TERATOGENIC MEDICATION SAFETY IN PRIMARY CARE

by

Nicole Licato

Paper submitted in partial fulfillment of the
requirements for the degree of

Doctor of Nursing Practice

East Carolina University
College of Nursing

Acknowledgments

I would like to thank the incredible East Carolina University faculty for supporting me throughout the program, both academically and personally. Specifically, Dr. Michelle Skipper and Dr. Tracey Robertson-Bell have helped me develop, implement, and evaluate my project each step of the way. They guided me and shaped the success of this project. I would also like to acknowledge Dr. Swati Shroff who gave me permission to use her framework in my project.

Additionally, Dr. Melissa Fike and Casey Jones were invaluable during the planning and implementation stages of the project at the site level. Dr. Fike spent time brainstorming with me to improve outcomes for the project and worked to make the project a success as my site champion. She also served as my mentor through the DNP and FNP program. Elizabeth Stern and Makeba Felton made this project possible at their site and were instrumental in bringing providers on board. I would also like to thank Dr. Deborah Allen who worked with me to gather data for the project and walked me through the site approval process. Additionally, Dr. Patrick Gregory who is helping to develop a best practice advisory for the electronic health record after project completion. I also acknowledge each of the providers at both clinics who attended the education session and supported this project.

Finally, I would like to thank my father Nicholas Licato who has supported me throughout my nursing career and always led by example with traits of kindness, generosity, caring, and perseverance.

Dedication

This project is dedicated to women everywhere who felt unaware of the potential risks of their medications. It is also dedicated to women who felt they did not receive the contraceptive counseling they deserved.

Abstract

Childbearing age women are often prescribed teratogenic medication without pregnancy risk or contraceptive counseling. With a 45% unintended pregnancy rate, women are at risk of unintentional teratogenic fetal exposure. The TARCC framework created by Shroff, McNeil, and Borrero (2017), is an acronym that providers can use while prescribing medication to reduce the risk of teratogenic exposure. Ultimately, the increase in TARCC usage could lead to decreased teratogen prescription, increased birth control use while on a teratogen, and reductions in birth defects and elective abortion. The purpose of the Doctor of Nursing Practice project was to increase primary care provider knowledge and use of the TARCC framework at two urban clinics in NC. The project interventions consisted of provider education, TARCC reminder cards, weekly teratogen information emails, and TARCC checklists to use during patient visits. The outcomes of the project included an increase in provider self-reported competence in TARCC usage and an increased provider awareness of safe prescribing. Site A had an average of 16% (SD=6.9%) use of the TARCC checklist over ten weeks. Overall, it was recommended to place a practice advisory in the electronic health record to help providers prescribe safely.

Key words: teratogen, contraception, TARCC, unintended pregnancy, childbearing, pregnancy, prescription, medication

Table of Contents

Chapter One: Overview of the Problem of Interest

In the United States, women of childbearing age are often prescribed teratogenic medication without a discussion of pregnancy risk or contraceptive counseling (Mody, Farala, Wu, Felix, & Chambers, 2015; Schwarz, Maselli, Norton, & Gonzales, 2005; Shroff, McNeil, & Borrero, 2017). Taken during pregnancy, teratogenic medication can cause fetal growth and development problems, including miscarriage. Considering high unintended pregnancy rates, a fetus may be exposed to teratogenic medication before prenatal care is initiated. In addition, North Carolina (NC) has restrictive abortion regulations, which may affect a woman's ability to terminate a pregnancy exposed to teratogenic medication early in pregnancy. Therefore, teratogenic effects on an unplanned or unintended pregnancy must be reduced. A Doctor of Nursing Practice (DNP) Project was conducted in two urban NC primary care clinics to increase provider awareness of the TARCC framework developed by Shroff et al. (2017). TARCC stands for teratogen, alternative, risks, contraceptive counseling, and charting (Shroff et al., 2017). Use of the framework leads to a decrease in teratogenic prescriptions to childbearing age women. It also increases contraceptive and pregnancy risk counseling for women taking teratogenic medication.

Background Information

Healthcare providers often prescribe teratogenic medications to women of childbearing age. Based on the National Health and Nutrition Examination Survey results from 1999 to 2006, 47% of childbearing age non-pregnant women were prescribed at least one medication in the past 30 days (Tinker, Broussard, Frey & Gilboa, 2015). Over half of the women were prescribed more than two prescriptions (Tinker et al., 2015). Five of the top ten prescribed medications require cautious use during pregnancy or were contraindicated (Tinker et al., 2015). Also,

between 2005 and 2009, approximately 10.1 million emergency department visits by childbearing age women resulted in teratogenic medication administration or prescription (Goyal et al., 2015). Last, between 1998 and 2001, 11.1% of primary care visits for childbearing age women resulted in teratogenic medication prescriptions (Schwarz et al., 2005). Therefore, childbearing age women are often prescribed teratogenic medications in both primary and acute care, increasing the risk of fetal exposure.

Unplanned pregnancy can result in fetal exposure to teratogenic medication during early pregnancy. In 2011, 45% of US pregnancies, that resulted in live births, were unintended (Finer & Zolna, 2016). Moreover, women in the United States may start prenatal care later than the first trimester. For example, in 2017, only 77.3% of women started prenatal care during the first trimester (Martin, Hamilton, Osterman, Driscoll, & Drake, 2018). Therefore, women who were on teratogenic medication before pregnancy could have exposed their fetus during the first trimester. In NC, 3% of babies are born with moribund birth defects (National Birth Defects Prevention Network [NBDPN], 2010). Those babies born with moribund birth defects account for 20% of NC infant mortality (NBDPN, 2010). Some of these birth defects develop in first trimester secondary to in-utero teratogen exposure (NBDPN, 2010). The hospital costs related to birth defects amounts to $2.6 billion in NC (NBDPN, 2010). Therefore, healthcare providers have an ethical and financial duty to reduce fetal teratogen exposure when prescribing the medication.

Contraceptive and pregnancy risk counseling when teratogenic medications are prescribed is not standard of care. Category D and X medications were part of the original Food and Drug Administration (FDA) classification system (FDA, 2008). Category D medications have shown human fetal risk, however in certain situations the benefit of the drug may outweigh

the risk of the drug (FDA, 2008). Opposingly, category X medications have shown to have fetal risk and never have benefits that outweigh the risk during pregnancy (FDA, 2008). Category X medications are therefore always contraindicated during pregnancy (FDA, 2008). Mody et al. (2015) found that family practice providers failed to advise contraception to 46.3% of women prescribed a category D or X medication. Similarly, 71% of women on teratogenic medications were not on contraception even though reproductive life plans were completed (DiPietro Mager, Mills, & Snelling, 2018). The problem extends to the Veterans Association where women are often placed on category D or X medications for mental illness or chronic disease (Shroff et al., 2017). Over two years, only 12% of veteran women on teratogenic medication received contraceptive counseling (Shroff et al., 2017). In addition, in emergency departments, between 2005 and 2009, 45.6% of women prescribed a D or X medication failed to have a pregnancy test. This fact illustrates providers' unawareness of teratogenic medication dangers for childbearing-age women (Goyal et al., 2015). Lastly, Schwarz et al. (2005) found that only 6% of primary care visits, in which a teratogenic medication was prescribed, had documented contraceptive counseling or prescriptions. Healthcare providers are ethically bound to do no harm. Therefore, it is their responsibility to provide education about pregnancy risk and contraceptive options when prescribing teratogenic medications to childbearing age women.

Of unintended US pregnancies in 2011, 42% were electively aborted (Finer & Zolna, 2016). Out of 1,209 abortion patients, 13% reported that one reason for choosing abortion was possible birth defects from prescription medications (Finer, Frohwirth, Dauphinee, Singh, & Moore, 2005). Abortion is a timely topic in light of changing and tightening state abortion regulations. Some states are decreasing the maximum gestational age at which an abortion is legal. The legislation may make it more difficult for women to have an abortion if they discover the

pregnancy after the first eight weeks. Therefore, fewer unintended pregnancies and abortions through effective contraceptive counseling benefit the community, social service system, and healthcare system. Contraceptive counseling when teratogenic medications are prescribed educates women about unintended pregnancy consequences of medication use.

Significance of Clinical Problem

Contraceptive counseling when prescribing teratogenic medication to childbearing age women is not routinely done. Providers reported three barriers, (1) lack of time, (2) knowledge deficit of alternative medications, and (3) proper methods for contraceptive counseling (Shroff et al., 2017). At one NC primary care practice, providers stated during informal discussions that they had no methods to ensure contraceptive counseling accompanied teratogenic medication prescriptions (M. Fike, personal communication, June 27, 2019). Providers reported they did not regularly provide counseling about pregnancy risk, reliable contraception, or Plan B when prescribing teratogenic medications (V. Dalalau, personal communication, June 27, 2019) . They also observed they did not habitually think of alternatives to teratogenic medications for childbearing age women (M. Fike, personal communication, June 27, 2019). Last, providers reported that lack of reminders and education were key barriers (M. Fike, personal communication, June 27, 2019).

In addition, baseline data for Fall 2018 were gathered from both primary care clinic project sites A and B. This period was chosen because the DNP project was implemented in Fall 2019. During that time, 2,865 women between the ages of 18 and 50 were seen at sites A and B. (D. Allen, personal communication, Jan 29, 2020). At site A, 33% of those women were taking a teratogenic medication in one of the teratogenic classes focused on in the DNP project (D. Allen, personal communication, Jan 29, 2020). At site B, 50% of women were taking a teratogen (D.

Allen, personal communication, Jan 29, 2020). In Fall 2018, a total of 301 teratogenic medications were prescribed to childbearing age women at both clinics (D. Allen, personal communication, June 27, 2019). Of the women on teratogenic medications who reported they were sexually active, between 55% and 60% were not on birth control at both clinics (D. Allen, personal communication, Jan 29, 2019). Therefore, over half of the women were at risk for fetal exposure to teratogens. There was significant room for improvement at both clinic sites to reduce teratogenic prescriptions and to increase contraceptive counseling for women on them.

Contraceptive counseling when teratogenic medications are prescribed would reduce unintended pregnancies and fetal exposure to teratogenic medications. Subsequently, termination rates and birth defect rates would decrease with subsequent lower healthcare costs (NBDPN, 2010). With the NC restrictions on abortion, preventing one need for abortion, i.e., probable birth defects, would benefit the community and the healthcare system. The project was in line with Healthy People 2020 goals of reducing the number of infants born with birth defects, reducing infant mortality, increasing intended pregnancies, and increasing preconception discussion with childbearing age women (United States Department of Health and Human Services [USDHHS], n.d.). The purpose of the DNP project was to increase primary care provider knowledge and use of the TARCC framework. TARCC is a decision tree framework that helps providers increase the percentage of women using contraception while on a teratogenic medication and reduce the number of teratogenic prescriptions (Shroff et al., 2017). It is an acronym that stands for teratogenic, alternative, risk counseling, contraceptive counseling, and charting (Shroff et al., 2017). First, providers determine if the medication they are prescribing is *teratogenic* and whether there is a safe and appropriate *alternative* (Shroff et al., 2017). If not, providers should discuss pregnancy *risk* and provide *contraceptive counseling* (Shroff et al., 2017). Finally,

providers should *chart* that an alternative was chosen or that appropriate risk and contraceptive counseling was performed (Shroff et al., 2017).

Question Guiding Inquiry (PICO)

Will an education session for family practice providers about the components of the TARCC framework increase their use of the framework and ultimately decrease the risk of fetal exposure to teratogenic medication?

Population. The DNP project population was all primary care providers at two urban NC family practice clinics, which are part of the same health system. There were 14 providers that were included in the education session; seven at each site. Five providers were family nurse practitioners (FNPs), eight were physicians, and one was a physician assistant (PA).

Intervention. The providers attended an education session about the importance of contraceptive and pregnancy risk counseling for childbearing age patients on teratogenic medications. They were introduced to a framework developed by Shroff et al. (2017) called TARCC. TARCC is a mnemonic that providers can use when they prescribe medication (Shroff et al., 2017). Providers gained awareness of commonly prescribed teratogenic medications in primary care based on literature review and safer alternatives. The pregnancy lactation labeling rule was discussed to give providers a tool in assessing risks/benefits of medications and providing accurate pregnancy risk counseling to patients (FDA, 2014). The Center for Disease Control (CDC) Medical Edibility Criteria and materials from the Family Planning National Training Center (FPNTC) was used to ensure guidelines were being followed for effective contraceptive counseling (CDC, 2016; FPNTC, 2019). Last, providers were given access to an easy method of documenting that this counseling was done in the electronic health record.

Comparison. Prior to the project, providers at the project sites did not routinely switch to safer medications for childbearing age women or document contraceptive counseling with prescription of teratogenic medications. There was no systematic way to identify teratogens or ensure reduced risk of fetal exposure. Providers had never used the TARCC framework as a routine part of medication prescription. Therefore, the purpose of the project was to increase provider knowledge and use of the TARCC framework.

Outcome(s). The primary outcomes were increases in provider knowledge, competency, and use of the TARCC framework. There was no national benchmark or baseline for TARCC use, therefore no specific goal was set for the project. As a consequence of increasing provider knowledge and use of the TARCC framework, two long term outcomes were evaluated. First, the percentage of sexually active childbearing age (18-50 years) women using contraception while on a teratogenic medication. Additionally, the percentage of childbearing age women taking a teratogenic medication at the two primary care sites. Again, there was no national benchmark for the outcomes, therefore the metrics were compared before and after the project without a specific outcome percentage.

Summary

Healthcare providers have an ethical and financial incentive to decrease the likelihood that a fetus is exposed to teratogenic medication. In addition, providers have a mandate to educate women about teratogenic effects on pregnancy and effective methods of contraception while on those medications. With the high rates of unplanned pregnancy in the US, providers cannot rely on the patient's desire to avoid pregnancy but must educate about contraception and prescribe as indicated. Providers reported barriers such as lack of time, knowledge about safer alternatives, and effective means of contraceptive counseling. To overcome the barriers, the DNP

student educated 14 primary care providers about TARCC. In addition, providers learned about commonly prescribed teratogenic medications, alternatives, and methods to perform and document contraceptive counseling. With project success, sustainability includes placing all or parts of the TARCC framework into the electronic health record (EHR) for provider use at all clinics in the health system.

The DNP Project outcome was to increase provider knowledge and use of the TARCC framework. As a result of this, two outcomes were assessed and compared to baseline data from Fall 2018. First, the percentage of women using birth control while on a teratogenic medication. Second, the percentage of women taking a teratogen. Long-term implications of the outcomes will be a reduction in fetal exposure to teratogens, reduction in birth defects, and reduction in the need for elective abortion. The project outcomes and long-term implications aligned with Healthy People 2020 goals to increase preconception discussion in primary care, reduce birth defects, reduce infant mortality, and increase the percent of intended pregnancies.

Chapter Two: Review of the Literature

A review of the literature assessed the gap between contraceptive counseling when prescribing teratogenic medication and current practice. Evidence identified contraceptive counseling barriers that were addressed in the DNP project intervention. In addition, the project outcomes aligned with national goals, Triple Aim, and professional organizational recommendations. Evidence limitations were explored. Lastly, the advantages and disadvantages of the project intervention were discussed.

