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Implementing Clinical Practice Guideline Recommendations to Address Prenatal Smoking: A Practice Change in a Community Health Department

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Implementing Clinical Practice Guideline Recommendations to Address Prenatal Smoking: A
Practice Change in a Community Health Department

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Abstract

According to the authors of current literature, pregnant women who smoke may be more resistant to change, and may not fully understand the harmful effects of smoking. Therefore, there is agreement among researchers that the use of psychosocial interventions for smoking cessation can be effective. At the time of this project many settings, including clinics, health departments, and providers, were implementing the 5As which guide healthcare and community workers to *ask, advise, and assess* the smoking status of pregnant women at every health visit, and then *assist and arrange* smoking cessation interventions if applicable. Despite these efforts, pregnant women are continuing to smoke. The purpose of this project was to implement the clinical practice guidelines of the 5Rs with pregnant women who smoke. The 5Rs were created to reach those people more resistant to change to make the facts and data seem more *relevant* to them in regards to *risks, rewards, and potential roadblocks*, and *repeat* the information as needed. The project involved educating staff of a local health department, which was experiencing a higher than average smoking rate among pregnant women, on the use of the 5Rs. Then the effectiveness with the pregnant women themselves was evaluated. The staff integrated the 5Rs during every visit with the women by talking to the women about the risks of continuing smoking, the rewards of quitting, and the roadblocks of cessation. The collected data were analyzed and results shared for possible dissemination among other county health departments and primary care offices.

Keywords: Pregnant women, smoking, 5Rs, clinical practice guidelines

Executive Summary

Smoking is one of the leading preventable causes of death in the United States, with a higher percentage of pregnant women who smoke than the general population (American Pregnancy Association, 2015; Centers for Disease Control and Prevention (CDC), 2016b; Danaei, et al., 2009).). The harmful effects of smoking have not gone unnoticed by the United States government and health departments around the country. A lot of work and campaigning have been done in the past decade to successfully decrease the smoking rates from nearly 25% (CDC, 2016a). However, despite the mass efforts to reduce smoking rates, and eliminate smoking altogether in pregnant women, there is still a large percentage of pregnant women who smoke. This has resulted in a high infant mortality rate, a significant percentage of babies being born premature, and a significant percentage of babies being born of low-birth weight (Kids Count Data, 2016).

A great opportunity is to reach these women at the community and primary care level. A study in 2010 found that around 70% of smokers visited a healthcare worker within the past year, and the advice they received from the healthcare worker, specifically related to smoking cessation, was “considered more superior in motivating smokers to quit than family pressure, strict regulations, tobacco taxes, or public campaigns” (Alzoubi et al., 2010, p 94). Therefore, for healthcare workers, it is recommended that because there are “successful smoking cessation strategies that are supported by clinical evidence [available, they] should be integrated into routine prenatal care for every pregnant women” seen (American College of Obstetricians and Gynecologists (ACOG), 2011, p. 4).

At the start of this project, practice at the health department was to utilize the 5As in regards to smoking cessation, at every prenatal visit, and to encourage the pregnant women to

pursue the smoking quit line. The 5As are in line with evidence-based practice for the community or primary care setting, to assess smoking status and provide advice to quit (Fiore et al., 2008). Despite following some of the guidelines for smoking cessation among pregnant women, the staff were continually battling with women who refused to believe that smoking causes any harm to their unborn child or their other children at home. This may be why the health department was noting smoking rates ranging from 22% to as high as 47% among pregnant women in some counties (Kids Count Data Center, 2016). Therefore, the updated evidence-based guidelines for these women would include the 5Rs in addition to the 5As (Fiore et al., 2008). The 5Rs (Relevance, Risk, Rewards, Roadblocks, Repetition), enhance the motivation of these women to quit by making the data and facts seem more relevant to them especially in regards to risks, rewards, and potential roadblocks. Motivational interviewing using the 5Rs is effective in increasing future quit attempts (Fiore et al., 2008, p 57; Malucky, 2010).

The purpose of this scholarly project was the implementation of the evidence-based guidelines of the 5Rs related to smoking cessation among pregnant women to address the gap in perception surrounding the negative effects of smoking on children. The project was a pilot for the implementation of the evidence-based guidelines of the 5Rs for use with pregnant women who smoke. The implementation took place in a community health department that deals with a large percentage of pregnant women who smoke. The ultimate goal was the successful implementation of the 5Rs, to help motivate pregnant women to quit smoking for the health of their children (unborn and/or alive). Successful implementation of the 5Rs and whether the project addressed the gap in perception was evaluated based on acceptability and effectiveness. Acceptability was measured by educating staff members on the use of the 5Rs and then analyzing the staff post-education surveys which asked about ease of use, and perception of

helpfulness. Effectiveness was measured by discussing with pregnant women their knowledge of the relevance, risks, rewards, and roadblocks related to smoking cessation for them.

Effectiveness was assessed before and after staff members implemented the 5Rs to grasp the extent of knowledge gained using the evidence-based guidelines.

Project outcomes after implementation included 100% of staff rating the acceptability and feasibility of use as a 3 or higher (see Appendix G for the significance of 3), meaning that they perceived the 5Rs to be effective and easy to use, and would use it the majority of the times with their pregnant smokers. A Wilcoxon Signed-Rank test revealed that intervention outcomes among the pregnant women clients included an immediate significant ($z = -2.8031$, $p = 0.00512$) increase in knowledge gained of the harmful effects of smoking. One hundred percent of the pregnant women increased their knowledge score by at least one point. This project successfully addressed the gap in knowledge of the harmful effects of smoking among pregnant women at a local health department. Recommendations to continue its use and spread the findings to other departments within the health department like the Women Infants Children (WIC) department, other health departments altogether, and primary care offices that work with pregnant women have been given. Potential considerations were given to increase health promotion, on the topic in schools, increase the length of implementation time and re-evaluate women's knowledge after a few months, and implement the pilot program in other counties.

Implementing Clinical Practice Guideline Recommendations to Address Prenatal Smoking: A
Practice Change in a Community Health Department

Introduction and Background

Smoking is one of the leading preventable causes of death in the United States (Centers for Disease Control and Prevention (CDC), 2016b; Danaei et al., 2009). It is estimated that around 10% of the population smoke and upwards of around 12-20% of pregnant women do so (American Pregnancy Association, 2015). According to the CDC, around 500,000 people die every year in the United States from smoking related causes, which includes nearly 50,000 pediatric deaths from exposure to secondhand smoke (2016b). Smoking has been known to have negative effects on the smoking pregnant mother and her children. These negative effects include but are not limited to, miscarriage, low birth weight, sudden infant death syndrome (SIDS), stillbirth, premature birth, congenital malformations, asthma, emotional or behavioral problems, respiratory illnesses, ear infections, tooth decay, cancer, heart disease, and death (American Lung Association, n.d.; American Pregnancy Association, 2015; CDC, 2016a). The CDC predicts that if current trends continue almost 6 million youth will die from a smoking-related illness. This is equivalent to about “one in every 13 American” youth alive today (CDC, 2016b, para. 2).

Much effort has been put forth in the past several decades to decrease smoking rates in the United States. This has resulted in moderate success. One of the efforts included the passing of the Family Smoking and Tobacco Control Act in 2009, which gave the federal government the authority to regulate sales, marketing, and manufacturing of all tobacco products in the United States (U.S. Department of Health and Human Services [HHS], 2016). Smoking in the general population has decreased, from upwards of 25% to around 10% (CDC, 2016a). Unfortunately,

the same results have not been noticed among pregnant women. Pregnant women continue to smoke despite the vast efforts to reduce rates (American Pregnancy Association, 2015). In Michigan, the average percentage of pregnant women who smoked was 19.3% in 2014. This is a small percentage compared to the average in the counties covered by one local community health department whose averages are 24.6% to 43.8% (Kids Count Data Center, 2016).

Women who smoke normally quit when they become pregnant for a variety of reasons; the most notable is an understanding of the harmful effects smoking has on them and their unborn child. Pregnant women who continue to smoke during pregnancy may be more resistant to change, and may not have a full understanding of the harmful effects of smoking on them and their children (Chamberlain et al., 2013; Olaiya et al., 2015). The United States Preventive Task Force (2015) recommends that clinicians *ask, advise, and assist* pregnant women who smoke, to quit. The task force gives this level of recommendation an “A” meaning that the benefit of implementation is substantial. The recommended *ask, advise, assist* approach is used at a local health department in Michigan; however, this has not been enough to reach the pregnant women. The women are resistant to change and do not fully understand the harmful effects smoking may have. The new evidence-based clinical practice guidelines recommend the use of the 5Rs in these women more resistant to change, which includes speaking about *relevance, risks, rewards, roadblocks, and repetition* (Fiore et al., 2008). The project implemented the 5Rs at the local health department to reach the pregnant women who smoke. The staff at the health department integrated the 5Rs in their everyday interaction with these pregnant women by spending time talking to the women about the risks of continuing smoking, the rewards of quitting, and the roadblocks of cessation. The 5Rs were implemented to help bridge the gap in knowledge of the effects smoking has on the women and their children.

