1	0
	Transtheoretical Model + Pregnancy + Smoking	23	4	0	1
MEDLINE	Self-Efficacy + Pregnancy + Smoking	96	0	0	0
	Self-Efficacy (title/abstract) + Pregnancy (title/abstract) + Smoking (title/abstract)	0	0	0	0
	Confidence + Pregnancy + Smoking	2299	0	0	0
	Confidence (title/abstract) + Pregnancy (title/abstract) + Smoking (title/abstract)	0	0	0	0
	Self-Efficacy + Pregnancy + Cigarettes	4	0	1	0
	Systematic Review + Self-Efficacy +	0	0	0	0

	Pregnancy + Cigarettes				
	Self-Efficacy + Pregnancy + E-Cigarettes	1	0	0	0
	Self-Efficacy + Pregnancy + Electronic Nicotine Delivery Systems	0	0	0	0
	Self-Efficacy + Pregnancy + Nicotine Replacement Therapy	10	0	0	0
	Stages of Change (title/abstract) + Pregnancy (title/abstract) + Smoking (title/abstract)	18	1	0	0
	Transtheoretical Model + Pregnancy + Smoking	17	2	0	0
Total		2814	10	11	2
Total Number of Studies Reviewed		9			

* Cochrane Database of Systematic Reviews

** A study that was identified twice through various search strategies

Table A-2 Articles Meeting Exclusion Criteria For Review

Reference	Database	Reason for Exclusion
Lee, M., Miller, S. M., Wen, K., Hui, S. A., Roussi, P., & Hernandez, E. (2015). Cognitive-behavioral intervention to promote smoking cessation for pregnant and postpartum inner city women. Journal of Behavioral Medicine, doi:10.1007/s10865-015-9669-7	PsycINFO	SE assessed during postpartum
Prusakowski, M. K., Shofer, F. S., Rhodes, K. V., & Mills, A. M. (2011). Effect of depression and psychosocial stressors on cessation self-efficacy in mothers who smoke. Maternal and Child Health Journal, 15(5), 620-626. doi:10.1007/s10995-010-0640-5	PsycINFO	SE assessed during postpartum

Table A-3 Articles Meeting Inclusion Criteria For Review

Reference	Database	Search Terms	Mode of Nicotine Investigated	Results
Cross-Sectional Designs				
devries, H., & Backbier, E. (1994). Self-efficacy as an important determinant of quitting among pregnant women who smoke: The ø-pattern. *Preventive Medicine, 23*(2), 167-174. doi:10.1006/pmed.1994.1023	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	Significant negative relationship between SE and smoking/cigarettes during pregnancy
Morasco, B. J., Dornelas, E. A., Fischer, E. H., Oncken, C., & Lando, H. A. (2006). Spontaneous smoking cessation during pregnancy among ethnic minority women: A preliminary investigation. Addictive Behaviors, 31(2), 203-210.	MEDLINE	Self-efficacy + Pregnancy + Cigarettes	Cigarettes	
Slade, P., Laxton-Kane, M., & Spiby, H. (2006). Smoking in pregnancy: The role of the transtheoretical model and the mother's attachment to the fetus. Addictive Behaviors, 31(5), 743-757.	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	
Stotts, A. L., Diclemente, C. C., Carbonari, J. P., & Mullen, P. D. (1996). Pregnancy smoking cessation: A case of mistaken identity. Addictive Behaviors, 21(4), 459-471. doi:10.1016/0306-4603(95)00082-8	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	
Cohort Designs				
Maxson, P. J., Edwards, S. E., Ingram, A., & Miranda, M. L. (2012). Psychosocial differences between smokers and non-smokers during pregnancy. Addictive Behaviors, 37(2), 153-159.	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	Significant negative relationship between SE and smoking/cigarettes during pregnancy
Quinn, V. P., Mullen, P. D., & Ershoff, D. H. (1991). Women who stop smoking spontaneously prior to prenatal care and predictors of relapse before delivery. Addictive Behaviors, 16(1-2), 29-40. doi:10.1016/0306-4603(91)90037-I	PsycINFO	Self-efficacy + Pregnancy + Smoking	Cigarettes	
Woodby, L. L., Windsor, R. A., Snyder, S. W., Kohler, C. L., & Diclemente, C. C. (1999). Predictors of smoking cessation during pregnancy. Addiction, 94(2), 283-292. doi:10.1046/j.1360-	PsycINFO	Self-efficacy + Pregnancy + Smoking	Cigarettes	

0443.1999.94228311.x				
Randomized Controlled Trials				
Naughton, F., Prevost, A. T., Gilbert, H., & Sutton, S. (2012). Randomized controlled trial evaluation of a tailored leaflet and SMS text message self-help intervention for pregnant smokers (MiQuit). Nicotine & Tobacco Research, 14(5), 569-577. doi:10.1093/ntr/ntr254	PsycINFO	Self-efficacy + Pregnancy + Smoking	Cigarettes	Treatment improved SE, but had no significant effect on abstinence
Stotts, A. L., DeLaune, K. A., Schmitz, J. M., & Grabowski, J. (2004). Impact of a motivational intervention on mechanisms of change in low-income pregnant smokers. Addictive Behaviors, 29(8), 1649-1657.	PsycINFO	Self-efficacy + Pregnancy + Smoking	Smoking (mode not specified)	

Appendix B – General Self-Efficacy Scale

Table B-1 General Self-Efficacy Scale (Schwarzer & Jerusalem, 2010)