Literature Appraisal Methodology

Sampling strategies. The literature search used East Carolina University's (ECU) Laupus Library One Search which searched all databases and journal subscriptions. Search terms

included “teratogen*,” “childbearing age women,” “contraception”, “prescription,” and “counseling” (see Appendix A for Literature Review Search Log). Limits for the search were sources published within the past five years, English language, scholarly and peer-reviewed, and excluded dissertations. 119 articles were reviewed of which nine were selected for the literature review.

A manual search of those nine articles’ references was another sampling strategy used for the literature review. Nine additional documents were found, including five articles >5 years due to their citation in other articles. Authors of the older documents are prominent US researchers in contraceptive counseling for teratogenic prescriptions. Three documents were national goals, organizational recommendations, or regulations rather than journal articles. One article was located with the “cited by” tool in One Search. In summation, 19 articles were used in the literature review.

Evaluation criteria. Articles were evaluated first by abstract. The abstract determined if the content directly related to the DNP project’s clinical question. For example, abstracts on the teratogenicity of specific drugs, managing medications and medical conditions during pregnancy, pregnancy planning in specific medical conditions, and Isotretinoin iPledge program were excluded.

Next, the subject sample was compared to US childbearing age women. Articles with interventions and outcomes specific to foreign or indigenous populations were not generalizable to US populations. Thus, they were excluded. Similarly, articles with samples of pediatric patients were excluded because the DNP project will include adult patients aged 18 to 50. Sample size was also used to exclude studies. Case reports and case studies with small sample sizes were excluded. Also, studies with vague implementation descriptions, low clinical

significance, and an inadequate discussion of statistical methods were excluded. Last, article methods and results sections were evaluated for rigor. For example, if data were gathered via survey, the authors must have addressed attrition, response rates, and confounding factors.

Based on the preceding evaluation of each study, a level of evidence was assigned to denote the type of research performed using Melnyk Levels of Evidence (Melnyk & Fineout-Overholt, 2011). All levels were included in the literature review except for levels II and VII (see Appendix B for DNP Project Literature Matrix) (Melnyk & Fineout-Overholt, 2011). Ten of the 19 documents were level VI evidence: descriptive and qualitative studies (Melnyk & Fineout-Overholt, 2011). One was level I evidence due to its inclusion of guidelines for clinical practice. One was level III because it was a cluster-randomized study. Three studies were level IV: correlational and case-control study designs (Melnyk & Fineout-Overholt, 2011). Two were systematic reviews of qualitative studies, i.e., level V evidence (Melnyk & Fineout-Overholt, 2011). Two documents were not assigned levels of evidence because one is a national regulation and the other lists national goals.

Literature Review Findings

The evidence were mostly descriptive and qualitative studies that evaluated frequency of teratogenic medication prescription and if patients received contraceptive counseling. There were no multi-site, randomized control trials on the DNP topic. Due to the nature of the topic, retrospective designs predominated. It would be unethical to willingly withhold contraceptive counseling to women on teratogenic medication. Therefore, studies reported retrospective data on women who received teratogenic medication and if contraceptive counseling accompanied the prescription. The studies used correlational designs to assess patient and provider factors that may have affected counseling. Also, provider and patient surveys were used to identify barriers

to counseling and perceptions of pregnancy risk and contraceptive counseling. In addition, the American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), American Academy of Family Physicians (AAFP), American Society for Reproductive Medicine (ASRM), and the National Association of Nurse Practitioners in Women's Health (NPWH) produced guidelines based on systematic reviews (ACOG & ASRM, 2019; Women's Preventive Services Initiative, 2016).

The need for improvement. There was a gap between (1) contraceptive counseling as part of routine, well-woman primary care, and (2) state of practice. National organizations such as ACOG, AAFP, ACP, ASRM, and NPWH called for contraceptive counseling and preconception planning at all health promotion visits for childbearing age women (ACOG & ASRM, 2019; Women's Preventive Services Initiative, 2016). Consequently, medication reconciliation in primary care should include assessment of teratogenic medication and contraception to decrease unintended pregnancy while on the medication (Women's Preventive Services Initiative, 2016). Also, Healthy People 2020 had goals around decreasing birth defects and increasing intended pregnancies (USDHHS, n.d.).

Despite these evidence-based guidelines, studies consistently illustrated less than 60% of women received pregnancy risk counseling or contraceptive counseling when prescribed a teratogenic medication (Bhakta, Bainbridge, & Borgelt, 2015; DiPietro Mager et al., 2018; Goyal et al., 2015; Schwarz et al., 2005; Schwarz et al., 2012; Schwarz et al., 2013; Schwarz, Postlethwaite, Hung, & Armstrong, 2007; Shroff et al., 2017; Quinzanos et al., 2015). Teratogenic medication was often prescribed by general and family practice providers in primary care, outpatient settings (Schwarz et al., 2005; Schwarz et al., 2013). This was likely due to the management of chronic disease in primary care with teratogenic medication. For example,

hypertension, anxiety, depression, hyperlipidemia, diabetes, heart disease, and arthritis are all commonly managed in primary care and have first line teratogenic medications (Callegari, Ma, & Schwarz, 2015; Holton et al, 2018; Mody et al., 2015; Schwarz et al, 2013). However, women with these conditions were less likely to discuss contraception planning with their provider than women without chronic conditions (Holton et al., 2018). It follows that women with chronic diseases were, therefore, more likely to have unintended pregnancies and higher rates of abortion (Horton et al., 2018). Unfortunately, when women had an unintended pregnancy while on a teratogenic medication, they experienced a miscarriage or chose an abortion (Bhakta et al., 2015).

Support for the intervention. Evidence supported the DNP intervention of provider education. Both general medicine faculty and residents expressed a desire to have more education about contraception counseling as part of their training and continuing education (Dirksen, Shulman, Teal, & Huebschmann, 2014). The project education intervention addressed barriers cited in the literature such as lack of education about alternatives to teratogenic medication, confidence in providing contraceptive counseling, and comfort in discussing pregnancy risks (Dirksen et al., 2014; Shroff et al., 2017). Another barrier to risk counseling was the original FDA pregnancy risk categories: A, B, C, D, and X. It was found that the categories lacked substantive information about risks and benefits, teratogenicity, and required contraception before or during treatment (FDA, 2014). As a result, the FDA issued a new pregnancy and lactation labeling rule in 2015 to combat these issues, which will be included in the provider education session (FDA, 2014).

Contraceptive counseling is supported in the literature and has shown to produce positive outcomes for women. For example, women who received contraceptive counseling, especially

from their primary care provider, were more likely to have used contraception during their last intercourse (Lee, Parisi, Akers, Borrerro, & Schwarz, 2011). The counseling alone was shown to increase contraceptive use with even higher rates of usage if a contraceptive was prescribed at the visit (Lee et al., 2011). In addition, women who received contraceptive counseling from their primary care providers reported they were both satisfied and well informed after the visit, perhaps due to shared decision-making (Lee et al., 2011). Shared decision-making was an effective method of counseling primary care providers often used to manage other chronic illnesses (Ferguson et al., 2016). Overall, primary care providers were well suited to provide effective contraceptive counseling.

Despite the effectiveness of contraceptive counseling, attempts to increase contraceptive counseling rates when prescribing teratogenic medication had mixed outcomes. In one study, a clinical decision support tool inserted into the EHR to alert providers of a teratogenic prescription produced insignificant provider behavioral change (Schwarz et al., 2012). However, the intervention did not address evidence-based barriers such as provider education about contraception counseling, alternatives to teratogens, or contraception methods (Dirksen et al., 2014; Schwarz et al., 2012; Shroff et al., 2017). Instead, 13% of the time, the provider replaced the teratogenic medication with another teratogenic medication (Schwarz et al., 2012). Therefore, the providers did not have the knowledge to choose a safer alternative medication. Despite lack of evidence in the EHR, providers reported that the clinical decision support tool made them more likely to discuss risks of medication, prescribe birth control, and provide preconception counseling (Schwarz et al., 2012). Other studies have reported similar discrepancies between the absence of change in the medical record compared to provider or

patient-reported behavioral change (Schwarz et al., 2013; Shroff et al., 2017). This may be due to a paucity of easy ways to document contraceptive counseling and pregnancy risk education.

The TARCC framework was developed by Shroff et al. (2017) to address provider-identified barriers to contraceptive counseling. The TARCC acronym stands for: is the medication *teratogenic*, is there a safe *alternative*, have you discussed the *risks* to pregnancy while on the medication, is the patient currently on or have you discussed and prescribed *contraception,* and has the counseling and risk education been *charted* (Shroff et al., 2017). It was used both as an educational tool and an EHR support tool (Shroff et al., 2017). TARCC helps providers go through specific steps when prescribing a new medication that is potentially teratogenic (Shroff et al., 2017).

The QI project leader, Dr. Shroff, approved the use of the TARCC framework in this DNP project. When the framework is used to educate providers, it trains them to use shared decision making to provide contraceptive counseling (Ferguson et al., 2016; Lee et al., 2011; Shroff et al., 2017). The last step in the framework is to chart the counseling in the EHR. This step was based on literature reports about missing documentation. Overall, evidence supported the intervention to educate providers about teratogenic pregnancy risk counseling, contraceptive counseling, and non-teratogenic alternatives.

Limitations of Literature Review Process

One limitation was the lack of randomized control trials that tested interventions to improve contraceptive counseling when prescribing teratogenic medication. Also, the sample sizes were often small. Studies were more likely to explore whether counseling was done and how often teratogenic medication was prescribed, not to improve outcomes. Also, survey responses in the articles were moderate to low. Thus, response bias was possible. Interventions

were limited to adding reminders and hard stops to the EHR rather than addressing provider barriers to knowledge and competency. Last, several studies focused on lupus, cancer, or epileptic patients which are not solely managed in primary care. Therefore, some findings were not from primary care managed chronic diseases.

Discussion

Conclusion of findings. Evidence illustrated the widespread lack of contraceptive counseling when primary care providers prescribed teratogenic medications. Yet, primary care providers manage chronic conditions that frequently require teratogenic medications. Providers reported a lack of knowledge about non-teratogenic alternatives, contraceptive counseling, and pregnancy risk counseling as barriers. Interviews with primary care clinic providers in urban NC, revealed they had no system in place to flag teratogenic medications or chart contraceptive counseling when they prescribe them (M. Felton, personal communication, August 20, 2019). The site's practice aligned with the evidence about provider barriers to teratogenic safety. In addition, preliminary data from the primary care clinics' EHR indicated that over half of the women were not using birth control while on a teratogen. Also, in three months, 30 to 50% of childbearing age women were using at least one teratogenic medication (D. Allen, personal communication, June 27, 2019). Thus, the TARCC framework was used to address provider barriers and improve teratogenic medication safety (Shroff et al., 2017).

Contraceptive counseling that uses CDC Medical Eligibility Criteria aligned with recommendations from ACOG, AAFP, ACP, ASRM, and NPWH for primary care providers (ACOG & ASRM, 2019; Women's Preventive Services Initiative, 2016). Contraceptive counseling to all childbearing age women at wellness visits, especially if teratogenic medication is prescribed, is a best, ethical practice (ACOG & ASRM, 2019; Women's Preventive Services

Initiative, 2016). By using the FDA's new pregnancy and lactation labeling rule, providers were equipped with pregnancy risk and teratogenic information to adequately counsel patients (FDA, 2014). In addition, decreasing fetal exposure to teratogens aligned with Healthy People 2020 goals (USDHHS, n.d.).

Advantages and disadvantages of findings. Education of providers has been shown in the literature to be an essential requirement to increase rates of contraceptive counseling (Dirksen et al., 2014; Shroff et al., 2017). Therefore, the intervention of provider education had evidence to support it. The new FDA pregnancy and lactation labeling rule was gradually changing the way providers make clinical decisions about prescriptions for potentially reproductive women (FDA, 2014). The FDA rule helped providers have a clearer understanding of risks and benefits for counseling women (FDA, 2014). Last, providing contraceptive counseling when prescribing teratogenic medication not only had ethical implications, but aligned with national organizational recommendations. The providers at the primary care sites belonged to several of these organizations. It was also in line with national preventive health goals. Overall, providers had incentive to participate in the DNP project.

The major disadvantage was that implementation of a clinical decision support tool into the EHR did not improve outcomes to increase contraceptive counseling (Schwarz et al., 2012). Yet, the intervention did not include provider education or educational resources, which were cited as significant barriers to increasing counseling rates. Also, the outcomes of the TARCC framework in the EHR were still being studied at the time of the literature review. Lack of randomized control trials to test interventions that increased pregnancy risk and contraceptive counseling was a disadvantage. However, provider education was supported by providers' informal interviews at the project site and barriers cited in the literature. Overall, the education

session and phrase to document the TARCC framework in the EHR were practical interventions to improve outcomes.

Utilization of findings in practice change. The evidence indicated that merely placing a decision-tree and alert in the EHR was ineffective for practice change (Schwarz et al., 2012). Also, providers requested continuing education on contraceptive counseling and teratogenic pregnancy risk counseling (Dirksen et al., 2014; Shroff et al., 2017). Therefore, the education session was in person with a follow-up email for links to outside resources for future reference. Topics for the session included commonly prescribed teratogenic medications, alternatives, risk counseling, and contraceptive counseling strategies (Callegari et al., 2015; DiPietro Mager et al., 2018; Mody et al., 2015; Schwarz et al., 2012; Schwarz et al., 2013). EHR data and provider surveys were used to track outcomes. The surveys assessed provider perception of behavioral change about the TARCC framework because evidence showed a discrepancy between EHR outcomes and provider perceptions (Schwarz et al., 2012).

Summary

Contraceptive counseling when teratogenic medications are prescribed reduces unintended pregnancy rates and fetal exposure to teratogenic medication. Healthy People 2020 had a goal of increasing intended pregnancy rates in the United States from 51% to 56% (USDHHS, n.d.). Contraception is the most effective way to decrease unintended pregnancy. It should be available to all women at a low cost and discussed at all health promotion visits. (ACOG & ASRM, 2019; Women's Preventive Services Initiative, 2016). Birth defects and abortion secondary to fetal exposure to teratogenic medication were also among Healthy People 2020 goals to decrease maternal and infant morbidity and mortality (Finer et al., 2005; USDHHS, n.d.).

The DNP project was also related to Triple Aim goals (Institute for Healthcare Improvement [IHI], 2019). Contraceptive counseling improves patient experience through shared decision making. It equips patients with information needed to make healthy choices for their families. Patients will feel well informed about the risks of their medications and how to safely avoid pregnancy while on those medications. Birth defects were responsible for $2.6 billion in NC hospital costs. Also, abortions are costly to families who need them (NBDPN, 2010). Therefore, reducing the frequency of birth defects or abortions by minimizing fetal exposure would improve per capita healthcare cost: part of Triple Aim (IHI, 2019). Last, population health improves when families can plan a pregnancy, and when babies are born without birth defects or developmental disabilities. This DNP project's long-term outcomes could improve population health when the TARCC framework is widely used at the project sites.

Chapter Three: Theory and Concept Model for Evidence-based Practice

Three key concepts of the DNP project were teratogenic medication, contraceptive counseling, and unintended pregnancy. Each concept was explored and defined using the literature and its specific applicability to the project was discussed (see Appendix C for DNP Project Concept Map). In addition, the DNP project was supported by a theoretical framework and evidence-based change model. Dorothea Orem's theory of self-care underlies the rationale and content of the project, whereas Kurt Lewin's Change Theory supported the method and format of the intervention.