Problem Statement

The lack of understanding of the harmful effects of smoking has contributed to pregnant women continuing to smoke while pregnant. Among the clients of a local health department the implemented evidence-based intervention of the 5As had not been enough to help pregnant women understand the effects of smoking, or eventually help them quit. A number of researchers suggest that this may be due to the pregnant women who continue to smoke not understanding the harmful effects of smoking. In these cases researchers suggest using an intervention like the 5Rs to help with motivation (Fiore et al., 2008). The project question was whether implementation of the clinical practice guidelines of the 5Rs, in addition to the already implemented 5As, would bridge the gap in knowledge about the harmful effects of smoking among pregnant clients who smoke. The 5Rs are an evidence-based initiative to reach those individuals who may be more resistant to change, including pregnant women who smoke, by helping them understand the implications of their smoking habits.

Evidence-Based Initiative

A review of the literature surrounding the topic of pregnant women who smoke was conducted to learn the current state of knowledge on the topic. The literature was categorized according to the characteristics of these pregnant women, and then based on the type of intervention researched. Pregnant women who smoke are normally women of a lower socioeconomic status; who are more addicted to nicotine; have a partner who smokes, or no partner at all; are of a younger age; have limited education; are depressed; have more than one child; utilize publicly funded maternity care; and have less of an understanding of the harmful effects of smoking on their unborn children (Chamberlain et al., 2013; Coleman, Chamberlain, Davey, Cooper, & Leonardi-Bee, 2015; Hubbard, Gorely, Ozakinci, Polson, & Forbat, 2016;

Minian, Noormohamed, Dragonetti, Maher, & Lessels, 2016; Miyazaki, Hayashi, & Imazeki, 2015; Olaiya, et al., 2015). The type of interventions reported by researchers are psychosocial interventions, telephone interventions, and use of medications. Psychosocial interventions have been researched most frequently. Because medication use is not appropriate and not common practice for the organization nor in the surrounding communities where the project occurred, any further discussion of medication use for smoking cessation among pregnant women is omitted from this report.

Psychosocial interventions are those based on behavioral therapy, social support, incentives, feedback, health education, counseling, and other techniques (Chamberlain et al., 2013). Many researchers have concluded that motivational interviewing is an effective intervention for smoking cessation with pregnant women, along with brief advice given by healthcare workers, and tailored self-help. Several authors, including Cahill, Lancaster, and Green (2010), and Karatay, Kublay, and Emiroglu (2009), also determine that “offering practical support to smokers trying to quit delivers higher success rates than ‘usual care’ or [only] assessing their smoking status” (Cahill, Lancaster, & Green, 2010, p. 14). Counseling and feedback are effective interventions for pregnant women compared to “usual care” (Chamberlain et al., 2013). However, Filion et al. (2011) also concluded that counseling, even though effective, may best be used in conjunction with another form of intervention.

Miyazaki, Hayashi, and Imazeki (2015) specifically reviewed the use of the 5As. The 5As are effective for use in pregnant women who smoke; however, not all studies reviewed by Miyazaki et al. (2015) reported significant results. Because of this, the authors concluded that these women were more resistant to change, and they suggested that a more tailored approach in these instances would be beneficial.

Telephone interventions are those that use text messages or phone calls for the purpose of helping individuals or groups abstain from smoking. Many authors, including Bombard et al. (2012), and Naughton et al. (2015) deem that telephone counseling for use in pregnant women is effective when the women use the quitline. However, many women, including pregnant women, do not actually access the smoking quitlines that are made available. This hinders the effectiveness of these resources (Naughton et al., 2015). Therefore, evidence is still inconclusive as to whether telephone interventions should be made routine for pregnant women (Lavender et al., 2013).

Several authors note that any intervention is better than no intervention when it comes to smoking cessation for pregnant women. The most researched literature is for psychosocial interventions. The authors of these interventions conclude that motivational interviewing, practical support, brief advice, counseling, feedback, and tailored self-help material are all effective for use with pregnant women. These interventions are deemed the most effective, based on the characteristics of pregnant women who continue to smoke, because the interventions target the psychosocial dimensions of these women. The 5As are a great intervention for use with pregnant women; however, many women may be resistant to change or do not understand the harmful effects of smoking. Therefore, authors note that a more tailored approach may be beneficial, such as the use of the 5Rs in addition to the 5As.

Conceptual Models

The 5Rs are based on the transtheoretical model (Prochaska, & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992). The transtheoretical model has been well studied and researched, especially in regards to smoking and other addictive behaviors. Most of the current evidence available has come from the stages of change described in the transtheoretical

model (See Appendix A). The model describes how a person goes through a series of psychological steps when modifying behavior. These steps can include precontemplation, contemplation, preparation, action, and maintenance (Pro-Change Behavior Systems, 2016; Prochaska, & DiClemente, & Norcross, 1992). Many pregnant women are in the precontemplation, contemplation, and preparation stages (Petersen et al., 2009). In these stages the women may be more resistant to change, which can contribute to their refusing to believe in the harmful effects of smoking on their children. Consequently, they continue to smoke. The 5Rs are based on the transtheoretical model with the goal to reach the women in the earlier stages in the process of change. The evidence-based guidelines for these women would include the 5Rs in addition to the 5As (Fiore et al., 2008). The 5Rs enhance the motivation of these women to quit by making the data and facts seem more relevant to them especially in regards to *risks, rewards, and potential roadblocks*. Motivational interviewing using the 5Rs is effective in increasing future quit attempts (Fiore et al., 2008, p. 57; Malucky, 2010).

To help implement the intervention, the Promoting Action on Research Implementation in Health Services (PARiHS) model was used. The PARiHS framework is a framework that “represents the interplay and interdependence of many factors influencing the effective uptake of research evidence into practice” (Kitson, Harvey, & McCormack, 1998, p. 149). The PARiHS model is derived from the equation $SI = f \{E,C,F\}$ (Kitson, Harvey, & McCormack, 1998, p. 150; Kitson et al., 2008). This means that successful implementation of evidence into practice depends on the “function of the relation between the nature of the evidence, the context in which the proposed change is to be implemented, and the mechanisms by which the change is facilitated” (Kitson, Harvey, & McCormack, 1998, p. 150). The authors of the model understand that these concepts need to be thought of simultaneously for successful implementation, and not

understood in linearity (See Appendix B). The PARiHS model is designed to embrace the complexity of the change process by looking at concepts in isolation, and then together, where each concept is as equally important as the other (See Appendix C). The PARiHS model originally emerged from working with clinicians (mainly nurses) to improve quality of care, but can be used in multiple disciplines. The PARiHS model is used to assess the organization to understand the context in which the proposed change is to be implemented, the nature of the evidence, and the mechanisms by which the change is facilitated.

Need and Feasibility Assessment of the Organization/Population

As stated earlier, the national percentage of pregnant women who smoke is between 12-20% (American Pregnancy Association, 2015, para. 2). In Michigan, the percentage is around 19.3%, and in the counties of one local health department, the percentage is between 24-48% (Kids Count Data Center, 2016). This health department, with the high percentage of smoking pregnant women among its clientele, was an ideal setting to implement the clinical practice guidelines of the 5Rs to reach the women more resistant to change.

The organization made a request to the University for a student assistant to help with their pregnant clients. The organization had a tobacco grant from the government which made the issue at the forefront of the agenda, even though the project was not in itself funded by the grant. The mission and vision of the organization was to better people and communities, and to improve population health and prevention. Working with pregnant women for the goal of smoking cessation addressed and fell under the health department's mission and vision to better their communities and improve population health, making it an ideal project.

The major stakeholders for the project were the nurses and social workers who worked directly with the pregnant women, the women themselves, and by association, their children.

Other stakeholders included the community as a whole, which included the hospitals and primary care providers. The nurses and social workers were the personnel who would be sustaining the intervention into the future, and trying to affect the women in a positive way to improve the women's health for themselves and for the health of their children. The nurses and social workers did not believe the 5As were enough to assist the pregnant clients to quit, and felt that their efforts to help these women quit were being wasted.

The threats, weaknesses, and potential barriers and challenges of the project had much to do with the population itself (See Appendix D). The population had high rates of smoking, and were from lower socioeconomic statuses. These factors made it difficult to work with these women to influence or effect change. This is why the implementation of the 5Rs was so important. The 5Rs are designed to work with individuals more resistant to change by bringing practical advice that emphasizes the relevance of the situation to them.

Project Plan

Purpose of Project with Objectives

The local health department was experiencing higher than average smoking rates among pregnant women. Despite implementing the recommended 5As for smoking cessation, pregnant women were continuing to smoke, and staff were feeling that their efforts were wasted. One of the first steps for potential cessation is understanding the harmful effects of smoking (Miyazaki et al., 2015). The pregnant women of the health department clientele were not understanding these effects, making them more resistant to change. The purpose of this project was to implement the clinical practice guidelines of the 5Rs in the local health department in order to decrease the gap in knowledge of pregnant clients regarding the harmful effects of smoking. The project objectives were to determine understanding, acceptability, and feasibility among staff

members for use of the 5Rs for purpose of sustainability; to evaluate recommended guidelines among pregnant clients, at the organization, addressing knowledge gained of the harmful effects of smoking; provide recommendations of continual use of the 5Rs based on project evaluation results.