Item	Not At All True	Hardly True	Moderately True	Exactly True
1. I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
2. If someone opposes me, I can find the means and ways to get what I want.	1	2	3	4
3. It is easy for me to stick to my aims and accomplish goals.	1	2	3	4
4. I am confident that I could deal efficiently with unexpected events.	1	2	3	4
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
6. I can solve most problems if I invest the necessary effort.	1	2	3	4
7. I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
8. When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
9. If I am in trouble, I can usually think of a solution.	1	2	3	4
10. I can usually handle whatever comes my way.	1	2	3	4

Appendix C – Variable Summary

Table C-1 Variable Summary

Variable Name	Measurement	Type
Self-Efficacy (Dependent Variable)	General Self-Efficacy Scale 10 questions 1=Not at all true 2=Hardly true 3=Moderately true 4=Exactly true Responses are summed to create a composite score between 10 and 40.	Treating as Continuous
Tobacco/Nicotine Use (Independent Variable)	0=Abstainers: Women who self-report no tobacco or nicotine use within the last 48 hours. 1=Cigarette Users: Women who self-report the use of cigarettes, within the last 48 hours. 2=ENDS/combination: Users: Women who self-report the use of ENDS with or without nicotine within the last 48-hours + Women who self-report the dual use of both cigarettes and ENDS within the last 48 hours.	Categorical
Current Gestational Age	Weeks	Continuous
Current Age	Years	Continuous
Sense of Mastery	Pearlin Mastery Scale 7 questions 1=Strongly agree 2=Agree 3=Disagree 4=Strongly disagree Questions 4 and 6 are reverse coded and then all 7 are summed to create a composite score between 7 and 28.	Treating as Continuous
Age of Onset (Ever Use of Cigarettes)	How old were you when you tried your first cigarette in years? 1 = Never smoked 2 < 16 3 ≥ 16 (Categorization based on findings from Chen, Stanton, Shankaran & Li, 2006)	Categorical
Age of Onset (Daily Use of Cigarettes)	How old were you when you first started smoking cigarettes daily in years? 1 = Never smoked dabily 2 < 16 3 ≥ 16	Categorical
Income	0 < $10000 1 ≥ $10000	Dichotomous
Diagnosis of Depression and/or Anxiety	0=Undiagnosed 1=Diagnosed	Dichotomous
Relationship Status	0=Single 1=in a relationship	Dichotomous

Pregnancy Programs	Use of prenatal services 0=Not accessed 1=Accessed	Dichotomous
Community Healthcare Services	Use of community health services 0=Not accessed 1=Accessed	Dichotomous
Ethnicity	0=Non-White 1=White (Categorization based on Czoli, Hammond, & White, 2014)	Dichotomous
Education	0 ≤ highschool 1 > than highschool	Dichotomous
Alcohol	In the last month how often did you drink beer, wine, liquor or any other alcoholic beverage? 0=Abstinence 1=Use during pregnancy	Dichotomous
Marijuana	In the last month, how often did you use marijuana or hash? 0=Abstinence 1=Use during pregnancy	Dichotomous
Other Drugs	In the last month, how often did you use or try other drugs, such as LSD or mushrooms, ecstasy, cocaine, speed, heroin or crystal meth? 0=Abstinence 1=Use during pregnancy	Dichotomous
Perceived General Health Status	In general, would you say your health is... 0=Poor 1=Good	Dichotomous

Appendix D – Model A

Table D-1 Multivariate Analysis Predicting Self-Efficacy in n = 630 Participants from the BC Healthy Connections Project (Model A)

Coefficients	Estimate	Standard Error	*T*	*P* *
Intercept	15.69	1.83	8.59	0.00 ***
Cigarette Users	0.04	0.34	0.13	0.90
ENDS/combination Users	1.13	0.91	1.24	0.21
Gestational Age	0.01	0.03	0.31	0.76
Age	0.05	0.06	0.83	0.41
Income	0.41	0.32	1.28	0.20
Perceived General Health Status	1.05	0.46	2.27	0.02 .
Diagnosis Depression/Anxiety	- 0.32	0.28	- 1.13	0.26
Relationship Status	- 0.05	0.32	- 0.16	0.87
Mastery	0.64	0.05	13.95	0.00 ***
Alcohol	0.31	0.59	0.53	0.59
Marijuana	0.28	0.33	0.84	0.40
Other Drugs	- 0.53	0.97	- 0.55	0.58
Age Onset Ever Use Cigarettes (<16)	0.66	0.53	1.25	0.21
Age Onset Ever Use Cigarettes (≥16)	- 0.25	0.51	- 0.48	0.63
Age Onset Daily Use Cigarettes (<16)	- 0.69	0.48	- 1.44	0.15
Age Onset Daily Use Cigarettes ((≥16)	0.18	0.44	0.41	0.69
Pregnancy Programs	0.62	0.28	2.19	0.03 .
Community Healthcare Services	0.34	0.80	0.43	0.67
Ethnicity	- 0.08	0.28	- 0.28	0.78
Education	0.65	0.31	2.11	0.04 .

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Appendix E – Model B

Table E-1 Multivariate Analysis Predicting Self-Efficacy in n = 630 Participants from the BC Healthy Connections Project (Model B)

Coefficients	Estimate	Standard Error	*T*	*P* *
Intercept	16.95	0.97	17.54	0.00 ***
Mastery	0.64	0.04	14.83	0.00 ***
Income	0.47	0.31	1.53	0.13
Perceived General Health Status	1.08	0.45	2.40	0.02 .
Education	0.75	0.29	2.58	0.01 **
Pregnancy Programs	0.68	0.28	2.43	0.02 .

* Significance Codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1