Concept Analysis

Teratogenic medication. The first concept was teratogenic medication. A teratogenic medication has a high risk of harming the growth and development of the fetus if the mother uses the medication during pregnancy (FDA, 2014). Teratogenic effects include cardiac defects,

neural tube defects, facial clefts, learning disabilities, miscarriage, fetal death, and growth restriction (Bhakta et al., 2015; Briggs et al., 2015; DiPietro Mager et al., 2018). Before 2015, the FDA assigned a category to each medication to denote the level of teratogenicity (FDA, 2008). Category C medications had limited data indicating the potential for fetal risk. However, the benefits often outweighed the risks (FDA, 2008). Categories D and X had the highest likelihood of teratogenicity based on human and animal studies, with X being contraindicated during pregnancy (FDA, 2008). As of 2015, the new Pregnancy and Lactation Labeling Rule replaced the letter categories with a narrative of potential risks, benefits, study data, and recommendations for women and men of reproductive potential for each medication (FDA, 2014). Therefore, part of the teratogenic medication definition included the use of these guidelines to discuss risks and benefits with women.

In the literature, teratogenic medications were defined as class D and X medications despite the recent change in FDA labelling (Bhakta et al., 2015; Goyal et al., 2015; Mody et al., 2015; Schwarz et al., 2005; Schwarz et al., 2012; Schwarz et al., 2007; Shroff et al., 2017). Study authors typically focused on the following teratogenic drugs: benzodiazepines, angiotensin-converting enzyme inhibitors, angiotensin receptor II antagonists, anticonvulsants, certain antibiotics, statins, lithium, isotretinoin, paroxetine, and warfarin (DiPietro Mager et al., 2018; Mody et al., 2015; Schwarz et al., 2005; Shroff et al., 2017). For the DNP project, teratogenic medication was defined as category D or X medications in the following classes: benzodiazepines, angiotensin-converting enzyme inhibitors, angiotensin receptor II antagonists, anticonvulsants, statins, and warfarin. These classes helped provide focus to ensure the project was manageable.

Contraceptive counseling. Contraceptive counseling is a shared decision-making process between a provider and patient that allows the woman to choose the best contraceptive option for her at that time given her values and preferences (Dehlendorf, Krajewski, & Borrero, 2014; Gavin et al., 2014). It includes risks, benefits, efficacy, method of use, and side effects of contraceptive options as well as safety of the method based on her medical and social history (Dehlendorf et al., 2014; Gavin et al., 2014). The information provided during contraceptive counseling should be based on the CDC Medical Eligibility Criteria, and the FPNTC with the most effective forms of contraception discussed first (Gavin et al., 2014). All options should be made available to women, including referrals to providers who offer implants and intrauterine devices (ACOG, 2015). Counseling includes prescription of appropriate medication, plan for follow up, discussion of barriers to effective use, and sexually transmitted disease protection if a barrier method was not chosen (Dehlendorf et al., 2014; Gavin et al., 2014).

Strategies for effective counseling included using open-ended questions, giving information in a non-judgmental manner, promoting discussion, and demonstrating trustworthiness and expertise (Dehlendorf et al., 2014; Gavin et al., 2014; Lee et al., 2011). Primary care providers know their patients' cultural, medical, and social histories well. Therefore, they can tailor counseling to the individual. It is for this reason that counseling done by primary care providers was well received and increased contraceptive use (Lee et al., 2011).

Unintended pregnancy. When a woman becomes pregnant while she is not purposefully trying to become pregnant, she is considered to have an unintended pregnancy. There are two types of unintended pregnancy; unwanted and mistimed (Finer & Zolna, 2016). Unwanted pregnancies occur if a woman never intended to become pregnant in the future (Finer & Zolna, 2016). Alternatively, if a woman wanted a pregnancy later than at the time of conception, the

pregnancy is considered mistimed (Finer & Zolna, 2016). Women are at risk for unintended pregnancy if they do not believe they can get pregnant, are nonusers of contraception, are misusing contraception, and are sexually active (Mosher, Jones, & Abma, 2015). Therefore, to determine if a woman is at risk for unintended pregnancy, she must be asked about her current pregnancy desires, sexual activity, and contraception use. In 2011, 45% of live US births were unintended (Finer & Zolna, 2016). Additionally, 42% of unintended pregnancies ended in elective abortion (Finer & Zolna, 2016). Therefore, this is a widespread phenomenon that is not being sufficiently tackled in primary care.

Unintended pregnancy is used as an indicator of a woman's reproductive autonomy and is deeply intertwined with the social determinants of health (Morse, Ramesh, & Jackson, 2017). Unfortunately, unintended pregnancy rates were proportionally higher in low income Black and Hispanic women (Finer & Zolna, 2016; Morse et al., 2017). This population of women was already at risk for poor outcomes such as low birth weight, inadequate prenatal care, and substance use, therefore, an unintended pregnancy can increase the risk even further (Finer & Zolna, 2016; Morse et al., 2017). Even though unintended pregnancy occurred in all religions and backgrounds, the phenomenon must be viewed through a cultural and social lens. Pregnancy may be viewed as an unplannable event or as something that happens when it is supposed to (Morse et al., 2017). Women may also not be in control of their contraceptive use yet may be welcoming of the pregnancy (Morse et al., 2017). Therefore, pregnancy is not always easily defined as unintended. Also, unintended pregnancy should not be correlated with unhappiness or lack of acceptance of the pregnancy. In the DNP project, pregnancy intentions were assessed by the provider upon teratogenic medication prescription. Pregnancy was considered unintended if

she chose to use the teratogenic medication and wished to abstain from pregnancy while on the medication.

Theoretical Framework

Naming the theory. Dorothea Orem's theory of self-care provided the theoretical framework for the DNP project. Orem (2001) theorized that people perform self-care behaviors to promote their health and well-being. Individuals have varying levels of self-care agency, which encompasses their ability to carry out self-care behaviors (Orem, 2001). For example, finances, motivation, knowledge, sociodemographic status, and culture all impact a person's self-care agency (Orem, 2001). Alternatively, self-care demands are a person's self-care needs which are based on the patient's situation at that time such as their health history, medications, and age (Orem, 2001). Orem (2001) postulated that a self-care deficit exists when a person's self-care demands are greater than their self-care agency. Therefore, Orem (2001) stated that nursing's role was to decrease self-care deficits to promote self-care behaviors in patients through nursing agency.

To do this, nurses, as care agents, must first help patients investigate the need for self-care and second, encourage them to decide to perform self-care behavior (Orem, 2001). Also, strategies such as teaching, guiding, and supporting build up patients' self-care agency and thus decrease self-care deficit (Orem, 2001). Anticipatory guidance is also used to help the patient prepare to overcome barriers in maintaining self-care in the future (Orem, 2001). At that point, the patient takes the final step, which is deliberate action to perform the self-care behavior (Orem, 2001). Orem (2001) developed three categories of self-care requisites: universal, developmental, and health deviation. Health deviation requisites are the most applicable to the DNP project as they are related to specific health conditions (Orem, 2001). For instance, new

self-care behaviors are needed with changes in medical history, current medications, age, or risk factors (Orem, 2001). For example, if a female patient with a family history of breast cancer turns 40, the self-care behavior of routine mammograms should be discussed with the patient.

Orem's theory of self-care has been used in research to improve self-care knowledge, behaviors, and outcomes in patients with diseases such as migraines, diabetes, hypertension, and coronary artery disease (Helou, Talhouedec, Shaha, & Zanchi, 2016; Johansson, Adamson, Ejdeback, & Edell-Gustafsson, 2014; Mahmoudzadeh Zarandi, Raiesifar, & Ebadi, 2016). The theory was used in each study to create self-care assessment tools, self-care education sessions, or individualized nursing interventions to increase self-care behavior and disease outcomes (Helou et al., 2016; Johansson et al., 2014; Mahmoudzadeh Zarandi et al., 2016). Experimental groups exposed to self-care strategies based on Orem's theory had improved outcomes compared to control groups (Helou et al., 2016; Johansson et al., 2014; Mahmoudzadeh Zarandi et al., 2016).

Application to practice change. Women are often ill-equipped to make self-care decisions to reduce unintended pregnancy. As discussed in the literature review, women do not receive pregnancy risk counseling or contraceptive counseling when teratogenic medications are prescribed. Therefore, women may not know there is a self-care demand to prevent pregnancy while on the medication. The risks of teratogenesis and unintended pregnancy raise self-care demand. A lack of knowledge about pregnancy risk and safe methods of contraception decrease self-care agency. A self-care deficit is apparent. The role of nursing and more broadly, that of primary care providers, is to reduce the self-care deficit and promote self-care agency. Therefore, the DNP project used Orem's theory of self-care to reduce fetal exposure to teratogenic medication.

Providing contraceptive counseling to women prescribed teratogenic medication was an implementation of Orem's theory of self-care. The use of the TARCC framework illustrated each step of the theory: investigating, decision making, and deliberate action. The provider first investigated whether the new medication is teratogenic and if there is an alternative. If the best option for the patient is the teratogenic medication, the provider must realize there is now a need for self-care behavior, specifically prevention of pregnancy. This is an example of a health deviation requisite for self-care. Discussing pregnancy risk with the patient introduced the idea that self-care measures are necessary to prevent fetal exposure. The investigation was continued by assessing the woman's plan for reproduction and thoughts on contraception.

The following step of contraceptive counseling represented the decision-making process and provider intervention to reduce self-care deficit. The discussion of risks, benefits, side effects, and efficacy increased the patient's self-care agency by adding to the patient's knowledge and ability to make an informed decision. Anticipatory guidance about barriers to the correct use of each method further increased self-care agency by helping the patient develop strategies to avoid those barriers. For example, how can she remember to take her oral contraceptive pill daily and what to do if she misses one. Counseling should include an exploration of the patient's culture, finances, and social norms to ensure the method chosen fits into the person's lifestyle. This is yet another example of promoting self-care agency and reducing the self-care deficit. Overall, counseling enhances the decision to use birth control correctly while on teratogenic medication, thus promoting patient self-care behavior.

Evidence-Based Practice Change Theory

Change model. Kurt Lewin's Change Theory was used to support the change in provider behavior in the DNP Project. Lewin developed the theory in the early 20th century to

address social change. He theorized that behavior exists at equilibrium within a forcefield, with equal driving and restraining forces (Lewin, 1947). The forces act as a balance scale, keeping the behavior from changing unless the level of restraining or driving forces changes (Lewin, 1947). Driving forces push change by increasing tension, whereas restraining forces oppose change (Lewin, 1947). Therefore, to produce behavior change, an intervention either needs to increase driving forces or reduce restraining forces (Lewin, 1947).

However, changing behavior is not enough to sustain the behavior. Therefore, Lewin added the act of unfreezing and refreezing to the theory (Lewin, 1947). Unfreezing has the following components: identifying the driving and restraining forces, recognizing the need for change, increasing motivation and confidence, and planning for change (Lewin, 1947). Refreezing ensures the new behavior is sustained in a new equilibrium (Lewin, 1947). Drivers of refreezing include building the new behavior into the culture or social norms and reducing factors that could allow the behavior to regress to the former state (Lewin, 1947).

It is also important to work with a group during the unfreezing and refreezing phases rather than individuals (Lewin, 1947). Lewin (1947) postulated that group motivation and decision to change have a higher likelihood of sustainability than individual decisions. Groups can affect social values and norms, thus making the new behavior more likely to refreeze (Lewin, 1947). Also, individuals tend to act as group members rather than based on personal preferences when making decisions (Lewin, 1947). Therefore, group decisions are more likely to stick as individuals are less likely to regress regardless of their personal thoughts on the new behavior (Lewin, 1947).

Application to practice change. Lewin's Change Theory supported the intervention in the DNP project. First, the literature review revealed driving and restraining forces that impact

teratogenic prescription and contraceptive counseling. This was an essential step in the unfreezing process and in planning an effective intervention. For example, providers' lack of knowledge about teratogenic alternatives, pregnancy risk counseling, and contraceptive counseling were restraining forces inhibiting change. Therefore, providing education reduced restraining forces and tipped the scale towards behavior change.

Similarly, the TARCC framework reduced restraining forces by helping the providers remember each step of the decision tree to ultimately reduce fetal teratogenic exposure. Also, the outdated FDA pregnancy risk categories were restraining factors due to their lack of comprehensive teratogenicity information. For this reason, the updated pregnancy and lactation labeling rule was discussed with the providers to equip them with better pregnancy risk information. Again, this reduced a restraining factor and made behavior change more likely. Not only was reducing restraining factors necessary but also increasing driving factors to promote change.

Examples of driving factors were professional organization recommendations, cost savings, ethical ramifications, improved patient outcomes, and national goals. These driving forces were used during the education session to highlight the importance of reducing fetal exposure to teratogenic medication and unintended pregnancy. Another piece of Lewin's theory utilized in the intervention was group motivation and decision to change. The education was done with a group of providers at two primary care practices rather than with an individual. If the group of providers decides to implement the practice change, it will be more likely that the change will be refrozen and will override individual resistance to change. Also, if this group of providers successfully implemented the change, the intervention could be spread to other groups of primary care providers in the network. This would allow for a systems-level change thus

further improving the likelihood of sustainability. An additional driver of refreezing was the potential to include the TARCC framework in the health record, thus making it part of the existing system in that office. Overall, the DNP project intervention increased the awareness of driving forces and decreased restraining forces to reduce fetal exposure to teratogens and unintended pregnancy.

Summary

Teratogenic medication, contraceptive counseling, and unintended pregnancy were essential concepts in the DNP project. To be consistent with the literature, teratogenic medication was defined as category D and X medications. The concept of contraceptive counseling included the content as well as the methods of counseling. Shared decision making, open-ended questions and eliciting patient preferences were essential to effective counseling. Also, counseling must be holistic to include risks, benefits, and efficacy of all method options using evidence-based contraception information. Lastly, unintended pregnancy was a complicated phenomenon that has reproductive, health, social, financial, and cultural ramifications. In the DNP project, if a woman chose to take teratogenic medication and avoid pregnancy, a subsequent pregnancy was considered unintended.

Orem's theory of self-care and Lewin's change theory both underlined the content and format of the DNP intervention. A woman's self-care agency was increased when she had pregnancy risk and contraceptive knowledge. By reducing her self-care deficit, she would have the ability to make an informed, deliberate decision to avoid pregnancy while on teratogenic medication. Also, Lewin's theory further supported the success and sustainability of the intervention by using a group education session, highlighting driving factors, and reducing restraining factors.

Chapter Four: Pre-implementation Plan

In the pre-implementation phase of the DNP project, it was essential to consider organizational readiness, approval procedures, cost-benefit analysis, outcome measurement, and interprofessional collaboration. The organizational approval and institutional review board (IRB) processes was explored for the project site and ECU. Interprofessional team members were essential to the approval process and continued to serve on the interprofessional team for implementation. Also, outcomes were developed to evaluate the project. The security of patient health information was also outlined.

Project Purpose

The purpose of the DNP project was to increase primary care provider knowledge and use of the TARCC framework at two urban clinics in NC (Shroff et al., 2017). Using the TARCC framework increased the safety of medication prescription to childbearing age women (Shroff et al., 2017). The first long-term outcome of the project was a reduction in teratogenic prescriptions to childbearing age women. The second outcome was increased contraceptive use when a teratogenic medication is used by childbearing age women. The outcomes of the DNP project aligned with Healthy People 2020 goals to reduce birth defect rates, infant mortality, and unintended pregnancies (USDHHS, n. d.) Additionally, a reduction in these three conditions could improve population health and healthcare costs, in alignment with the Triple Aim (IHI, 2019).