Type of Project

The project was a clinical practice change and pilot intervention implementing the 5Rs at the local health department. The 5Rs are part of the clinical practice guidelines approved by the U.S. Department of Health and Human Services for treating tobacco use and dependence (Fiore et al., 2008). Additionally, because the health department utilized the 5As for addressing tobacco use among its clients, the implementation of the 5Rs was part of the pilot intervention to justify its continual use, and potential dissemination to other health departments and primary care providers.

Setting and Needed Resources

This project took place at a local health department that served a rural/underserved community. The main resource needed was cooperation from the health department nurses and social workers who worked directly with the pregnant women. The nurses and social workers were vital to proper implementation and sustainability. Other resources included transportation to and from the visits, along with time to implement the project and analyze the results. The staff needed an extra 3-5 minutes in order to implement the 5Rs effectively, and time to get acquainted with the 5Rs before the visits, along with documentation. The project also needed ample amounts of paper for the staff and patient surveys and reminder sheets for the staff.

Design for the Evidence-Based Initiative

The intervention included the DNP student educating the health department staff of nurses and social workers, in the use of the 5Rs. A pre-education and post-education survey were given to the nurses and social workers addressing the understanding, feasibility, and presumed effectiveness of the 5Rs (See Appendices F and G). A printed card summarizing the 5Rs was also given as a quick, easy reminder of the use of the 5Rs (See Appendix H). The nurses and social workers implemented the 5Rs with all the pregnant women smokers with whom they came in contact during their monthly visits. The 5Rs were used to increase the knowledge of the pregnant women regarding the harmful effects of smoking.

Participants

Pregnant women over the age of 18 who smoked and were served by the local health department personnel, were the target population of the project. The seven nurses and social workers who worked directly with these pregnant women were the ones implementing the 5Rs to assist the women in smoking cessation. For the pilot project, these nurses and social workers recruited all pregnant women of their caseloads who smoked, and were over age 18, and determined if proper implementation could be achieved. As noted earlier, pregnant women who continue to smoke during pregnancy may be more resistant to change (Chamberlain et al., 2013; Olaiya et al., 2015). Therefore, all pregnant women over the age of 18, who continued to smoke during pregnancy, qualified for participation in this project.

Measurement: Sources of Data and Tools

Two surveys were used to measure the success of the project in meeting objectives. One survey was given to the nurses and social workers before and after an educational meeting (See Appendices F and G). It was used to measure nurse and social worker understanding of the 5Rs

and perceptions of feasibility and acceptability. Feasibility was defined, or operationalized for use in this project, as nurses' and social workers' perceptions of the ease of using the 5Rs in practice. Acceptability was operationalized, for use in this project, as the staff's knowledge and perceived comfort in use of the 5Rs for intervening with pregnant smokers. An additional reminder handout of the 5Rs was given to staff to foster acceptability (See Appendix H). Feasibility and acceptability were used in these pre- and post- educational surveys as a way to measure sustainability. The authors of research literature indicate that feasibility and acceptability can be used to "evaluate and improve sustainment likelihood" (Palinkas et al., 2015, p. 3). The pre- and post- educational survey evaluating the social workers' and nurses' understanding of the 5Rs was based on a survey used previously by Aloubi et al. (2010). The survey questions were deemed reliable and valid by those researchers. Reliability was measured with a test/retest method one week apart leading to a stability coefficient between 0.74 and 0.87. Validity was determined by face validity and re-adjusted based on expert feedback.

The second survey was a pre- and post- intervention survey given to the pregnant women before and after the nurses and social workers administered the 5Rs (See Appendices I and J). This survey given to the pregnant women measured knowledge gained about the harmful effects of smoking. The questions and format of the surveys were deemed to have face validity as they were based on a previous survey conducted by the health department, and included information obtained from research literature.

Steps for Implementation of Project, including Timeline

For the implementation of the clinical practice guidelines, the DNP student spent 10 minutes educating the nurses and social workers on the 5Rs, and the importance of the use of the method by way of a power point presentation, in a face-to-face meeting. During the meeting, the

DNP student spent about 1 minute discussing each point of the 5Rs and their use, and an additional 3 minutes reviewing the stages of change and the importance of the 5Rs at each stage. The survey for the nurses and social workers addressing knowledge gained on the 5Rs, feasibility, and acceptability was administered at the beginning and end of the educational meeting which took an additional 2 minutes. In total, the meeting took 10 minutes for the DNP student to review all the information, and an additional 5 minutes answering questions and clarifying the procedure.

Over the course of the following month, the nurses and social workers continued the use of the 5Rs with all pregnant women smokers, over age 18, with whom they had contact. Visits were completed each month for the purposes of promoting healthy pregnancies, positive birth outcomes, and healthy infant growth and development. The pregnant women completed a pre-intervention and post-intervention survey at the beginning and end of each visit to track and document their change in knowledge of the harmful effects of smoking. The staff members collected the surveys and placed them in an individual envelope and brought the envelope back to the health department. The visits took place either at the local health department or at the client's home, depending on what was pre-established between the staff and the clients. Following the 5As staff were required to complete at each visit, the 5Rs were and are, a natural discussion and conversation. The DNP student was available during the implementation process to answer any questions from the staff members by phone or email. A diagram of the timeline regarding the steps for implementation can be seen in Appendix E.

Project Evaluation Plan

The DNP student administered a brief pre-educational and post-educational survey to the nurses and social workers before and after the 10 minute educational meeting. The anonymous

survey consisted of 6 questions assessing knowledge of the use of the 5Rs and 3 questions assessing feasibility and acceptability of the 5Rs (See Appendix F and G). Feasibility and acceptability were considered to be met if over half of the nurses and social workers chose an answered of 3 or higher, on a scale of 1 (not helpful at all, not easy at all, will never use) to 5 (very helpful, very easy, will use it at every visit) to questions about understanding of the 5Rs, and considering the 5Rs easy to understand and follow.

The pre-intervention and post-intervention surveys for the pregnant women were administered by the nurses and social workers when they met with the women. The pre-intervention survey was administered at the beginning of the client meeting, and the post-intervention survey was administered at the end of the client meeting after the nurse or social worker utilized the 5Rs. On average, the client meetings took between 30-60 minutes, meaning the time between the pre- and post- intervention surveys could range from 5 minutes up to 30-60 minutes depending on when during the client meeting the staff members utilized the 5Rs. After completion the surveys were placed in an individual envelope by the staff member and brought back to the organization. The surveys were then collected by the DNP student for analysis and compilation of findings.

Because the pre- and post- intervention surveys were newly created and lacked thorough documentation of reliability and validity, a paired t-test based on a total score or reliability analysis could not be completed particularly considering a sample size of only 10 women. For fewer than 10 completed surveys, a nonparametric test examining responses to the individual questions to observe the shift in answers was planned, with a small Bonferroni correction of the p value of 0.05. To make results easier for stakeholders to understand, findings were also

compiled into a bar chart, and a table of the pre-intervention answers compared to the post-intervention answers to visually depict the shift in knowledge.

Ethics and Human Subjects Protection

Prior to implementation this project was determined by Grand Valley State University (GVSU) Human Research Review Committee (HRRC) to not meet federal definitions for research covered under human subjects protections regulations (See Appendix K). Therefore, it was considered a process improvement project. The project also received approval by the project committee at the organization where the work was implemented. The surveys were anonymous; no identifying information was included on the surveys. The pre-educational and post-educational meeting survey of the staff members were collected directly after the meeting by the DNP student, avoiding review by organizational supervisors. The pre-intervention and post-intervention surveys were placed in an individual envelope and given to the DNP student for analysis, and to store them separately from usual health department records. The data from the surveys were typed into a computer in Excel and saved on an encrypted flash drive, password protected, which was stored in a locked safe at the home of the DNP student. The paper surveys were then shredded using a medical information shredding service.

Budget

The DNP student conducted and led the 10 minute educational meeting for staff. The student's time was provided without charge to the organization. If new staff members were oriented to the organization during the 4 week implementation time, the DNP student would have talked to them individually to orient them to the 5Rs and administer the same pre-educational and post-educational survey. The organization did, however, have to cover the cost of the staff members attending the meeting, which averaged about \$4-5 per staff member (n = 7)

for the 10 minutes as calculated from the average salary of a public health nurse in Michigan (Nurse Journal, 2017). This totaled about \$28 - \$35 for this pilot. The organization also covered the cost of the extra 3-5 minutes it takes staff members to implement the 5Rs at each visit, which was an additional \$1-2 per visit. If the organization decides to adopt the practice change, the cost of the extra 3-5 minutes it takes to utilize the 5Rs at each visit with the pregnant women who smoke would become a permanent budget consideration. The extra 3-5 minutes at each visit would not change the daily workload of the staff members.