Project Management

Organizational readiness for change. Organizational leadership was committed to providing excellence and safety in patient care. The DNP student met with senior leadership who thought all primary care providers should receive education about TARCC. They were

committed to project sustainability by ensuring TARCC was shared with all practices after the project was complete. The DNP student also met with practice providers at two clinics who stated there were no safety measures when prescribing teratogenic medication to childbearing age women (M. Felton, personal communication, August 20, 2019; M. Fike, personal communication, June 27, 2019). The providers also reported they did not routinely consider whether a medication was teratogenic and therefore, did not co-prescribe contraception (M. Felton, personal communication, August 20, 2019; M. Fike, personal communication, June 27, 2019). Both practice medical directors agreed with the DNP project goals and were willing to allocate provider meeting time to the project. Last, organizational data showed a need for the project because 55-60% of sexually active women at the site who received a teratogenic medication had no recorded contraception (D. Allen, personal communication, Jan 29, 2020).

Interprofessional collaboration. Four team members essential to project success were the health center administrator (HCA), two practice medical directors, and an FNP at one of the sites. At site A, the HCA provided project site approval. He was responsible for clinic improvement projects and led monthly provider meetings. He gave the DNP student time at two provider meetings to introduce the project and to implement the education session. The practice medical director at each clinic evaluated the project from a provider perspective and to ensure it aligned with evidence-based practice. Both directors were FNPs at their practice site. Therefore, they were instrumental in bringing other practice providers on board with the project. The director at site B gave the DNP student time at provider meetings for introductions and the education session. Last, an FNP was the site champion for site A and helped engage other providers in the project. She also provided feedback on the project during the planning stage. During project implementation, this FNP took over as the practices' medical director.

Risk management assessment. A strengths, weaknesses, opportunities, and threats analysis (SWOT) was completed to assess project risks.

Strengths. The primary project strength was clinic staff buy-in at site A. Another strength was that the DNP student already had a positive working relationship with the clinic staff at site A from a prior clinical rotation. A third strength was alignment of organizational safety and excellence values with project outcomes. Clinic baseline data showed that less than half of patients used contraception while on teratogenic medication. This data gave providers an incentive for change, which increased the chance of project success. Finally, organizational leaders and an FNP at one of the sites were involved in project development and approval, which further increased the likelihood of successful implementation.

Weaknesses. One potential project weakness was the inability to use medical assistants (MAs) during implementation. Both clinics had a high rate of support staff turnover. Therefore, the administration thought additional tasks for the MAs would be burdensome. Consequently, the project was entirely provider driven. Providers had competing demands to see high numbers of patients and meet quality metrics. Their competing demands may supersede project goals. Additionally, site B was saturated with quality improvement projects and were not as involved in the planning stage of the DNP project. Therefore, site B providers were less inclined to fully participate in the DNP project. To use the TARCC framework, providers must spend more time prescribing medication or discussing pregnancy risk and contraception use. With short patient visits, this may be a challenge to implementation. Last, the organization had a complicated IRB process which excluded the DNP student from accessing the electronic health record. Therefore, all data outcomes were extrapolated by the Director of Nursing Research & Evidence-Based

Practice. Relying on a third party to pull data could delay data collection thus delay project outcome evaluation.

Opportunities. The project's foremost opportunity was its alignment with national goals and professional organization recommendations (ACOG & ASRM, 2019; Women's Preventive Services Initiative, 2016). Further, some states outlawed abortion or decreased the gestational age at which it is legal. Therefore, a project which reduces the need for an abortion by preventing unintended pregnancy aligned with current policy changes. Last, there was an opportunity to expand the project to other network primary care sites and integrate TARCC into the medical record.

Threats. Project threats included a conservative patient population at site A that may be unreceptive to contraception use. Thus, despite an increase in contraceptive counseling, there may not be an increase in contraception use. Also, few medications may be prescribed during the three-month implementation window, thus threatening TARCC framework use. Last, the FDA's new pregnancy labeling rule may obscure which medications are teratogenic. Changed labeling rules may complicate provider decision- making since there are no longer strict medication categories. With the new rules, providers may need to spend more time researching pregnancy risk, which lengthens provider visit times.

Organizational approval process. The DNP student initiated a professional relationship while working in the urgent care attached to site A. At that time, the HCA covered urgent care and primary care. Therefore, discussion about the DNP project occurred early with the HCA and the FNP, who would become the project champion and eventually the site medical director. Both stakeholders provided feedback on the project, outcomes measurements, and whom to meet for approval in the organization. The DNP student was referred to the Director of Nursing and

Patient Care Services. This individual gave feedback and advice on whom next to meet for project approval. A meeting with the Director of Nursing Research & Evidence-Based Practice solidified outcomes' measurements and initiated the formal, organizational approval process.

First, the organizational feasibility form was completed and signed by the Director of Nursing Research & Evidence-Based Practice. At that point, it was sent to the new HCA at site A. Both the HCA and practice medical director approved the project (see Appendix D for Clinic Site Letters of Approval). The biggest approval process challenge was meeting with the Director of Nursing and Patient Care Services, Associate Chief Nursing Officer, and Associate Chief Medical Officer for Innovation and Improvement. These organizational leaders were essential to project planning and were required to sign the feasibility form before project approval. The leaders recommended that a second clinic be included in the DNP project, site B. The DNP student was referred to the practice medical director for site B who also approved the project (see Appendix D for Clinic Site Letters of Approval). After being approved by organizational leaders and both clinics, the proposal was reviewed by the Vice President of Patient Care and System Chief Nurse Executive for final approval.

Information technology. Baseline and outcomes data were pulled from [redacted] Enterprise Data Unified Content Explorer™ (DEDUCE™). DEDUCE™ extracted data from the Epic Electronic Health Record without directly accessing patient records. The Director of Nursing Research & Evidence-Based Practice used DEDUCE™ rather than the DNP student. Box™, a cloud content sharing service on the organization's server, was used to send data to the DNP student. Also, Microsoft Excel was used to manipulate the data from DEDUCE™ to derive baseline and outcomes metrics. Excel was also used to create tables, graphs, and figures to

present the data after implementation. Last, during the education session, Microsoft PowerPoint was used to display the session's content.

Cost Analysis of Materials Needed for Project

The significant costs of the project were paper materials and food (see Appendix E for DNP Project Budget). The estimated total cost of the project was under $350. Each provider received a toolkit with educational materials during the session, which contributed to cost. Additional costs included provider time doing surveys, which is estimated at 25 minutes, and a one-hour education session. Implementing the TARCC framework also added time to the visit if the provider performed pregnancy risk and contraceptive counseling. However, cost savings related to reduced fetal exposure to teratogens made the project benefits outweigh its costs.

Savings from one abortion prevention would yield a net benefit from this project. On average, women spend between $450 and $550 for a first-trimester abortion and between $750 and $5,000 for a 20-week abortion in the US (Jerman & Jones, 2014). Therefore, savings from one abortion is more than project costs. Last, there is the emotional cost of an abortion that could occur for some women that would be prevented.

Similarly, one birth defect prevention saves healthcare dollars from birth until death. For example, the US spends an estimated $2.6 billion on hospital costs for children with birth defects each year (NBDPN, 2010). Therefore, the estimated yearly hospital cost of one child with a birth defect is $78,000 (NBDPN, 2010; Parker et al., 2010). Overall, savings accrued from preventing one abortion or birth defect significantly outweigh the project costs.

Plans for Institutional Review Board Approval

The project site and ECU had an IRB process for all quality improvement and research projects. At the project site, the process began with a completed organizational feasibility form

that was signed by all stakeholders for the project, including the Director of Nursing Research & Evidence-Based Practice. Once approved, the Director submitted the feasibility form to the institution's IRB. The DNP project was deemed quality improvement since it did not meet the research definition and was approved for implementation (See Appendix F for Site IRB Approval Form).

The DNP student also completed the IRB Program Evaluation Self-Certification Process through ECU. Because this project was quality improvement, the self-certification process indicated that a full IRB review was not required (See Appendix G for ECU IRB Approval Form). The DNP student also completed the Collaborative Institute Training Initiative course for Social and Behavioral Research Investigators in Human Research. The course ensured that best research practices were followed to ensure no harm to participants. Modules were completed both for ECU and for the practice site.

Plan for Project Evaluation

Demographics. Two aspects of demographic data were collected (see Appendix H for Data Collection Tools). The first piece of demographic information was the professional role of the participant: MD, NP, or PA. The data were reported as a percentage of the participants. The results were presented in a pie chart to illustrate the makeup of the participants in the education session. The second piece of demographic information was the number of years of primary care experience for each participant. This data was reported as a mean with a standard deviation and range.

Knowledge outcome measurement. The first outcome measure was an increase in provider self-reported competency in using the TARCC framework. Providers also rated how likely they were to use the TARCC framework in the future. Increased future framework use

likely indicated increased provider competence in using TARCC as well as their perceived importance of the framework in improving the quality of their care. Therefore, increased future use of the TARCC framework was used as an indicator of increased provider knowledge and competency.

Evaluation tool. A DNP student-created data collection tool was used to evaluate TARCC framework knowledge (see Appendix H for Data Collection Tools). Providers completed a data collection tool at three points during the project. First, during the first week of implementation, second at mid-implementation, and finally after completion of the project. The preliminary tool, given after the education session, included two demographic questions, two knowledge uptake questions, two competency questions, and one future behavior question. The mid-implementation tool contained one question to assess the frequency of TARCC use, one future behavior question, one knowledge uptake question, one competency question, and one open ended question. The final tool included one competency question, one frequency of use question, one future behavior question, and several questions about sustainability and evaluation. The tools allowed the student to capture similar information at three time points without placing a burden on providers.

Data analysis. Before the project, the providers did not use the TARCC framework and did not know the framework. There were no national benchmarks for TARCC usage. Providers' knowledge and competence in TARCC framework use was therefore simply tracked over the course of implementation to evaluate for change and to guide improvement measures. However, no numeric goal was set for the rate of improvement because there was no current national or site benchmark.

Additionally, a report with the number of times the TARCC framework dot phrases were documented in the EHR was supposed to be pulled weekly by the Health Center Administrator. However, this report was deemed not possible by the site IT team.

Data management. The data collection tool results were placed into Excel for manipulation. There was no personal health information on the surveys. The excel file with results was saved on the DNP student's personal computer. Hard copies of the surveys were kept by the DNP student in a folder as the primary storage method. The secondary method of storage was scanned copies of the completed surveys on the student's personal computer. Both the excel file and scanned copies were saved on an external hard drive. Data will be kept for two years. After two years, the surveys will be shredded, and the electronic files deleted.

Long-term outcome one. The first long-term outcome was the percentage of sexually active, childbearing age women without contraception while on a teratogenic medication. One year before implementation, 56% of women aged 18 to 50 seen at clinic A were not using contraception while on a teratogen (D. Allen, personal communication, Jan 29, 2020). Clinic B had a similar percentage of 57% (D. Allen, personal communication, Jan 29, 2020). This was a long-term project outcome because increased TARCC use would lead to increased contraceptive counseling. Ideally, increased counseling would lead to an increase in patient contraception use. This outcome should lead to a reduction in birth defects, unintended pregnancy, and the need for an abortion.

Evaluation tool. The Director of Nursing Research & Evidence-Based Practice obtained the baseline data using DEDUCE™. The outcome data was collected one month after the end of the project because DEDUCE™ information lagged 30 days behind provider-patient encounter dates. The DNP student used Excel to merge the reports for contraceptive use, sexual activity,

and medication use. A pivot table in Excel enabled the DNP student to extract the percentage for the outcome metric. The denominator was the number of women, age 18 to 50, seen in Fall 2019 who reported they were sexually active and had a teratogenic medication in their active medication list. The numerator was the number of women who reported they were using a form of contraception.

Data analysis. There was no national or site benchmark for the long-term outcome therefore there was no exact goal percentage. However, baseline data from one year before implementation showed a 56% and 57% rate, respectively showing room for improvement. Therefore, the goal was to decrease this percentage by any amount. The metric was calculated for a three-month window one year prior to implementation and during implementation for comparison. This metric improvement relied on proper data input into the EHR regarding current sexual activity, medication reconciliation, and contraceptive documentation. Therefore, this outcome was not solely a byproduct of the TARCC framework use. Over time, the outcome should continue to decrease as providers use the TARCC framework in daily practice. A large change in this metric is not expected by the end of implementation.

Long-term outcome two. The second long-term outcome was a reduction in the percentage of childbearing age women taking a teratogenic medication. In the Fall of 2018, 33% of the women aged 18 to 50 who attended clinic A had a teratogenic medication on their medication list. Clinic B had a higher percentage at 50%. A reduction in this number represents the successful use of the TARCC framework because it implies a teratogenic medication was changed to a safer alternative.

Evaluation tool. Similar to outcome one, the Director of Nursing Research & Evidence-Based Practice gathered the data from DEDUCE™. Excel was again used to manipulate the data

to find the outcome result. The data was pulled 30 days after project completion. The denominator was the number of women, aged 18 to 50, seen in Fall 2019. The numerator was the number of women who had a teratogenic medication listed in their active medication list. The classes of teratogenic medications included were benzodiazepines, angiotensin receptor blockers, angiotensin-converting enzyme inhibitors, anticonvulsants, statins, and warfarin.

Data analysis. There was no national benchmark for the percentage of childbearing age women taking a teratogenic medication. The goal was therefore to decrease the percentage by any amount and not to meet a specific target. Again, this data was evaluated for a three-month window one year prior to implementation and during implementation. There were two ways to improve this metric. The first way was a reduction in newly prescribed teratogens. During the education session, providers were encouraged to use the TARCC framework when prescribing a new medication to increase the use of safer alternatives. However, the outcome could also be improved by switching current medications to safer alternatives by doing a medication reconciliation. Due to the limited timeframe and scope of the DNP project, the education session did not focus on this. Therefore, there will only be a modest, if any, improvement in this long-term outcome during the project. As the TARCC framework is used more consistently and MAs become involved, this outcome will more quickly improve. This may be a focus for future projects and to increase the sustainability of the project.

Data management. The reports pulled from DEDUCE™ had patient medical record numbers that were used to merge the files. There were no other patient identifiers or patient health information on the reports. The files were stored in secure cloud storage called Box™ that was on the organization's server in a file that was only accessible by the DNP student and Director of Nursing Research & Evidence-Based Practice. Once merged in Excel, a new

spreadsheet was made without any patient health information. This spreadsheet that contained only raw data with no patient health information was stored on the DNP student's personal computer for manipulation. Therefore, the reports with medical record numbers were only saved in the organization's secured server, thus protecting the private information. The de-identified excel sheet was saved on the student's personal computer and an external hard drive. After two years, the de-identified excel sheet and DEDUCE™ reports will be erased from the computer, external hard drive, and organizational server. If the DNP student leaves the organization before this time, the DEDUCE™ reports will be moved to ECU's departmental pirate drive, which is approved for electronic storage of personal health information.

Summary

The project sites and critical stakeholders approved the DNP project. To receive approval, the DNP student met with organizational leaders such as the HCA, practice medical directors, FNP at the site, Director of Nursing Research & Evidence-Based Practice, Director of Nursing and Patient Care Services, Associate Chief Nursing Officer, and Associate Chief Medical Officer for Innovation and Improvement. These stakeholders were not only critical to the approval process but also in the planning stage of the project. Each person offered feedback to improve the project, which therefore increased the likelihood of success. Also, data at the project site illustrated an organizational readiness for the project. Less than half of the childbearing age women seen in Fall 2018 stated they were using contraception while on a teratogenic medication at both clinics. Finally, IRB approval was needed at both ECU and the project site. However, due to the quality improvement nature of the project, a full IRB was not needed at either site.

The cost-benefit analysis of the project showed cost savings to be higher than the cost of the project. The project is estimated to cost less than $350. However, the savings from the prevention of one abortion or one birth defect could save $450-$5000 and $78,000, respectively. Time spent by providers is another cost of the project, both in using the TARCC framework during visits and in attending the education session and completing project surveys. However, it was expected that the project's cost savings would outweigh the costs.

The purpose of the DNP project was to increase primary care provider knowledge of the TARCC framework. Therefore, the first outcome of the project was to increase provider knowledge. This was evaluated using data collection tools to test for competence, knowledge uptake, and future use of the TARCC framework. Providers completed the data collection tools at three points during implementation. Also, two long-term outcomes were selected to capture the desired effects of using the TARCC framework. The first long-term outcome was a decrease in the percentage of childbearing age women without contraception while on a teratogenic medication if they report they are sexually active. The second long-term outcome was a reduction in the percentage of childbearing age women taking a teratogenic medication. Data from DEDUCE™ was used to evaluate the long-term outcomes. Importantly, patient data was secured on the organization's cloud service, which is an approved method by the project site.

Chapter Five: Implementation Process

This chapter describes the DNP project sites, participants, and their engagement. The implementation process will be detailed, including variations throughout the project. Multiple plan do study act (PDSA) cycles were carried out at both sites throughout implementation. Each one will be explored in the timeline in which they occurred.

Setting

The DNP project setting was two primary care clinics within an extensive university hospital network. The clinics were non-profit and privately funded in an urban area in central NC. The clinics served patients with Medicaid, Medicare, private insurance, and uninsured. The providers at the practices cared for patients of all ages. The clinics provided primary family care, including pediatrics. However, there were no obstetrical or gynecological services. Thus, the practices had no specialty providers, only general medicine physicians, PAs, and FNPs. Minor procedures, i.e., suturing, incision and drainage, and wart removal, were performed at the practices.

Medication reconciliation occurred at every primary care visit. Primary care providers frequently prescribe most medications young women receive. Therefore, the practices were dedicated to safe prescribing to childbearing-age women. Specifically, the practices wanted to ensure that women were either not prescribed teratogenic medication or did not become pregnant while on teratogens. Further, it was the primary care provider's responsibility to coordinate care for the patient. For example, if a patient was prescribed a teratogen by another provider, the primary care provider should educate her about pregnancy risk and contraception. The practices had provider visits with 2,865 women of childbearing age over a three-month period one year before implementation (D. Allen, personal communication, June 27, 2019). This number of patients suggests that the TARCC framework could be used often for safe prescribing.

Participants

Project participants were 14 primary care providers consisting of five FNPs, eight physicians, and one PA. Two FNPs, one at each site, were the practice medical directors. Inclusion criteria were that each participant was a project site primary care provider during implementation. Thus, all clinic providers were invited to participate in the education session. No

primary care provider was excluded from participation because each one cared for childbearing age women.

Recruitment

The participants represented a convenience sample because they were all project site primary care providers. Recruitment of participants began by engaging the practices' medical directors and Health Center Administrator for site A. At site A, an additional FNP was already engaged as the site champion. She had completed a DNP project and was a former clinical instructor and coworker. During implementation, this FNP took over as the practice medical director of site A. Next, the medical directors recommended that the DNP student introduce and receive feedback on the project at a provider meeting. Engagement and recruitment of the other providers occurred at these two provider meetings two months before project implementation for site A and one month before for site B.

At clinic A's meeting, the providers showed interest in the project purpose and gave feedback to improve TARCC implementation. Most providers agreed their clinic had a problem because they had omitted contraception discussions while prescribing teratogenic medications. The providers stated the EHR should flag a reminder each time a teratogenic medication was prescribed. The providers' biggest hesitation was the ability to remember to use TARCC and routinely document it in the EHR. Each provider requested frequent reminders throughout implementation. The providers requested a list of their patients who were on teratogenic medications without contraception. Because their requests were not part of the DNP project and would require further IRB and EHR access, the student could not comply. Their requests illustrated perceived project need and eagerness to improve the safety of teratogenic prescriptions.

At the provider meeting at site B, providers also felt TARCC and its concepts were an essential part of safe care. However, providers were hesitant to incorporate more work into their daily practice due to high turnover and quality improvement burnout. Nevertheless, providers were eager to attend the DNP project education session and participate as much as possible during the project. The practice medical director at site B suggested a PA as the site champion. The PA was passionate about women's health and was interested in helping the project succeed and therefore became the site champion for site B.

Implementation Process

Provider Education Sessions. The sessions were scheduled for one hour with 40 minutes for didactic and 20 minutes for the preliminary data collection tool and questions (See Appendix H for Preliminary Data Collection Tool). The sessions at sites A and B were held during previously scheduled provider lunch meetings. At site A, the session was done during the first week of implementation, and it was cut short to 25 minutes due to a last-minute confidential provider meeting on the same day (See Appendix I for Site A PowerPoint Slides). Data collection tools were deferred to the week after the education session. All seven providers attended the education session as well as the Health Center Administrator. The education session at site B occurred one month after implementation started with all seven providers (See Appendix J for Site B PowerPoint Slides). Providers completed the preliminary data collection tool surveys immediately after the education session as planned. Results from the preliminary surveys were compared to the mid and final surveys to monitor for improvement. No numerical goal was set because there is no national benchmark or previous use of the TARCC framework.

The education session content was based on each step of the TARCC framework (See Appendix I and J for Education Session PowerPoint Slides). For example, determining if a

medication is teratogenic and choosing an alternative was included in the session. To discuss effective contraceptive counseling, recommendations from the FPNTC and CDC were used. Further, literature review and baseline clinic data were used to discuss current practice gaps, both nationally and at the clinic. Last, connections between the project goals and current policy were discussed. Providers were given Teratogenic Medication Safety in Primary Care Toolkits to reinforce learning from the education session. The toolkit included session PowerPoint slides, U.S. Medical Eligibility Criteria Wheel, and Summary Chart, Birth Control Methods Options Chart, and a teratogen alternatives chart (CDC, 2016; FPNTC, 2019).

Dot phrases. Dot phrases were quick ways for providers to document pre-written sentences using a one or two-word phrase in the electronic medical record. The site A champion helped create and share two dot phrases with all providers the week of their education session. These phrases allowed providers to document the TARCC framework in the EHR easily. The first phrase was ".teratogenalternative." When the provider typed the dot phrase, the following statement appeared in the progress note: "A safer alternative medication has been chosen for this patient to avoid exposure to a potentially teratogenic medication." The second dot phrase was ".teratogencounseling." When this dot phrase was typed, the following statement populated the progress note: "The patient was adequately counseled on the risks of pregnancy while taking [blank for medication name]. Contraceptive counseling was performed to reduce the risk of pregnancy while on the medication. The patient verbalized understanding." The initial plan was for a report to track the number of times the dot phrases were used to monitor TARCC usage at both primary care sites. However, based on feedback from the EHR specialists, the phrases were challenging to build and would not be built in time for the project. This occurred two weeks

before project implementation. Therefore, the dot phrases were available for providers to use; however, they were not monitored as a project outcome.

Mid-implementation data collection. Eight weeks into the implementation period, a mid-implementation data collection tool was administered to 13 providers at both sites A and B (see Appendix H for Mid-Implementation Data Collection Tool). One provider at site A was on sabbatical starting the week after the educations session and returned the week the mid implementation tools were administered. This provider was not given a survey since he had not been at the clinic to use the TARCC framework. Outcomes were compared to preliminary survey results and guided PDSA cycles.

Site A PDSA cycles. Five PDSA cycles were performed at site A throughout project implementation. The goal of each cycle was to improve provider knowledge and use of the TARCC framework. First, TARCC reminder cards were given out to all providers to place on their computer screens to help them remember to use the framework in practice (See Appendix K for TARCC Reminder Card and Appendix L for Site A Plan Do Study Act One). Next, the site champion and DNP student developed a checklist that included each component of the TARCC framework (See Appendix M for TARCC Checklist). Checklists were to be used with all women aged 18 to 50, which was compared to the number of women aged 18 to 50 seen by a provider each week (See Appendix N for Site A Plan Do Study Act Two). Outcomes were tracked weekly; however, no goal was set due to the lack of baseline and national benchmark.

The next PDSA cycle added weekly emails to providers that highlighted weekly checklist data and one teratogenic class of medication with references (See Appendix O for Site A Plan Do Study Act Three). During PDSA four, the DNP student and physician attempted to recruit an MA to help him identify which of his patients were eligible for a TARCC checklist (See

Appendix P for Site A Plan Do Study Act Four). Due to MA overburdening and understaffing, this strategy was not helpful and was not continued. At the end of implementation, the final PDSA included beginning to create a decision tree and best practice advisory for the electronic health record (See Appendix Q for Site A Plan Do Study Act Five).

Site B PDSA cycles. The implementation at site B occurred one month after implementation started at site A; therefore, some changes were made at site B at the education session. For example, providers were given the TARCC reminder card (See Appendix K for TARCC Reminder Card) in their provider toolkit and were offered to use the TARCC checklists as was being done at site A. However, due to provider turnover and staff burnout, the providers opted not to add the checklists to their daily tasks. Three PDSA cycles were performed at site B throughout implementation. First, the site champion placed the TARCC framework and checklist into her well-woman physical exam template in the EHR and shared this idea with other providers (See Appendix R for Site B Plan Do Study Act One). The template was used during all female physicals and therefore ensured addressing teratogenic medication at all encounters. Next, the DNP student met with a pharmacist who worked at the clinic to help manage complicated chronic disease medications (See Appendix S for Site B Plan Do Study Act Two). The pharmacist helped set the plan to work on a decision tree and best practice advisory for the EHR (See Appendix T for Site B Plan Do Study Act Three). Additionally, site B providers were added to the weekly teratogenic information emails being sent to the site A providers at the recommendation of the site champion. Last, the site champion advocated for the consistent collection of last menstrual period and contraceptive use at all female provider visits.

End of implementation. Providers were given a final data collection tool during weeks 13 and 14 of project implementation (see Appendix H). Outcomes of the survey were compared

to mid implementation and preliminary surveys. Additionally, DEDUCE™ was used to extract reports on two long-term project outcomes. DEDUCE™ is a database that pulls electronic health record information from Epic indirectly. Reports were pulled by the Director of Nursing Research & Evidence-Based Practice one month after project implantation because data in DEDUCE™ [1] lag one month behind. Outcomes data during project implementation were compared to outcomes one year before implementation. The outcomes included the percentage of sexually active childbearing age women without contraception while on a teratogen and the percentage of women taking teratogenic medication. No percentage was set as a goal because there was no national benchmark and no baseline for TARCC usage.

Plan Variation

The first variation was the stark difference in project implementation strategies between sites A and B. Site A was able to perform a daily task to track objective outcomes using the TARCC checklist. Site B was burnt out with provider and staff turnover as well as quality improvement saturation. Additionally, site A had a long-term relationship with the DNP student and had worked through the planning phase of the project. Site B, however, was added later in the project and therefore missed the planning and relationship building stages. Therefore, provider investment in the project was decreased at site B.

Additionally, working with a pharmacist at site B was an unexpected variation. The pharmacist was instrumental in building the best practice advisory and decision tree framework for the EHR. The pharmacist not only provided feedback on the framework but also helped coordinate feedback from clinical staff and information technology professionals. Likely, an interdisciplinary team with the pharmacist, two site champions, and other providers at the two clinics will serve as the pilot for a potential EHR advisory. This outcome was in line with

provider feedback on data collection tools and was, therefore, a positive outcome of the DNP project.

Summary

Fourteen providers at two primary care clinics in an extensive university health system were recruited and engaged to participate in the DNP project. The practice medical directors helped plan meetings before implementation to discuss the project with all providers. At the meetings, providers expressed eagerness to improve medication prescription safety while addressing concerns about remembering to use TARCC.

Education sessions to discuss the TARCC framework were performed in Fall, 2019. The session described the best practice and current practice gaps at the clinic and nationally. Dot phrases were created to ensure easy documentation. Also, data collection tools were given to providers at three-time points in the project: post-education session, mid-implementation, and project completion. Multiple PDSA cycles were performed at each clinic to promote TARCC usage. Additionally, a new relationship was formed with a pharmacist that will help propel the sustainability of the project.

Chapter Six: Evaluation of the Practice Change Initiative

Short-term, intermediate, and long-term outcomes were evaluated in the DNP project. Data collection tools were administered to participants at three time points throughout implementation to assess for change. Data from DEDUCE™ was also gathered to evaluate long-term outcomes. Participant demographics were gathered using the preliminary data collection tool. Last, figures were used to illustrate the improvement in project outcomes.

Participant Demographics

The participants of the DNP project were the primary care providers located at sites A and B. Demographic data about participants were collected using the preliminary data collection tool, which was completed by participants during the first week of implementation. Participants were asked to select their role and to record how many years of primary care experience they had. There were 14 participants across the two sites. The range of site A participants' years' experience was 1 to 22 with a mean of 11.3 (SD= 7.4 years). At site B, the range was 1 to 18 years with a mean of 7.1 (SD=5.6 years).

At site A, a total of 1567 women aged 18 to 50 were seen by a provider over the last 10 weeks of implementation. This was not monitored at site B. The number of women was tracked each week to compare to the number of TARCC checklists used at site A.

Figure 1. The pie chart in Figure 1 illustrates the roles of the participants in the DNP project across sites A and B. The majority of participants were MDs, followed by NPs and PAs.

Figure 1. DNP Project Participant Roles

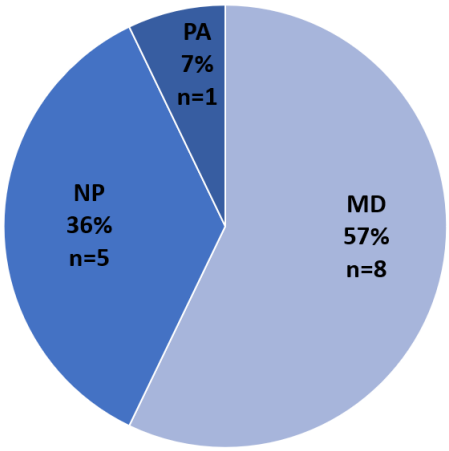


Figure 1. DNP Project participant roles. This figure illustrates the breakdown of roles for project participants at both sites A and B.

Intended Outcomes

The DNP project focused on short-term outcomes such as provider competence in using the TARCC framework, frequency of use, and how likely providers were to use the framework over the next month. These short-term outcomes were evaluated using the preliminary, mid-implementation, and end of implementation data collection tools. Changes in these short-term outcomes were assessed from beginning to the end of the project without a set goal due to a lack of national benchmarks and no previous use of the TARCC framework at either project site.