Project Outcomes

Project outcomes consisted of evaluating staff understanding of the updated clinical practice guidelines, judging the likelihood of sustainability related to acceptability and feasibility among staff members, and analysis of the clinical practice guidelines protocol and use among pregnant women smokers served by the health department. The collected project data was entered into Excel and SPSS software for analysis using the Wilcoxon Signed-Rank test by the DNP student. Data and outcomes were then reviewed by a graduate student of Grand Valley State University Statistics department for confirmation and accuracy of results.

Staff Member Outcomes

Quantitative outcomes.

The educational meeting, led by the DNP student, occurred in late April 2017 prior to the implementation of the project intervention. A combination of 7 nurses and social workers of the health department attended the meeting and completed the pre- and post-educational surveys. The educational meeting of staff members verified and enhanced the understanding of the 5Rs among them. A visual representation of the responses and results can be seen in Appendices L and M. All staff members rated responses at a 3 or higher (possible range of 1 to 5) on the post-

educational survey questions 7, 8, and 9 addressing feasibility and acceptability. Again, feasibility and acceptability was used in these pre- and post-educational surveys as a way to measure sustainability. It was assumed that with a higher feasibility and acceptability score among staff members, it would be more likely that they would continue the use of the intervention. The project outcomes related to the pre- and post-educational meeting surveys verified that the staff members understood the ideas represented by the 5Rs, and perceived the 5Rs to be feasible and acceptable to use.

Intervention Outcomes

After verifying understanding of the 5Rs with staff members following the educational meeting, the staff members were asked to implement the 5Rs with the pregnant women smokers, and to administer the pre- and post-intervention surveys. This pilot period occurred between April 26, 2017 and May 26, 2017. A total of 10 surveys were completed by the pregnant women clients, returned to the health department by the staff members, and collected by the DNP student for analysis. A total score was given to each survey with the highest score possible being 14. The scoring comprised of allotting the correct answer a point value of 2, allotting a “maybe” answer a point value of 1 (as it is neither correct nor incorrect), and allotting an incorrect answer a point value of 0. The mean score of the pre-intervention survey was 7.9 (SD = 2.2828), whereas the mean score of the post-intervention survey was 11.6 (SD = 3.2042). The points for the pre-intervention survey ranged from a total of 3 to 12 (Mdn = 8), compared to the post-intervention survey which ranged from 4 to 14 (Mdn = 12.5).

The questions answered incorrectly by most of the women in the pre-intervention survey were related to ear infections, and emotional or behavioral problems. In the post-intervention survey the question addressing diabetes was the one most often answered incorrectly. The

question regarding low birth weight was the one most often answered correctly in both the pre- and post-intervention surveys. Responses to both the pre- and post- intervention surveys can be seen in Appendix N. Due to the low number of surveys completed, a Wilcoxon Signed-Rank Test was run to analyze the paired data. A visual representation of the data and analysis can be seen in appendices N, O, and P. The Z score was -2.8031, the two-tailed *p*-value was 0.00512, and the W-value was 0. In this analysis, the results of the intervention are deemed significant.

Four questions on the pre-intervention survey asked the pregnant women smokers about family dynamics and the current number of cigarettes smoked each day. Seventy percent of women stated they were married or had a partner at home; 71.42% (5 out of 7) of those partners smoked. Eighty percent of the women acknowledged they had other children at home, and of those, 50% (4 out of 8) were homes where both parents and adults smoked. Finally, the range of cigarettes smoked per day was between 3 to 15 (Mdn = 7) cigarettes, with 70% of women smoking 10 or less a day, and 30% smoking less than 4 cigarettes a day (See Appendix P).

Qualitative Outcomes

Apart from the pre- and post- educational surveys, staff members were able to verbally describe their perceived benefits and/or concerns regarding the project to the DNP student. The DNP student was available during the month long pilot intervention period to answer questions, listen to concerns, and acknowledge praises and benefits of the intervention. Over the course of 4 weeks, no staff member approached the DNP student with any concerns regarding the intervention. Staff members had only positive things to say including how easy the 5Rs were to use with their pregnant clients, and how they could see the 5Rs being very helpful for pregnant clients over the long run in helping them quit smoking, or reduce the amount smoked. The feedback from staff verified the high feasibility and acceptability among staff members for use of

the 5Rs, as seen in the post-educational surveys. These qualitative data helped add to the assumption that a high acceptability and feasibility among staff members would increase the likelihood of sustainability.

Implications for Practice

This project follows the nursing profession's goal to prevent illness and injury for individuals, communities, and populations by adding to the literature surrounding smoking cessation interventions. It does so through actions for decreasing the gap in knowledge for pregnant women, by utilizing the 5Rs. In order to improve the health of the population, the goal of the intervention was to improve the health of the mother, and also the health of her children. Healthier children will lead to healthier communities, which will decrease healthcare costs. According to the American Nurses Association (ANA) (2016), nursing is "prevention of illness and injury...and advocacy in the care of individuals, families, groups, communities, and populations" (para. 1).

For the local health department, this project helps the organization in accomplishing its mission and vision to improve the health of its communities, by helping its clients take another step in the direction towards smoking cessation and reduction. The more practice the staff members have with implementing the 5Rs and acknowledging the client's current stage of change, the more tailored the intervention will become. This will be most beneficial for clients on the road to smoking reduction and cessation.

Successes and Difficulties Encountered

Overall, the implementation of the clinical practice guidelines of the 5Rs was very successful. Part of that success was the overall knowledge and skill of the nurses and social workers in motivational interviewing and the transtheoretical model. Considering the staff

members' previous experience with these concepts, more time in the educational meeting could be spent explaining the 5Rs and their uses, instead of going into depth on the points of motivational interviewing and the transtheoretical model. If this project and implementation was to be used in another setting, more training of staff members may have to be focused on explaining and practicing motivational interviewing and the transtheoretical model.

Another success was the ease at which the 5Rs were implemented at the health department with the pregnant clients. The staff members already used the 5As for smoking cessation intervention and the 5Rs were an easy transition, resulting in ease of conversation and success of intervention, as mentioned in the section reporting qualitative responses of the staff members' outcomes. Staff members had access to the DNP student for any questions or concerns that presented themselves at any time during the implementation process. However, no major concerns were ever reported to the DNP student, leading to the assumption that the 5Rs are easy to implement and the project was successful in this regard.

The major difficulty of the intervention was the uniqueness it presented due to the clientele that it tried to reach and impact. The clientele by nature are resistant to change, making them a hard population to impact. This is especially true given the fact that the number of pregnant women who smoke could be higher, for many may refuse to confess to smoking because of the stigma (American Pregnancy Association, 2015). For example, this project and implementation resulted in 10 completed surveys by pregnant women who smoke, but there was no information regarding whether any clients refused to complete the surveys, or whether any clients did not confess to smoking.

Strengths and Sustainability

Strengths of the project include a high acceptance among staff members, and a significant improvement in the immediate client knowledge of the harmful effects of smoking post-intervention. All staff members involved in the project rated items representing acceptability and feasibility of the method at 3 or higher, meaning that they thought the 5Rs would be easy to use, helpful in smoking cessation efforts, and they would use it over 50% of the time with their clients. Again, the high acceptability and feasibility among staff members are potential indicators of sustainability of a project and guideline, and illustrate sustainability likelihood (Palinkas et al., 2015). There was also significant improvement in client knowledge of the harmful effects of smoking post-implementation of the 5Rs ($p = 0.00512$). The improvement in client knowledge and staff perceptions of acceptability and feasibility were major strengths of the project, and also add to the likelihood of sustainment within the organization.

Weaknesses and Limitations

Some limitations and weaknesses of this project are the lack of documented reliability of the intervention surveys, the limited number of client surveys collected, and the limited amount of time between the pre- and post-intervention surveys. The Wilcoxon Signed-Rank Test of the surveys reached significance; however, with the limited number of surveys completed, and the lack of documented reliability of the surveys, the significant result could be an overstatement of the actual client outcomes. Also, having the clients take the pre- and post- intervention surveys so close together, the significant results may be more of an indication of immediate effectiveness of the 5Rs intervention, than long term effectiveness and permanent change in the pregnant women's knowledge about the harmful effects of smoking.

Another limitation was the inability to track smoking status among the pregnant clients. The surveys included questions about how many cigarettes the clients smoked a day, but as the surveys were anonymous, there was no way to track smoking status of the individual women over time. There was also a limited amount of time available for implementing the intervention. The limited time made it impossible to follow up about smoking status with the pregnant clients for the health department. With an inability to track smoking status and follow up with the clients, it will be very difficult to confirm that the women are reducing their smoking rates due to the inclusion of the 5Rs in the staff members' regime.