Intermediate outcomes included provider ranking of the importance of placing the TARCC framework into the EHR, sharing the education with other primary care sites in the network, and how helpful providers felt TARCC was in improving the quality of their care. Each outcome was assessed using a 5-point scale with 5 being "most important" or "most helpful." Providers ranked their perceived importance or helpfulness on the final data collection tool at the end of implementation. These outcomes represent possible future use of the TARCC framework and sustainability of the DNP Project based on provider perception.

Two long term outcomes were assessed using EHR data that were pulled from DEDUCE™ by the Director of Nursing Research & Evidence-Based Practice. These outcomes directly related to patient outcomes that may have occurred with the increased use of the TARCC framework. The first was a reduction in the percentage of childbearing age women taking a teratogenic medication. The second was a reduction in the percentage of sexually active, childbearing age women without documented contraception while on a teratogenic medication.

Findings

At site A, TARCC checklist use was tracked over the last 10 weeks of implementation. A total of 1567 women aged 18 to 50 were seen by a provider over the 10 weeks. Each week the number of TARCC checklists used was compared with the number of women aged 18 to 50 seen

by a provider. The implementation percentage ranged from 8% to 29% with a mean of 16% (SD=6.9%) as shown in Figure 2.

Both sites had an improvement in self-assessment of provider competency in using the TARCC framework throughout the project. For example, 86% of providers stated they were "very" or "extremely competent" in using the framework by the end of the project compared to 43% and 57% at sites A and B, respectively, at the beginning of the project. At site A, 86% of providers stated that they used the framework more than seven times during implementation compared to only 14% of providers at site B. Last, both sites had an increase in the likelihood of use of the framework over the next month from beginning to end of implementation. At site A, 86% of providers stated they would be "very" or "extremely" likely to use TARCC in the next month compared to 71% at the beginning of implementation. Similarly, at site B, 71% of providers stated they would be "very" or "extremely" likely to use TARCC in the next month compared to 57% at the beginning of implementation.

A 5-point Likert scale was used to measure intermediate outcomes with 5 being "extremely important" or "extremely helpful." Providers rated their perception of importance or helpfulness on each outcome. The analysis indicated a high rating for the importance of adding TARCC to the EHR with a mean rating of 4.6 (SD= 0.5) and 4.4 (SD= 0.8) at sites A and B, respectively. Similarly, both sites rated high importance of sharing the education session with other primary care sites with an average rating of 4.6 (SD= 0.5) on a 5-point scale. Finally, providers rated the usefulness of the TARCC framework in improving their quality of care with providers at site A giving average rating of 3.7 (SD= 0.8) and at site B, an average of 3.9 (SD= 0.4).

Long term outcomes did not show a substantial change from baseline to end of implementation as shown in Table 1. Overall, there was a minimal decrease in the percent of women on a teratogen and a minimal increase in the percent of women without documented birth control.

Figure 2. Weekly TARCC Use at Site A

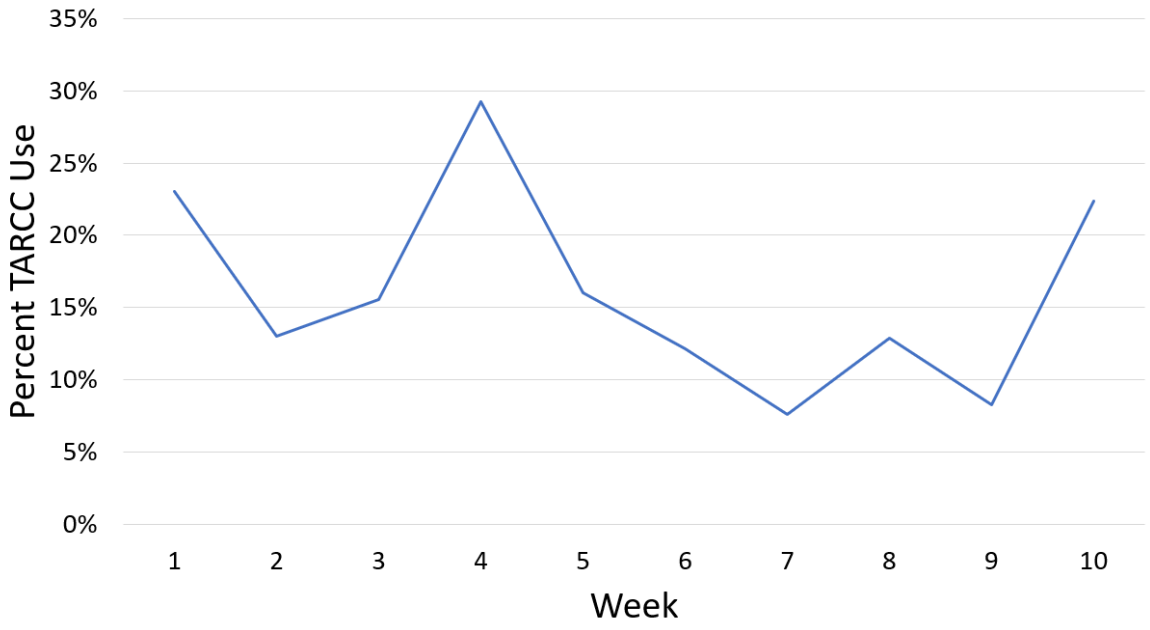


Figure 2. Weekly TARCC Use at Site A.

Table 1. DNP Project Long Term Outcomes

Long Term Outcome	Site A Baseline	Site A Implementation	Site B Baseline	Site B Implementation
Percent of Women on a Teratogen	33%	31%	50%	48%
Percent of Sexually Active Women Without Documented Birth Control While On a Teratogen	56%	58%	57%	58%

Summary

Outcomes of the DNP project were gathered from data collection tools and DEDUCE™. Demographic data on the 14 participants illustrated that the majority were MDs, followed by NPs, and PAs. The range of years' experience was vast, from one to 22. Short-term outcomes showed an improvement from the beginning of implementation to the end. Overall, there were increases in self-reported provider competency in using the TARCC framework as well as provider reported likelihood of using TARCC in the next month. TARCC was used more often at site A than at site B throughout implementation. At site A, TARCC use was tracked over the last ten weeks of implementation. Percent use varied week to week with a mean of 16% (SD=6.9%).

Conversely, long-term outcomes did not show substantial change from baseline data one year before implementation compared to during implementation. Both sites A and B had a 2% decrease in the number of women actively using a teratogen. However, both sites had a small increase in the percent of women without documented birth control use despite being sexually active and on a teratogen.

Chapter Seven: Implications for Nursing Practice

The Essentials of Doctoral Education for Advanced Nursing Practice were created by the American Association of Colleges of Nursing (AACN) in 2006. The eight Essentials are qualities, skills, and competencies that all advanced practice nurses prepared at the doctoral level must obtain through their education and DNP project (AACN, 2006). The Essentials distinguish DNP graduates from PhD graduates by emphasizing the implementation of evidence-based practice rather than the generation of new knowledge (AACN, 2006). Each Essential will be defined as it relates to the DNP project. Additionally, implications from the DNP project will be explored as they relate to each Essential. Some implications have occurred throughout the

project, and some have implications after the completion of the project in future advanced nursing practice.

Practice Implications

Essential I: Scientific underpinnings for practice. The first essential highlights the importance of using multidisciplinary science and theory to improve patient outcomes and advanced nursing practice (AACN, 2006). Two primary care sites were found to have a problem with unsafe prescription of teratogenic medication. Data from one year before implementation showed that over 50% of sexually active childbearing age women prescribed a teratogenic medication did not have contraception documentation (D. Allen, personal communication, June 27, 2019). During informal discussions with primary care providers, there were no frameworks or safety mechanisms in place when prescribing teratogenic medication (M. Fike, personal communication, June 30, 2019). Therefore, the DNP project utilized biophysical science about teratogenic medications, psychosocial science to explore unintended pregnancy, pregnancy risk, and contraceptive counseling, and implementation science to improve patient outcomes. A framework was researched to help providers increase the safety of teratogenic prescriptions (Shroff et al., 2017). A future implication to advance nursing science is sharing outcomes of the DNP project with the authors of the TARCC framework. This sharing will allow the authors to broaden their understanding of TARCC's use in practice and may inform their current research. Also, the science behind safe contraceptive prescribing and teratogenic alternatives was not routinely used by all providers before the DNP project. To promote the scientific underpinning of practice, the DNP student will share the framework with all practices at the Practice Medical Director meeting, thus reaching more providers in the health system.

Essential II: Organization and systems leadership for quality improvement and systems thinking. Essential II highlights the importance of systems change, patient safety, ethical practice, and population health (AACN, 2006). The success of the DNP project has implications for improving patient safety by ensuring safe teratogenic medication management for childbearing age women. Organizational data from two primary care clinics in the same health system showed a need for change to enhance patient safety. However, the organizational culture and practice dictated how each site implemented the project. Therefore, the DNP student tailored quality improvement strategies to each organization and system to ensure success and sustainability, which is part of Essential II (AACN, 2006). For example, at site B, providers were burnt out from high rates of turnover and repeated quality improvement initiatives. Therefore, they did not want to add any tasks to provider visits. To implement the TARCC framework at site B, providers had the option to add the framework to their physical exam template, and the DNP student worked with the pharmacist to begin to develop a decision tree for the medical record. Opposingly, at site A, providers were not burnt out and had a low turnover rate. Therefore, providers were willing to implement a checklist at each female visit to increase the use of TARCC. Weekly data was pulled by the Health Center Administrator to track an objective measure of TARCC usage at site A which was not possible at site B.

The DNP project also helped to manage the ethical dilemma between do no harm and the need to treat. Medications such as angiotensin-converting enzyme inhibitors, statins, and angiotensin blocking agents are first-line treatments in national guidelines for hypertension, hyperlipidemia, and diabetes. However, each one is a teratogen, and the provider has the responsibility to do no harm to the patient and a potential fetus during treatment. The use of the TARCC framework allowed the provider to weigh risks and benefits and provide patient

education and counseling. Therefore, the success of the project enhances ethical and safe patient care.

Essential III: Clinical scholarship and analytical methods for EBP. Essential III focuses on the analysis of evidence to promote evidence-based care (AACN, 2006). A critical role of the DNP is the ability to discern whether research is valid, reliable, generalizable, and done with rigor before bringing the evidence into practice (AACN, 2006). Therefore, the DNP student used the skills of performing a literature review and evidence evaluation using the Melnyk Levels of Evidence to promote evidence-based care in two primary care sites (Melnyk & Fineout-Overholt, 2011). Evidence was used to support the problem that women in primary care are not likely to receive contraception with the prescription of a teratogen. Additionally, evidence supported the high risk and high rate of unintended pregnancy and the barriers that prevent providers from prescribing safely. The DNP student evaluated evidence-based interventions to increase teratogenic medication safety in primary care before the implementation of the TARCC framework (Shroff et al., 2017). Last, the DNP student shared valuable articles with providers at each site over email every week. The articles deepened provider understanding of teratogens and the importance of the TARCC framework. Providers' increased knowledge will carry on past the end of implementation, thus promoting clinical scholarship.

Essential III also promotes the evaluation of improvement projects with an emphasis on dissemination and comparison to national benchmarks (AACN, 2006). The DNP project outcomes were in line with Healthy People 2020 goals and will allow the practices to improve patient outcomes for childbearing age women (USDHHS, n.d.). Project outcomes will be used to disseminate findings to all Practice Medical Directors in the network and to promote the inclusion of TARCC into organizational systems such as the electronic health record.

Essential IV: Information systems/technology and patient care technology for the improvement and transformation of healthcare. This Essential highlights the importance of information systems in providing quality care and in evaluating health outcomes (AACN, 2016). The most significant implication for practice for Essential IV was placing the TARCC framework into the EHR and provider workflow. It was difficult for providers to remember to use the TARCC checklist and reported on the final data collection tool a high rating for placing TARCC into the EHR. Without a consistent reminder to use the TARCC principles when they are prescribing a medication, it would not be possible to sustain the behavior change. Therefore, after implementation, the DNP student worked with the pharmacist and an interdisciplinary team to create a best practice advisory for the EHR. The DNP student will communicate the need to primary care management for TARCC in the medical record to ensure women are not exposed to teratogens when they are at risk for pregnancy. Additionally, the student will work to make the advisory trackable which will allow data to show improved patient outcomes.

Essential V: Healthcare policy for advocacy in healthcare. DNP graduates must be able to evaluate existing policies and advocate for policy changes at all levels to enhance patient outcomes and reduce healthcare disparities (AACN, 2006). A policy already exists that outlines what should be included with all patient intakes before the provider visit. However, the policy is not being followed thoroughly. Therefore, not all patients have regular updates to their sexual activity, last menstrual period, and contraceptive use at site B. Advocacy for adherence and clarity of this policy is vital to providing safe prescribing of teratogenic medication. Therefore, the site champion brought attention to this policy during morning huddles and reported that more visits had included last menstrual period by the end of implementation (E. Stern, personal communication, November 20, 2019).

Additionally, the DNP student may advocate for changing the policy that dictates all women must have a physical within one year to receive birth control based on project outcomes. This is not something that occurred during the project. However, it may be necessary once outcomes are evaluated. Providers may prescribe other medications to control hypertension, cholesterol, or a seizure disorder; however, they may not be able to prescribe contraception with these medications. This policy may put the patient at a higher risk for unsafe teratogenic use. The DNP student will explore this policy with the practice medical directors to determine the key drivers and rationale for this policy. Working with stakeholders such as the medical directors, providers, and organizational leaders may help ensure this policy serves patients rather than reduce patient safety.

Essential VI: Interprofessional collaboration for improving patient and population health outcomes. Essential VI calls for the DNP student to lead an interprofessional team through excellent communication and collaborative skills to implement quality improvement (AACN, 2006). To develop the project, the DNP student worked with a nurse practitioner, a Health Center Administrator, Director of Nursing Research, Associate Chief Medical Officer for Innovation and Improvement, and faculty members. The team worked together to gather baseline data and to create the scope, outcomes, and interventions during the planning stage. Throughout the project, the DNP student worked closely with a nurse practitioner and physician assistant as site champions to guide project implementation at their respective sites. They both helped create plan-do-study-act cycles with innovative interventions that fit their provider workflow.

Additionally, a Health Center Administrator at site A was critical to collecting data to track program outcomes. A weekly report was generated by this administrator to identify the number of women aged 18 to 50 with provider encounters. This data was used as the

denominator in a project outcome regarding the percent of women screened with the TARCC framework. The DNP student also worked with a pharmacist at site B to start developing a best practice advisory and decision tree that could be placed into the electronic health record. After project implementation, the DNP student continued to work with the pharmacist, site champions, and other providers at the two clinics to receive feedback on the decision tree. Additionally, information technology professionals will be pulled in to provide feedback and build the framework into the health record if it is approved. The last interdisciplinary team members were the Practice Medical Directors that will be vital to sharing the project with practices across the network. At the end of implementation, the DNP student will present at the system-wide Practice Medical Director meeting, therefore allowing the TARCC framework to be shared across the health network.

Essential VII: Clinical prevention and population health for improving the nation's health. The DNP is trained to address population health through the lens of cultural diversity by using aggregate level data for health outcomes (AACN, 2006). An implication for practice for the DNP project was an improvement in certain Healthy People 2020 goals such as improvement of the intended pregnancy rate and a decrease in infant mortality and birth defect rates for women aged 18 to 50 (USDHHS, n.d.). During the project, the TARCC framework was applied to all women aged 18 to 50 at two primary care clinics, thus improving outcomes for a specific population, which is part of Triple Aim (IHI, 2019). The DNP project also improved the patient experience by enhancing shared decision making around medication risk/benefit and contraceptive use (IHI, 2019).