Finally, the other limitations and weaknesses involve the lack of information about the staff members' relationship with their clients, and the lack of personal information on the pregnant clients. This project includes no information on how long the staff members have been working with each pregnant client who smokes, nor any information about the pregnant clients besides partner smoking status, and number of other children at home. Without information on staff members' previous encounters with these pregnant clients it is difficult to attest to how much information the clients were exposed to, and how much knowledge they had about smoking cessation, prior to this project. Therefore, significant results of this project could be an overstatement or understatement of the actual population outcomes. Additionally, there are limited data on the pregnant clients themselves. There is no information about previous amount of quit attempts, prior pregnancies involving prenatal smoking, any information on the outcomes of those prior pregnancies (Do they have any children at home with asthma? ADD? Were their other children born with low birth weights? Did they have previous pregnancy or birth complications?, etc.), nor any information on socioeconomic status, educational level, or history of depression, all of which can affect smoking status among pregnant clients.

Reflection on Enactment of DNP Essentials

The Doctor of Nursing (DNP) *Essentials* were enacted by the DNP student when working on this scholarly project (American Association of Colleges of Nursing (AACN), 2006). The “*Essentials of Doctoral Education for Advanced Nursing Practice* articulates the competencies for all nursing practice at this level” (AACN, 2006, p. 7). The *Essentials* are “designed to prepare nurses for the highest level of leadership in practice and scientific inquiry” (p. 7).

Essential I. Scientific Underpinnings for Practice. The scientific underpinnings of practice helped form the basis for the potential practice change initiated through the scholarly project. The organizational assessment, literature review, and included theories assisted in the evidence-based approach to the practice change targeted by the scholarly project. The DNP student partnered with the organization to determine the nature and significance of the phenomena in order to develop and evaluate new practice approaches. The DNP student utilized the PARIHS model and transtheoretical model to help guide the project and determine best evidence and approach for implementation.

Essential II. Organizational and System Leadership for Quality Improvement and Systems Thinking. Essential II directs the DNP student’s development as a leader seeking to meet the needs of the populations for whom they serve. This Essential was enacted by performing the organizational assessment using the PARIHS model, and by helping the health department implement the updated clinical practice guidelines of the 5Rs. The implemented new protocol for the organization not only demonstrated sensitivity to the diverse unique population of pregnant women, but also establishing sustainability in a protocol by evaluating acceptability and feasibility parameters among staff members. By applying the organizational assessment for quality improvement within the health department the DNP student utilized the skills of

advanced communication, and employment and implementation of an initiative to improve quality of care; analyzed cost effectiveness; and demonstrated sensitivity to the organizational cultures and populations in order to “ensure accountability for quality of health care and patient safety” (AACN, 2006, p. 10).

Essential III. Clinical Scholarship and Analytical Methods for Evidence-Based Practice. This Essential was enacted by critically appraising existing literature on the phenomena of interest in order to determine best practice. From the literature review and organizational assessment the best practice was to implement the updated clinical practice guidelines for smoking cessation among pregnant women. The results of the pilot study and practice change were analyzed in order to generate meaningful evidence for nursing practice and enact the best practice for the patient population. The pilot study resulted in immediate improvements in knowledge of the harmful effects of smoking among pregnant clients. This led the DNP student to recommend continual use in the health department, and disseminate findings to other facilities in order to improve healthcare outcomes among pregnant women and their unborn children. Finally, the DNP student acted as a consultant during the implementation stage within the organization to effectively implement a feasible and acceptable intervention.

Essential VI. Interprofessional Collaboration for Improving Patient and Population Health Outcomes. This Essential stresses collaboration among and between different professions in order to improve health outcomes for populations (AACN, 2006). This Essential was met by effectively collaborating and communicating with different professions within the organization in order to improve health outcomes for pregnant women and their children. The DNP student collaborated and communicated with nurses, social workers, tobacco cessation counselors, and quality improvement specialists in the development and implementation of the

clinical practice guidelines of the 5Rs in the organization. The DNP student helped lead the initiative, using interprofessional skills, to translate evidence-based guidelines of smoking cessation into practice within the health department organization.

Essential VII. Clinical Prevention and Population Health for Improving the Nation's Health. Clinical prevention and population health were addressed by analyzing epidemiology and scientific data in an organizational assessment in order to address and improve the individual and population knowledge of health behaviors. The DNP student evaluated the current care delivery approaches related to smoking cessation interventions for pregnant women, and helped determine the most appropriate method to reach these individuals in this population. Concepts like psychosocial, community, environmental, and socioeconomical dimensions of health were synthesized into implementing the clinical practice guidelines in the organization. Based on the synthesis of the concepts related to the dimensions of health, the 5Rs were deemed best practice to address health promotion and improve health status among the pregnant population. The DNP student performed an organizational assessment and literature review surrounding the population of interest, which resulted in the implementation and evaluation of the 5Rs of smoking cessation.

Essential VIII. Advanced Nursing Practice. Fulfilling this Essential involves the DNP student to embody the advanced nursing practice role by demonstrating advanced levels of clinical judgement and knowledge in complex situations in order to improve patient outcomes and achieve excellence in nursing practice (AACN, 2006). This Essential was addressed by including and conducting a systematic assessment of health and illness parameters within the organization and the population of interest by means of an organizational assessment. The DNP student developed and sustained therapeutic relationships and partnerships in order to effectively

implement and evaluate the clinical practice change initiative. For example, the DNP student developed relationships with the department supervisor, and staff nurses and social workers which led to an easy and accepted implemented initiative. The DNP student was there to guide and support other nurse and professions in achieving and delivering the highest level of evidence-based care to their populations by means of the updated clinical practice guidelines. The DNP student was there to answer questions, and receive feedback on the pilot intervention in order to deliver and sustain the recommended 5Rs for smoking cessation. The outcomes were analyzed and findings disseminated to help facilitate optimal care and patient outcomes.

Dissemination of Outcomes

The project was disseminated in the academic setting to student peers and faculty members through a poster presentation, and a public defense presentation. The final outcomes of the project are also being published on ScholarWorks@GVSU. The findings, outcomes, and continued recommendations of the scholarly project were also disseminated back to the organization via email, to the department supervisor. Based on the outcomes of the project and the results achieved, recommendations were made to the organization regarding the considerations to continue the utilization of the 5Rs within the current health department, and to disseminate the findings to other health departments and primary care providers in the area. Potential considerations were also given to start a partnership with the schools in the community, due to the young age at which many individuals start smoking. Based on the recommendations to disseminate the findings, the hope is for the eventual statewide adoption of the clinical practice guidelines at all facilities and organizations who service pregnant women.

Summary

Pregnant women who smoke may be more resistant to change, and may not fully understand the harmful effects of smoking. Current literature supports the use of psychosocial interventions with these women, and includes the use of the 5Rs. The 5Rs are based on the transtheoretical model stages of change to influence these women more resistant to change (Prochaska, & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992). This scholarly project assisted the staff of a local health department with implementation of the 5Rs with its pregnant clients who smoke. Proper implementation and evaluation of objectives were based on a pre-educational and post-educational survey administered to the health department staff members carrying out the proposed project with their clients, and a pre-intervention and post-intervention survey administered to the pregnant women themselves by the staff members after the 5Rs were utilized. Project outcomes were a high acceptability and feasibility of use among staff members, and an immediate increase in knowledge gained for the pregnant women of the harmful effects of smoking. The outcomes help verify the need of the organization working with pregnant women who smoke to implement the updated clinical practice guidelines into their routine prenatal care. During this project the facilitator fulfilled the DNP *Essentials* (AACN, 2006).

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Appendix A
 Transtheoretical model: Stages of Change

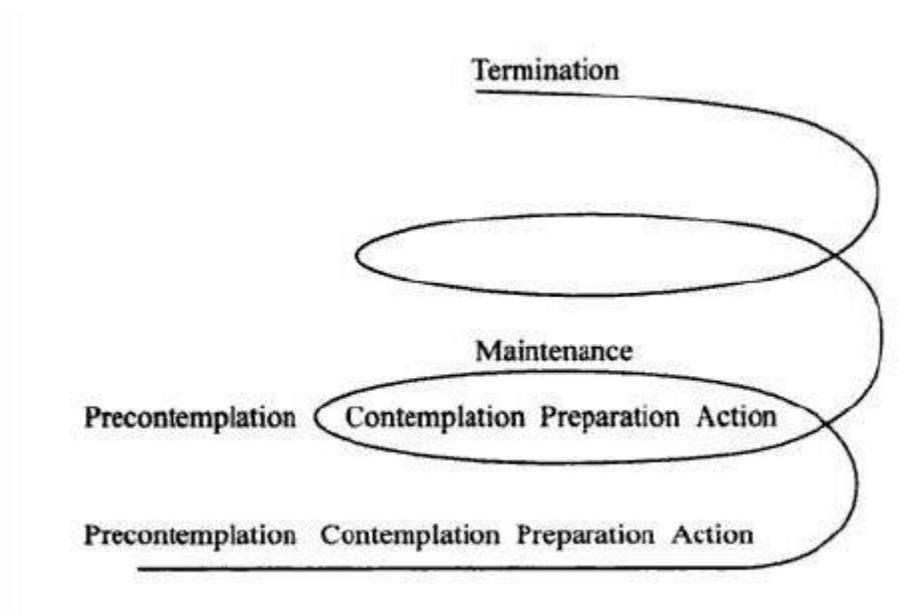


Figure 1: “A Spiral Model of the Stages of Change” by Prochaska, J. O., DiClemente, C. C., & Norcross, J. C., 1992, *American Psychologist*, 47, p. 1104. Copyright, 1992. Reproduced with permission.

Appendix B
 PARiHS framework: Evidence, Research, Facilitation

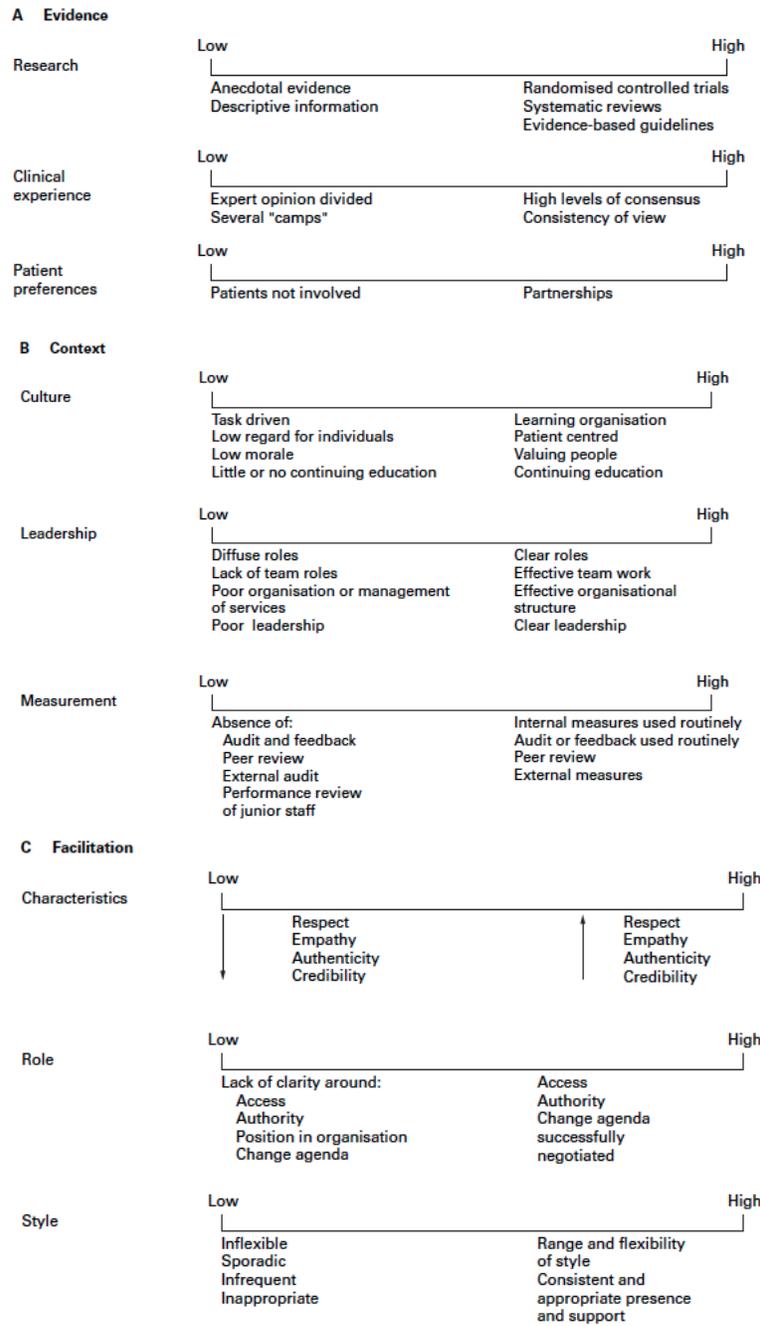


Figure 2: “Conditions for evidence, context, and facilitation” by Kitson, A., Harvey, G., & McCormack, B., 1998, *Quality in Health Care*, 7, p. 151. Copyright 1998. Reproduced with permission.

Appendix C
 PARIHS framework: Interplay of evidence, context, and facilitation

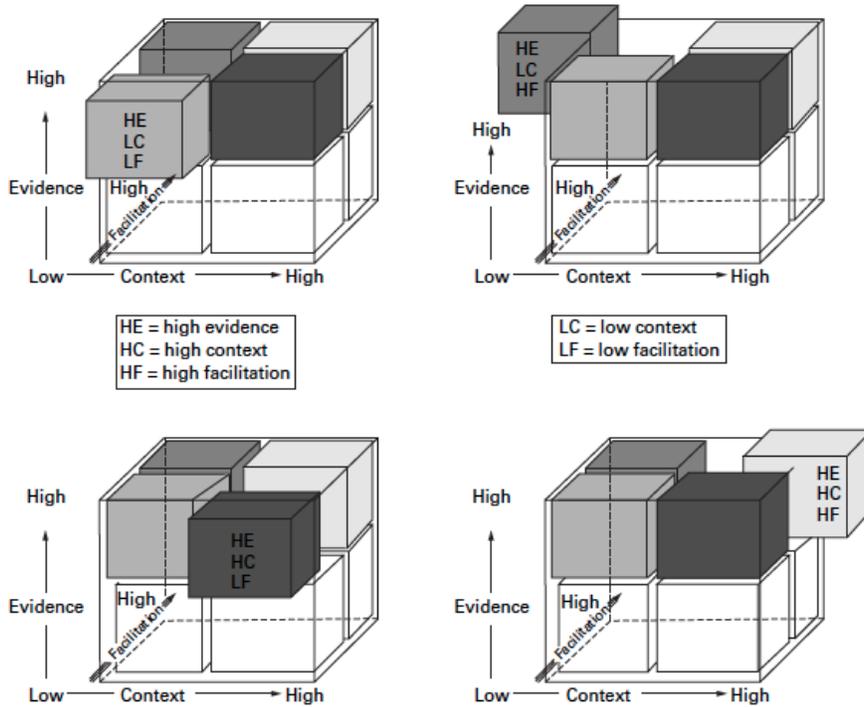


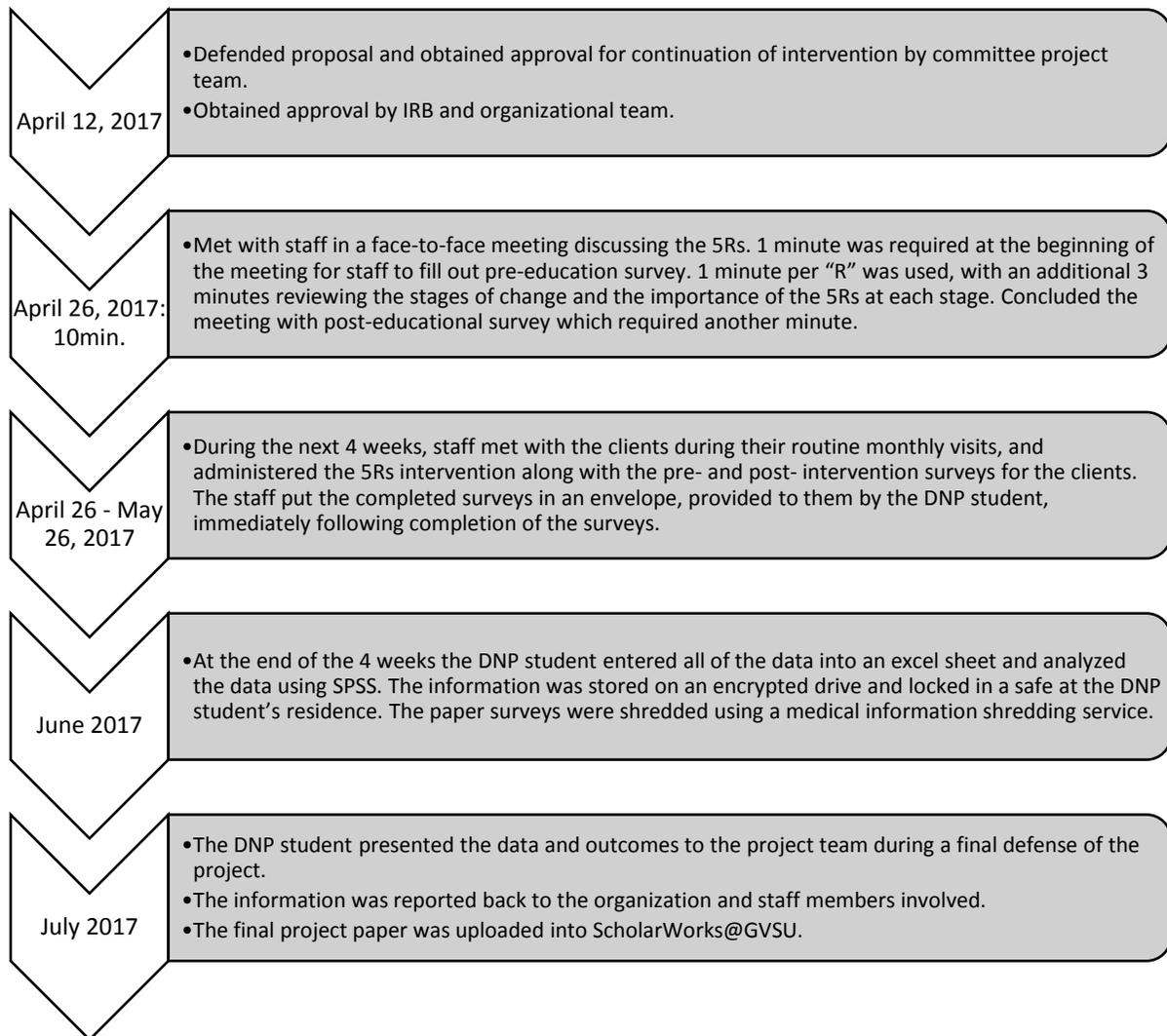
Figure 3: “A three dimensional matrix in which evidence, context, and facilitation can either be expected to influence the outcome in a positive or negative way” by Kitson, A., Harvey, G., & McCormack, B., 1998, *Quality in Health Care*, 7, p.153. Copyright 1998. Reproduced with permission.