Additionally, a reduction in healthcare costs through the prevention of birth defects, unintended pregnancy, and abortion is a vital aspect of increasing value in Triple Aim and could

be a potential long-term outcome of this project (IHI, 2019). A further cultural implication for a future project would be to look at contraceptive use and teratogenic medication use by race, ethnicity, age, or income in each clinic. For example, unintended pregnancy rates are proportionally higher for low income Black and Hispanic women in the US (Finer & Zolna, 2016; Morse et al., 2017). Therefore, if data from the clinics supported higher rates of teratogen use or lower contraceptive use for these populations, the student could target the TARCC framework for the most vulnerable aggregate, and the intervention could be tailored to be culturally appropriate for that particular group.

Essential VIII: Advanced nursing practice. Essential VIII emphasizes the need for advanced clinical judgment and maintaining therapeutic relationships when implementing, evaluating, and providing evidence-based care (AACN, 2006). By working in two different sites, the DNP student had to form relationships with two site champions and two groups of providers. Advanced clinical judgment was needed to evaluate the workflow at each site and develop interventions to implement the TARCC framework effectively. The implication of using the TARCC framework and how to adjust medications accordingly is providing advanced clinical judgment. The provider must evaluate and weigh individual patient risks and preferences to determine the best medication and counseling needed for safe prescribing. Therefore, the DNP student advocated for a higher level of practice by all the providers in the project by implementing the framework.

Summary

The eight DNP Essentials were imbedded into the DNP project and will carry on past implementation. Aspects of each essential were utilized during implementation to enhance patient safety, improve population health, and translate quality evidence-based care into practice.

Including the TARCC framework into the medical record is an example of information systems being maximized to improve patient outcomes. Additionally, an interdisciplinary team and organizational buy-in will be critical to the inclusion of the framework into practice after implementation. During the project, the DNP student worked with two clinics with different organizational workflows and barriers to implementation. Therefore, becoming an interdisciplinary leader with excellent communication skills was a paramount and direct implication of the Essentials.

Overall, the project mandates a higher level of advanced nursing practice by all providers involved. It encouraged providers to think through risk and benefit when treating patients for common chronic diseases. Providers were given the scientific underpinning for teratogenic medication and contraceptive management and should continue to use this knowledge after the DNP project. The project also highlighted the importance of the ethical dilemma of doing no harm and the need to treat. By implementing the TARCC framework, providers practiced a higher level of care that increased the safety of teratogenic medication prescriptions.

Chapter Eight: Final Conclusions

The DNP project produced an increase in provider awareness of teratogenic medication and safe prescribing. The project highlighted a need for the systematic use of the TARCC framework to reduce the risk of teratogenic effects. Based on the findings from the project, it was recommended to place a best practice advisory into the EHR to prompt consistent framework use. It was also recommended to share the project education session, TARCC framework, and EHR advisory with other practices in the network.

Significance of Findings

At the end of the DNP project, providers reported a higher level of confidence in using the TARCC framework and a higher likelihood of use in the next month. Providers at both sites were creative in how they chose to merge TARCC with their current practice. Some providers decided to put the TARCC framework and checklist into their EHR templates for well-women physical exams. This would allow providers to discuss contraception and medication reconciliation during a visit that typically allows for more time. Another provider used the TARCC checklist each morning while looking over her schedule and flagged any patients that were on teratogenic medications without birth control. She was able to use the checklist with those patients to improve the safety of prescribing. Therefore, the TARCC framework was flexible enough for providers to merge with their current practice in different ways. This flexibility made the framework applicable to providers in different settings with different workflows.

Additionally, four providers, in particular, were impacted by the use of the framework during the project implementation. A PA at site B had a patient who was going through infertility insemination treatments for over one year while on lisinopril. Lisinopril is in the class of ACE inhibitors, which is a teratogenic class. The infertility specialists had not taken her off the medication despite several failed insemination attempts. The PA used the TARCC framework and stopped the lisinopril and started her on a safer medication. Therefore, the provider reduced the risk of teratogenic effects on future pregnancy and stated that she was much more aware of teratogenic medication after the DNP project (E. Stern, personal communication, January 4, 2020). An FNP at site A was also empowered to discuss the risk of starting a teratogenic antibiotic to prevent acne. Her patient refused all forms of birth control and had a history of several abortions. The FNP reported she knew from the project education session to refuse to

prescribe the teratogenic medication without a plan for contraception (V. Dalalau, personal communication, October 7, 2019). A physician at site A also reported she used the framework many times and appreciated how easy it was to use (M. Fike, personal communication, September 12, 2019). Last, another FNP at site A prescribed phentermine and topiramate, which were both teratogenic mediations. She realized she had not discussed pregnancy risk or contraception with the patient until she saw the TARCC reminder card on her desk (M. Fike, personal communication, October 16, 2019). She promptly had the MA bring the patient back to the exam room to discuss pregnancy risk and contraceptive counseling. This is also an example of how providers used awareness of teratogenic medication and applied it to classes of medications not addressed during the education session.

The patient stories illustrated how impactful the TARCC framework and knowledge of safe prescribing were for providers and patients. The education session increased provider awareness when prescribing teratogenic medications. The framework also helped providers do a more thorough medication reconciliation to ensure women were not on teratogens or had contraption if they were. Based on the final data collection tool, providers across the two sites used the TARCC framework at least 86 times during implementation. At site A, 249 TARCC checklists were used over ten weeks. Before the project, the TARCC framework was not in use, and providers did not routinely or systematically assess the safety of medication for childbearing age women. Therefore, a 16% average use of the TARCC checklist at site A implied improvement.

Project Strengths and Weaknesses

The strengths of the project included the support of site champions, the flexibility of the TARCC framework, and the low cost of the project. The site champions were instrumental in

reminding providers to use the framework and in brainstorming PDSA cycles to improve the project. The site champions ensured all providers participated in the three data collection surveys and attended the education session. The site champion at site B came up with the idea of adding the framework to physical exam templates and shared this with other providers. She also encouraged the DNP student to meet with a pharmacist who became part of the sustainability of the project by helping to create a best practice advisory for the EHR. The flexibility of the framework allowed providers to implement it into their workflow. It helped to change the provider's thought process when doing medication reconciliation and prescribing medication. Therefore, the framework may have impacted more patients than is evidenced by the number of checklists collected. Last, the cost of the project was around $300, which was well under the potential savings of preventing one birth defect or one abortion.

The weaknesses of the project included a lack of MA participation and electronic health record access. The MAs at both sites were overburdened and short-staffed. It is possible that with MA support, the TARCC framework would have been used more often. During triage, the MAs do medication reconciliation, which could have been an opportunity to flag teratogenic medication for providers before the visit. MAs could have also flagged women aged 18-50 and attached a TARCC checklist to prompt provider use. However, after trying this with one provider and MA, it was determined that the MAs did not have time for this additional task. Also, the DNP student was not able to pull reports or flag patients in real-time to help providers target their use of TARCC. A chart review would have helped find patients being seen who were on a teratogenic medication without documented contraception. Last, there was no reminder in the electronic health record to use the TARCC framework, therefore the project relied solely on paper checklists that were hard to incorporate into everyday workflow.

Project Limitations

The limitations of the project were the short duration of implementation, confounding factors affecting long-term outcomes, and decreased involvement of site B during the planning phase. The project implementation at site A was three months, and at site B for about two months. It was difficult to change provider behavior in a short time. Additionally, the long-term outcomes were difficult to assess for change due to the short duration of the project. The long-term outcomes also relied on data entry for current sexual activity, birth control use, and medication reconciliation. The DNP student did not have access to the EHR or involve the MAs. Therefore, it was difficult to ensure data entry was timely, accurate, and thorough. Thus, the lack of change in long-term outcomes could be related to those confounding factors. Last, the long-term outcomes did not fully reflect whether TARCC was being used. For example, if providers used the framework and provided counseling, the woman may not have chosen to use birth control. Therefore, even though providers changed their practice, it was not reflected in the percent of women using birth control while on a teratogen.

Site B was not involved in the initial planning phase of the DNP project. The site was added after a meeting with senior management at the end of the planning phase. Additionally, the DNP student had no previous relationship with site B providers or managers. As a result, site B providers were not willing to incorporate the TARCC checklists and were not as responsive to the weekly teratogen emails. Site B also had competing quality improvement project initiatives while also being short-staffed. Overall, providers at site B did not have as much time to incorporate TARCC into their practice or participate in the development of PDSA cycles.

Project Benefits

The project benefited the providers and organization because it illuminated a gap in safe practice. Providers realized they were not routinely evaluating the risk of teratogenic medication for childbearing age women. The TARCC framework helped providers change their thought process when prescribing medication and when performing medication reconciliation. Additionally, the education session gave providers tools to use when performing contraceptive counseling and in determining safer alternative medications. Even though the session focused on six commonly used classes of teratogenic medications, providers extended their learning to other drugs such as phentermine, topiramate, and doxycycline. Therefore, the most significant benefit was increased provider awareness of teratogenic medications and how to prescribe them safely. The providers felt the education session and framework were important enough to share with other primary care sites in the network. Also, providers felt the TARCC framework should be incorporated into the EHR despite the burden best practice advisories often have on provider workload. An extra stop in the EHR when prescribing medication would take more provider time. However, providers felt strongly that patient safety was at stake if the TARCC decision tree was not used as a regular part of their workflow. Also, the potential cost saving is considerable. Preventing the need for an abortion could save $450-$5000. Additionally, the prevention of one severe birth defect could save $78,000 in hospital costs in one year.

Practice Recommendations

The most significant recommendation for organizational change was to incorporate a best practice advisory into the electronic health record. Providers felt the TARCC framework was useful to improve medication prescription safety; however, it was difficult to remember to implement it routinely. As a result, the DNP student will work with an interdisciplinary team, including providers, information technology, and a pharmacist, to create the advisory. When a

teratogenic medication is prescribed for a woman of childbearing age, the EHR will trigger an advisory message. The advisory will alert the provider of the teratogenicity of the medication and recommend that action be taken to ensure safe prescribing. The provider will then be able to choose an appropriate response such as “no pregnancy risk,” “contraceptive/pregnancy risk counseling provided,” “contraception prescribed,” or “alternative medication chosen.” The advisory will imbed the TARCC concepts into the workflow of all providers in the network. Also, the education session and advisory framework will be shared with other practices in the system via a voiceover PowerPoint or live session.

The concepts of the TARCC framework can be applied to any setting where women of childbearing age receive care. However, it requires systematic integration into the practice’s workflow. The TARCC checklist was an easy way for providers to incorporate safe prescribing into their practice. Yet, it was challenging to remember to use it with all patients. The TARCC reminder cards for provider computers helped some providers remember to use the framework. However, it was not consistent. Therefore, integration into the workflow or the EHR would be recommended for future project replication. For example, MAs can flag patients during triage that are on teratogenic medication without birth control. Another option would be a report that shows providers which of their patients use teratogenic medications without birth control. Therefore, the concepts of the DNP project can be used in other settings to improve medication safety; however, the framework must be integrated into that office’s workflow. Without better integration, providers forget to incorporate TARCC components into their practice routinely.

Final Summary

The DNP project was successful in increasing provider awareness of teratogenic medication safety for childbearing age women in primary care. Providers began to change their

practice by incorporating TARCC principles into their workflow. Throughout the project, providers reported increased competence in using the framework and increased likelihood of using the framework in the future. Patient stories illustrated how impactful the DNP project was on provider prescribing practices. Additionally, the providers felt the education session should be shared with other primary care sites in the network and that TARCC should be embedded in the EHR. Based on provider feedback, a best practice advisory will be developed for the EHR. The advisory will alert providers to teratogenic medications when they are prescribed and prompt the provider to take action to increase the safety of prescribing.

There were also barriers to success, including the short duration of the project, lack of site B involvement in planning, and lack of access to MAs and the EHR. It was difficult to change provider behavior without the help of MAs, personalized EHR reports, and a short project. Additionally, without TARCC in the EHR, paper checklists were challenging to remember to use regularly. Thus, there was a 16% average TARCC checklist use at site A. However, patient stories and provider feedback on data collection tools illustrated there was evidence of practice change and an increase in overall awareness of teratogenic medication safety.

The DNP project will be sustained by sharing the education session and advisory framework with providers across the primary care network. Additionally, the best practice advisory will be developed in conjunction with an interdisciplinary team that will be implemented for all primary care sites. Overall the TARCC framework, checklist, and education session materials could be used at other facilities where childbearing age women are prescribed medications. However, an essential aspect of replication would be incorporating the framework into provider workflow systematically to ensure a higher rate of TARCC usage.

References

American Association of Colleges of Nursing. (2006). The essentials of doctoral education for advanced nursing practice. Retrieved from https://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf

American College of Obstetricians and Gynecologists. (2015). Access to contraception: Committee opinion number 615. Retrieved from https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception

American College of Obstetricians and Gynecologists & American Society for Reproductive Medicine. (2019). Prepregnancy counseling. *Fertility and Sterility, 111*(1), 32-42. doi:10.1016/j.fertnstert.2018.12.003

Bhakta, J., Bainbridge, J., & Borgelt, L. (2015). Teratogenic medications and concurrent contraceptive use in women of childbearing ability with epilepsy. *Epilepsy and Behavior, 52,* 212-217. doi:10.1016/j.yebeh.2015.08.004

Briggs, G. G., Polifka, J. E., Wisner, K. L., Gervais, E., Miller, R. K., Berard, A., . . . Towers, C. V. (2015). Should pregnant women be included in phase IV clinical drug trials? *American Journal of Obstetrics and Gynecology, 213*(6), 810-815. doi:10.1016/j.ajog.2015.05.047

Callegari, L. S., Ma, E. W., & Schwarz, E. B. (2015). Preconception care and reproductive planning in primary care. *Medical Clinics of North America, 99*(3), 663-682. doi:10.1016/j.mcna.2015.01.014

Center for Disease Control and Prevention. (2016). United States Medical Eligibly Criteria. Retrieved from https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html

Dehlendorf, C., Krajewski, C., & Borrero, S. (2014). Contraceptive counseling: Best practices to ensure quality communication and enable effective contraceptive use. *Clinical Obstetrics and Gynecology, 57*(4), 659-673. doi:10.1097/GRF.0000000000000059

DiPietro Mager, N., Mills, C., & Snelling, A. (2018). Utility of reproductive life plans in identification of potentially teratogenic medication use: A pilot study. *Birth, 45*(1), 50-54. doi:10.1111/birt.12318

Dirksen, R. R., Shulman, B., Teal, S. B., & Huebschmann, A. G. (2014). Contraceptive counseling by general internal medicine faculty and residents. *Journal of Women's Health, 23*(8), 77-713. doi:10.1089/jwh.2013.4567

Family Planning National Training Center. (2019). Putting the QFP into practice series toolkit. Retrieved from https://www.fpntc.org/resources/putting-qfp-practice-series-toolkit

Ferguson, S., Trupin, L., Yazdany, J., Yelin, E., Barton, J., & Katz, P. (2016). Who receives contraception counseling when starting new lupus medications? the potential roles of race, ethnicity, disease activity, and quality of communication. *Lupus, 25*(1), 12-17. doi:10.1177/0961203315596079