Appendix D
Health department SWOT analysis

Strengths	Weaknesses
<ul style="list-style-type: none"> -around 23% of staff with over 20 years of experience -Good with change/learning organization/flexible -10 essential services including utilizing research and mobilizing partnerships -has established QI department which has worked on multiple QI projects. -Look for best practice -client/patient- centered care -All about population health and prevention as described by the organization’s mission and vision to better people and communities -Has different departments that address and focus on different health issues -tobacco cessation/prevention as a “winnable battle” -1 of only 3 health departments in the state to receive National Public Health Accreditation 	<ul style="list-style-type: none"> -Made up of 10 counties spread apart in area -around 23% of staff with over 20 years of experience -Funded mainly through grants -Patient population resistant to change and/or cessation -potential for miscommunication -lack of successful training for new employees or existing employees -lack of substantial marketing and advertising for the health department
Opportunities	Threats
<ul style="list-style-type: none"> -Michigan’s smoke-free air law of 2009 -Grant funding made available -In 2006, Medicaid programs covered cessation counseling services for pregnant women in 14 states, including Michigan -CDC, addressing smoking as the leading preventable cause of death -Public Health Code requiring annual community reports of service progress 	<ul style="list-style-type: none"> -State funding to the health department, Medicaid funding -Grant funding for different projects -Weather (traveling purposes) -Patient population: high smoking rates, low SES. -Public Health Code requiring annual community reports of service progress -MDCH changing their guide to public health

Appendix E

Timeline diagraming the steps for implementation of the proposed project.



Appendix F
Initial survey assessing staff knowledge of the clinical base guidelines of the 5Rs.

Please circle your answer

1. Are you familiar with the 5Rs of the smoking cessation guidelines?
Yes No Somewhat/Maybe

2. The goal of “Relevance” is to identify personal motivational factors to quit
Yes No Don’t Know

3. “Risk” involves identifying potential negative consequences of smoking.
Yes No Don’t Know

4. “Rewards” involves giving praise or financial incentives for quitting.
Yes No Don’t Know

5. The goal of “Roadblocks” is to help the women identify barriers to quitting.
Yes No Don’t Know

6. The 5Rs should be used with clients once a year.
Yes No Don’t Know

Appendix H

Reminder handout for staff of the 5Rs

The 5Rs

Relevance

- Identifying motivational factors
 - Encourage discussion of why quitting may be personally relevant i.e. there are other children in the home, or have a baby on the way and want them to be as healthy as possible
- Goal is to link the motivation to quit to the patient's personal situation
Being as specific as possible

Risk

- Identifying potential negative effects of continued smoking
 - Encourage discussion of the potential negative effects of smoking on her and her baby if she continues to smoke
 - An idea to start this section is “Although you do not want to or are not ready to quit now, what have you heard about smoking during pregnancy?”
 - If the woman seems unaware of risks, this is good time to give pregnancy-related information
 - ✓ i.e. smoking while pregnant increasing the likelihood of miscarriage, stillbirth, SIDS, emotional problems in your child like ADD, ear infections, asthma, and low birth weight.
 - If the woman has a healthy child at home, she may be unconvinced to quit
 - ✓ Good time to talk about benefits of quitting for this pregnancy and for her current living children
 - ✓ Also this is the time to talk about how each pregnancy is different and she herself is different: she's older which means a higher chance of complications and chronic diseases. The absence of complications in previous pregnancy does not guarantee future pregnancies free of trouble. Is she ok with this risk?

Rewards

- Identifying how quitting would benefit her and her family
 - Encourage discussion on the benefits of quitting.
 - i.e. the woman will have more energy, she'll be a good example for her baby and other children, saving money, preventing sickness in her child like asthma, etc..

Roadblocks

- Identifying barriers to quitting
 - Encourage discussion on the barriers to quitting.
 - Many women can think of lots of barriers to quitting
 - i.e. withdrawal symptoms, weight gain, other smokers around, emotional consequences, etc..
 - Reassure patient assistance is available
 - i.e. quit-line, counseling at the health department, etc...

Repetition

- Repeat at every visit for patients who smoke
 - Tell patients who have tried to quit but failed/relapsed that it takes many people multiple attempts before they are actually able to quit completely. She can learn from each attempt, and the more attempts the increased likelihood of quitting. If quitting is not an option, then a reduction in amount smoked is also extremely beneficial: this is important to emphasize.

Appendix I
Pre-Intervention survey for the pregnant women who smoke

Initial Survey

Do you think smoking can cause the following in your unborn baby?

(Place a check mark in the box of your answer)

	NO	MAYBE	YES
Asthma			
Ear Infections			
Emotional or Behavioral problems (like ADD)			
Diabetes or high blood sugar			
Miscarriage/Stillbirth			
Low birth weight			
Sudden Infant Death Syndrome (SIDS)			

(Circle your answer)

Are you married or have a partner? Yes / No

Does your partner Smoke? Yes / No

Do you have other kids in The home? Yes / No

How many cigarettes do you smoke a day? _____

Appendix J
 Post-Intervention for the pregnant women who smoke

Final Survey

Do you think smoking can cause the following in your unborn baby?

(Place a check mark in the box of your answer)

	NO	MAYBE	YES
Asthma			
Ear Infections			
Emotional or Behavioral problems (like ADD)			
Diabetes or high blood sugar			
Miscarriage/Stillbirth			
Low birth weight			
Sudden Infant Death Syndrome (SIDS)			

Appendix K
IRB approval

DATE: April 17, 2017

TO: Rachel Danks
FROM: Grand Valley State University Human Research Review Committee
STUDY TITLE: [1057181-1] Implementing clinical practice guideline recommendations to address prenatal smoking: A practice change in a community health department
REFERENCE #: 17-203-H
SUBMISSION TYPE: Non-Human Subject Research Determination Form

ACTION: Not Research
EFFECTIVE DATE: April 17, 2017
REVIEW TYPE: Administrative Review

Thank you for your submission of materials for your planned research study. Upon review of the aims and description of your study, it has been determined that this project *DOES NOT* meet the definition of covered human subjects research* according to current federal regulations. The project, therefore, *DOES NOT* require further review and approval by the HRRC.

According to your study description, you are conducting a training program within a public health department to determine if this program is feasible and acceptable for staff members and if the program improves the services provided by the health department. It has been determined that this study is a quality improvement project that is not "designed to develop or contribute to generalizable knowledge." Therefore, it does not meet the definition of "research" under federal regulation 45 CFR 46.102(d).

Should you change the aims and activities of your project such that it would then meet the definition of human subjects research, please cease any contacts with potential human subjects until such time as you submit the project protocol to the HRRC and receive the committee's approval to proceed. Should you change the aims and activities of your project such that you are unsure if it meets the definition of human subjects research, please submit a new Non-Human Research Determination Form for review by the Office of Research Compliance and Integrity.

If you have any questions, please contact the Office of Research Integrity and Compliance at (616) 331-3197 or rci@gvsu.edu. Please include your study title and reference number in all correspondence with our office.

Appendix L
Understanding of the 5Rs by staff members

Table L1

Staff Answers to the Pre- and Post- Educational Surveys

Question Focus	Yes n (%)	No n (%)	DK/SWM n (%)	Correct n (%)
Pre-Educational Survey				
Familiar with 5Rs	0 (0%)	3 (42.9%)	4 (57.1%)	
“Relevance” Goal	5 (71.4%)	0 (0%)	2 (28.6%)	5 (71.4%)
Identifying “Risk”	5 (71.4%)	1 (14.3%)	1 (14.3)	5 (71.4%)
“Rewards” Goal	6 (85.7%)	0 (0%)	1 (14.3%)	0 (0%)
“Roadblocks” Goal	6 (85.7%)	0 (0%)	1 (14.3%)	6 (85.7%)
5Rs used once/year	0 (0%)	3 (42.9%)	4 (57.1%)	3 (42.9%)
Post-Educational Survey				
Familiar with 5Rs	6 (85.7%)	0 (0%)	1 (14.3)	6 (85.7%)
“Relevance” Goal	7 (100%)	0 (0%)	0 (0%)	7 (100%)
Identifying “Risk”	7 (100%)	0 (0%)	0 (0%)	7 (100%)
“Rewards” Goal	2 (28.6%)	5 (71.4%)	0 (0%)	5 (71.4%)
“Roadblocks” Goal	7 (100%)	0 (0%)	0 (0%)	7 (100%)
5Rs used once/year	0 (0%)	5 (71.4%)	2 (28.6%)	5 (71.4%)

Note: This table gives a shortened version of the actual questions on the survey found in Appendix F.
Note: DK/SWM stands for don't know or Somewhat/Maybe.

Table L2

Descriptive Statistics of Post-Educational Survey Questions 7-9

Question	Min.	Max.	Mdn	M	SD
7	3	5	3	3.7	0.95
8	3	5	4	4	0.816
9	3	5	4	4.14	0.69

Note: This table gives the question number of the expanded questions found in Appendix G

Appendix M
Project outcomes of pre- and post-educational meeting

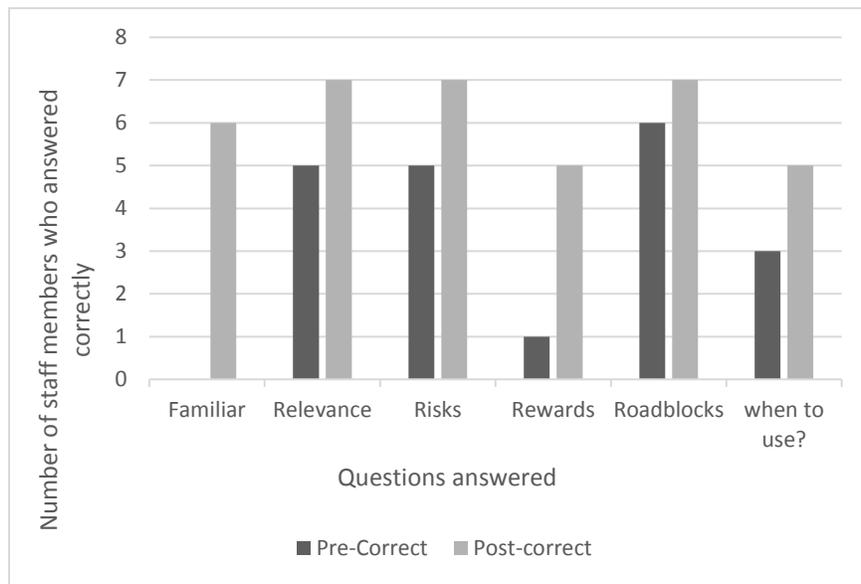


Figure 4: “Staff answers Pre- and Post- Educational Meeting”. This figure portrays the number of staff members providing correct answers to the first six questions of the pre- and post-educational surveys. In this figure Pre-Correct symbolizes the number of staff members providing the correct answer on the pre-educational survey. Post-Correct symbolizes the number of staff members providing the correct answer on the post-educational survey.

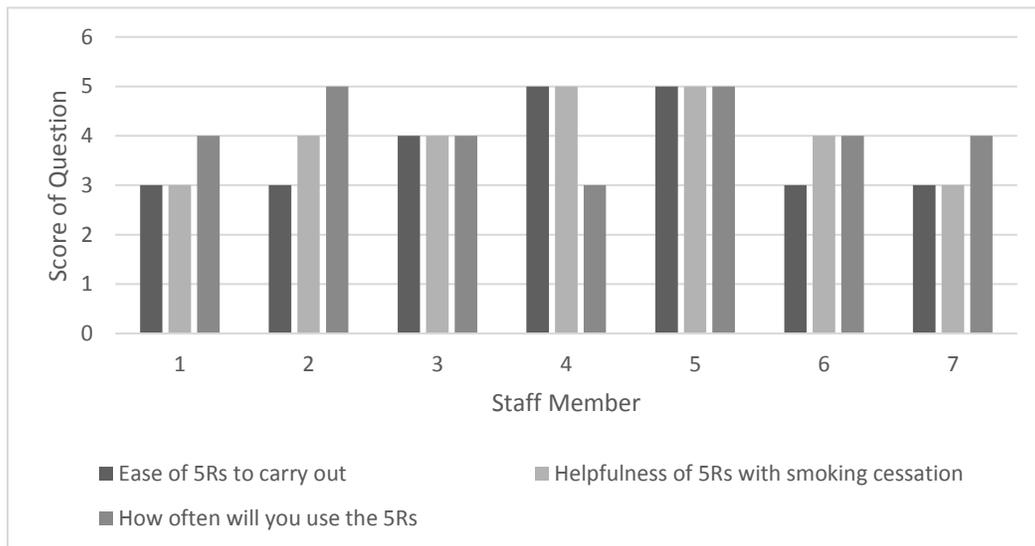


Figure 5: “Acceptability and Feasibility among Staff Members”. This figure portrays the answers to the feasibility and acceptability questions on the post-educational meeting survey only. Each staff member was randomly labeled as a number.

Appendix N
Intervention results

Table N

Client Answers to Pre – and Post- Intervention Surveys

Variable	No n (%)	Maybe n (%)	Yes n (%)	Correct n (%)
Pre-Intervention Survey				
Asthma	1 (10%)	6 (60%)	3 (30%)	3 (30%)
Ear Infections	3 (30%)	5 (50%)	2 (20%)	2 (20%)
Behavioral Problems	3 (30%)	5 (50%)	2 (20%)	2 (20%)
Diabetes	3 (30%)	6 (60%)	1 (10%)	3 (30%)
Miscarriage	1 (10%)	5 (50%)	4 (40%)	4 (40%)
Low birth weight	0 (0%)	3 (30%)	7 (70%)	7 (70%)
SIDS	2 (20%)	7 (70%)	1 (10%)	1 (10%)
Post-Intervention Survey				
Asthma	1 (10%)	2 (20%)	7 (70%)	7 (70%)
Ear Infections	1 (10%)	1 (10%)	8 (80%)	8 (80%)
Behavioral Problems	1 (10%)	2 (20%)	7 (70%)	7 (70%)
Diabetes	5 (50%)	3 (30%)	2 (20%)	5 (50%)
Miscarriage	1 (10%)	1 (10%)	8 (80%)	8 (80%)
Low birth weight	0 (0%)	0 (0%)	10 (100%)	10 (100%)
SIDS	1 (10%)	1 (10%)	8 (80%)	8 (80%)

Note: SIDS symbolizes Sudden Infant Death Syndrome

Note: some of the variables are shortened versions of the titles in the surveys as seen in Appendices I and J

Appendix O
Intervention results and project outcomes

Table O1

Pre- and Post- Intervention Descriptive Statistics

Variable	n	M	SD	Min.	Max.	Percentiles		
						25th	50th(Mdn)	75th
Pre- Intv	10	7.9	2.2828	3	12	7	8	9
Post-Intv	10	11.6	3.2042	4	14	12	12.5	14

Note: Intv symbolizes intervention

Table O2

Table of Signed Ranks

Client	Pre-5R Intv Score	Post-5R Intv Score	Difference	Absolute difference	Rank	With tied Ranks	Signed Ranks
1	8	12	-4	4	5	6	-6
2	8	12	-4	4	6	6	-6
3	9	13	-4	4	7	6	-6
4	7	14	-7	7	10	10	-10
5	7	8	-1	1	1	1.5	-1.5
6	3	4	-1	1	2	1.5	-1.5
7	7	13	-6	6	9	9	-9
8	12	14	-2	2	3	3	-3
9	9	12	-3	3	4	4	-4
10	9	14	-5	5	8	8	-8

Note: Intv stands for intervention, therefore Pre-5R Intv score stand for pre-intervention survey score.

Note: client number symbolize a random number allotted one of the pregnant women smokers

Appendix P
Intervention results and project outcomes

Table P1

Table of Ranks

Ranks	n	M Rank	Sum of Ranks
Negative	10	5.5	55
Postivive	0	0	0
Ties	0		
Total	10		

Table P2

Client Answers to Psychosocial Questions

Client	Married/Have Partner	Partner Smokes	Other Kids in the Home	Number of Cigarettes smoked per day
1	Yes	Yes	Yes	≤ 10
2	Yes	Yes	Yes	7
3	No	N/A	Yes	4
4	Yes	No	Yes	10-15
5	Yes	No	Yes	10-12
6	No	N/A	No	10
7	Yes	Yes	No	3
8	Yes	Yes	Yes	4
9	No	N/A	Yes	12
10	Yes	Yes	Yes	5-8