Finer, L. B., Frohwirth, L. F., Dauphinee, L. A., Singh, S., & Moore, A. M. (2005). Reasons U.S. women have abortions: Quantitative and qualitative perspectives. *Perspectives on Sexual and Reproductive Health, 37*(3), 110–118. Retrieved from https://www.guttmacher.org/sites/default/files/article_files/3711005.pdf

Finer, L. B., & Zolna, M. R. (2016). Declines in unintended pregnancy in the United States, 2008–2011. *The New England Journal of Medicine, 374*(9), 843-852. doi:10.1056/NEJMsa1506575

Food and Drug Administration. (2008). Content and format of labeling for human prescription drug and biological products: Requirements for pregnancy and lactation labeling. *Federal Register, 73*(104). Retrieved from https://www.govinfo.gov/content/pkg/FR-2008-05-29/pdf/E8-11806.pdf

Food and Drug Administration. (2014). Pregnancy and lactation labeling rule. Retrieved from https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf

Gavin, L., Moskosky, S., Carter, M., Curtis, K., Glass, E., Godfrey, E., . . . Zapata, L. (2014). Providing quality family planning services: Recommendations of CDC and the U.S. office of population affairs. *Morbidity and Mortality Weekly Report: Recommendations and Reports, 63*(4), 1-54. https://www.jstor.org/stable/24832591

Goyal, M. K., Hersh, A. L., Badolato, G., Luan, X., Trent, M., Zaoutis, T., . . . Walthall, J. (2015). Underuse of pregnancy testing for women prescribed teratogenic medications in the emergency department. *Academic Emergency Medicine, 22*(2), 192-196. doi:10.1111/acem.12578

Helou, N., Talhouedec, D., Shaha, M., & Zanchi, A. (2016). The impact of a multidisciplinary self-care management program on quality of life, self-care, adherence to anti-hypertensive therapy, glycemic control, and renal function in diabetic kidney disease: A cross-over study protocol. *BMC Nephrology, 17*(1), 88. doi:10.1186/s12882-016-0279-6

Holton, S., Thananjeyan, A., Rowe, H., Kirkman, M., Jordan, L., McNamee, K., . . . Fisher, J. (2018). The fertility management experiences of Australian women with a non-

communicable chronic disease: Findings from the understanding fertility management in contemporary Australia survey. *Maternal and Child Health Journal, 22*(6), 830-840. doi:10.1007/s10995-018-2454-9

Institute for Healthcare Improvement. (2019). The IHI triple aim. Retrieved from http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx

Jerman, J., & Jones, R. K. (2014). Secondary measures of access to abortion services in the United States, 2011 and 2012: Gestational age limits, cost, and harassment. *Women's Health Issues, 24*(4), 419-424. doi:10.1016/j.whi.2014.05.002

Johansson, A., Adamson, A., Ejdebäck, J., Edéll-Gustafsson, U. (2014). Evaluation of an individualized program to promote self-care in sleep-activity in patients with coronary artery disease – a randomized intervention study. *Journal of Clinical Nursing, 23*(19-20), 2822-2834. doi:10.1111/jocn.12546

Lee, J. K., Parisi, S. M., Akers, A. Y., Borrerro, S., & Schwarz, E. B. (2011). The impact of contraceptive counseling in primary care on contraceptive use. *Journal of General Internal Medicine, 26*(7), 731-736. doi:10.1007/s11606-011-1647-3

Lewin, K. (1947). Frontiers in group dynamics: Concept, method and reality in social science; social equilibria and social change. *Human Relations, 1*(1), 5-41. doi:10.1177/001872674700100103

Mahmoudzadeh Zarandi, F., Raiesifar, A., & Ebadi, A. (2016). The effect of Orem's self-care model on quality of life in patients with migraine: A randomized clinical trial. *Acta Medica Iranica, 54*(3), 159-164.

Martin, J. A., Hamilton, B. E., Osterman, M. J., Driscoll, A. K., & Drake, P. (2018). *Births: Final data for 2017* (NVSS Publication No. 8). Retrieved from https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_08-508.pdf

Melnyk, B.M. & Fineout-Overholt, E. (2011). *Evidence-based practice in nursing and healthcare: A guide to best practice*. Philadelphia: Lippincott, Williams & Wilkins. Retrieved from http://guides.lib.umich.edu/c.php?g=282802&p=1888246

Mody, S. K., Farala, J. P., Wu, J., Felix, R., & Chambers, C. (2015). Using the electronic medical record to assess contraception usage among women taking category D or X medications. *Birth Defects Research, 103*(10), 887-891. doi: 10.1002/bdra.23419

Morse, J. E., Ramesh, S., & Jackson, A. (2017). Reassessing unintended pregnancy: Toward a patient-centered approach to family planning. *Obstetrics and Gynecology Clinics of North America, 44*(1), 27-40. http://dx.doi.org/10.1016/j.ogc.2016.10.003

Mosher, W., Jones, J., & Abma, J. (2015). Nonuse of contraception among women at risk of unintended pregnancy in the united states. *Contraception, 92*(2), 170-176. doi:10.1016/j.contraception.2015.05.004

National Birth Defects Prevention Network. (2010). Birth defects state profile- North Carolina. Retrieved from https://www.nbdpn.org/docs/NC_BDprofile_2010_2016DEC15.pdf

Orem, D. E. (2001). *Nursing concepts of practice* (6th ed.). St. Louis, MO: Mosby, Inc.

Parker, S. E., Mai, C. T., Canfield, M. A., Rickard, R., Wang, Y., Meyer, R. E., . . . Correa, A. (2010). Updated national birth prevalence estimates for selected birth defects in the United States, 2004-2006. *Birth Defects Research. Part A, Clinical and Molecular Teratology, 88*(12), 1008-1016. doi:10.1002/bdra.20735

Quinzanos, I., Davis, L., Keniston, A., Nash, A., Yazdany, J., Fransen, R., . . . Zell, J. (2015). Application and feasibility of systemic lupus erythematosus reproductive health care quality indicators at a public urban rheumatology clinic. *Lupus*, *24*(2), 203-209. doi:10.1177/0961203314552832

Schwarz, E. B., Maselli, J., Norton, M., & Gonzales, R. (2005). Prescription of teratogenic medications in united states ambulatory practices. *The American Journal of Medicine, 118*(11), 1240-1249. doi:10.1016/j.amjmed.2005.02.029

Schwarz, E. B., Parisi, S. M., Handler, S. M., Koren, G., Cohen, E. D., Shevchik, G. J., & Fischer, G. S. (2012). Clinical decision support to promote safe prescribing to women of reproductive age: A cluster-randomized trial. *Journal of General Internal Medicine, 27*(7), 831-838. doi:10.1007/s11606-012-1991-y

Schwarz, E. B., Parisi, S. M., Handler, S. M., Koren, G., Shevchik, G., & Fischer, G. S. (2013). Counseling about medication-induced birth defects with clinical decision support in primary care. *Journal of Women's Health, 22(*10), 817-824. doi:10.1089/jwh.2013.4262

Schwarz, E. B., Postlethwaite, D. A., Hung, Y., & Armstrong, M. A. (2007). Documentation of contraception and pregnancy when prescribing potentially teratogenic medications for reproductive-age women. *Annals of Internal Medicine, 147*(6), 370. doi:10.7326/0003-4819-147-6-200709180-00006

Shroff, S., McNeil, M., & Borrero, S. (2017). An innovative framework to improve teratogenic medication risk counseling. *Journal of Midwifery & Women's Health, 62*(3), 353-357. doi:10.1111/jmwh.12604

Tinker, S. C., Broussard, C. S., Frey, M. T., & Gilboa, S. M. (2015). Prevalence of prescription medication use among non-pregnant women of childbearing age and pregnant women in the

united states: NHANES, 1999–2006. *Maternal and Child Health Journal, 19*(5), 1097-1106. doi:10.1007/s10995-014-1611-z

U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Healthy People 2020. (n. d.). *2020 topics and objectives: Maternal, infant, and child health.* Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives

Women's Preventive Services Initiative. (2016). Recommendations for preventive services for women : Final report to the U.S. Department of Health and Human Services, Health Resources & Services Administration. Retrieved from https://www.womenspreventivehealth.org/recommendations/final-report/

Appendix A

Literature Review Search Log

Date of Search	Database	Key Word Searches	Limits	# of Citations Found / Kept	Rationale for Inclusion / Exclusion (include rationale for excluding articles as well as for inclusion)
3/25/2019	East Carolina University Laupus One Search	teratogenic medication AND childbearing age women AND prescribing AND contraception AND education AND counseling	Last 5 y ears, English language, Scholarly and peer review, excluded book reviews and newspaper articles	41 found / 4 kept	31 did not relate directly to clinical question, 2 are poorly done or very small study, 4 were specific to foreign country outcomes and not generalizable to US
3/27/2019	East Carolina University Laupus One Search	Manual search of previously found articles' references	Besides seminal articles, last 5 years.	9	Articles are related to clinical question and cited by another source found in previous database search. Schwarz and Lee articles are seminal articles as they are repeatedly cited in other more current articles. Schwarz is a key member in this research field. Other articles by manual review of references from included articles.
3/27/2019	East Carolina University Laupus One Search	teratogen* AND primary care AND family planning AND contraception AND counsel* AND prescription AND provider education	Last 5 y ears, English language, Scholarly and peer review, excluded book reviews and newspaper articles	38 found / 2 new kept/ 2 same from previous search	2 are discussion-based articles not research study, 1 specific to foreign country outcomes and not generalizable to US, 31 did not relate directly to clinical question
3/27/2019	East Carolina University Laupus One Search	teratogen AND contraception AND primary care AND counsel* AND prescription	Last 5 y ears, English language, Scholarly and peer review, excluded book reviews and	40 found/ 3 new kept / 5 are from previous search used	33 not related directly to clinical question

			newspaper articles		
3/28/2019	East Carolina University Laupus One Search	"The impact of contraceptive counseling in primary care on contraceptive use" and "Cited By"	Last 5 years	20 found / 1 new kept / 1 from previous search	18 not directly related to clinical question or population in study not generalizable to clinical question

Appendix B

DNP Project Literature Matrix

Article	**Level of Evidence** (I to VII)	**Data/Evidence Findings**	**Conclusion or Summary**	**Use of Evidence in EBP Project Plan**
Shroff, S., McNeil, M., & Borrero, S. (2017). An innovative framework to improve teratogenic medication risk counseling. *Jour nal of Midwifery & Women's Health, 62*(3), 353-357. doi:10.1111/jmwh.12604	Level VI	At the VA 12% of women at risk of pregnancy were given teratogenic risk counseling within 6 months of teratogenic prescription. Barriers based on provider surveys were 1) time constraints, 2) lack of familiarity with nonteratogenic medication alternatives, 3) lack of comfort discussing risks and benefits of teratogenic medications, 4) not thinking about or lack of comfort in providing appropriate contraception counseling, and 5) inadequate documentation of teratogenic risk counseling.	Developed TARCC framework and put into EMR as a PCP clinical reminder. Also links to an online database for clinical pharmacology , an electronic drug reference Web site, contraceptive efficacy chart, contraceptive order set, a women's health consult for contraceptive counseling, and a gynecology consult for contraceptive options requiring an invasive procedure , pharmacist e-consult. Once through framework-documents note	QI project, has not done formal outcomes until 1 year after implementation. Framework is useful for provider education and possibility of EMR inclusion.

Bhakta, J., Bainbridge, J., & Borgelt, L. (2015). Teratogenic medications and concurrent contraceptive use in women of childbearing ability with epilepsy. *Epilepsy and Behavior, 52*, 212-217. doi:10.1016/j.yebeh.2015.08.004	Level VI	74% of women with epilepsy on teratogenic AED were NOT on contraception. Less than 7% of women received counseling on a contraception plan. 18% received counseling about the possible teratogenic effects of the medication on the fetus and a planned pregnancy. Two women not taking the contraception became pregnant while on the category D or X AED. One had a miscarriage, and one received an abortion after learning of the pregnancy.	Women with epilepsy on teratogenic AED are not given contraceptive counseling or pregnancy risk education	Limitation-retrospective observational study, only women with epilepsy, small sample size (n=115). Does show significant evidence of problem in women with epilepsy.
Ferguson, S., Trupin, L., Yazdany, J., Yelin, E., Barton, J., & Katz, P. (2016). Who receives contraception counseling when starting new lupus medications? the potential roles of race, ethnicity, disease activity, and quality of communication. *Lupus, 25*(1), 12-17. doi:10.1177/0961203315596079	Level VI	1/3 of women who started new teratogenic medication for lupus were not given contraceptive counseling. Patients who rated their providers low on the shared decision-making scale were less likely to receive counseling	Women on teratogenic lupus medications are not always given contraceptive counseling	Limitation-prospective observational study, based on patient report, small sample size (n=68) so could not find significance with multivariate analysis. Brings up importance of shared decision making with patients

Holton, S., Thananjeyan, A., Rowe, H., Kirkman, M., Jordan, L., McNamee, K., . . . Fisher, J. (2018). The fertility management experiences of Australian women with a non-communicable chronic disease: Findings from the understanding fertility management in contemporary Australia survey. *Maternal and Child Health Journal, 22*(6), 830-840. doi:10.1007/s10995-018-2454-9	Level IV	Women with non-infectious chronic disease (NCD) less likely to talk about contraception/pregnancy planning than those without (45% vs 54.4%). Women with NCD more likely to have unintended pregnancy (33.7% vs 25.5%) and abortion (20.3% vs 14.2%). No difference in contraceptive use between groups.	Women with an NCD may be using contraception but be unaware of any interaction between their illness-related medication and contraception. Women with an NCD may also not be using the most appropriate and effective contraceptive methods, given their illness. NCD less likely to get contraceptive counseling yet they all have diseases that are likely managed with medication and some of which are teratogenic.	Limitation- patient survey, self-report. Strength- good sample size and randomization (n=1543) and able to find statistical significance. Women with chronic disease are managed in primary care oftentimes, therefore PCP responsibility to provide counseling and contraception
ACOG and ASRM. Prepregnancy counseling. (2019). *Fertility and Sterility, 111*(1), 32-42. doi:10.1016/j.fertnstert.2018.12.003	Level V	Committee opinion, no findings	ACOG and ASRM recommend medication review as part of pre-pregnancy counseling. Each visit with childbearing	Limitation- opinion. Strength- expert committee opinion by 2 organizations trusted in the field

			age women should include some discussion of pregnancy planning. Specifically mentions ACE and ARB as contraindicated.	
Callegari, L. S., Ma, E. W., & Schwarz, E. B. (2015). Preconception care and reproductive planning in primary care. *Medical Clinics of North America, 99*(3), 663-682. doi:10.1016/j.mcna.2015.01.014	Level V	Commonly prescribed medications in primary care: Seizures and AEDs, thrombophilia and warfarin, hypertension - ACE/ARB, depression- Paroxetine, hyperlipidemia- statins	Review discusses common conditions treated and managed in primary care that could be treated with teratogenic medications therefore preconception counseling/contraception should be provided by PCPs	Review does not include methods of literature review or exclusion/inclusion. Helps case that contraceptive counseling needs to be done in primary care

Schwarz, E. B., Postlethwaite, D. A., Hung, Y., & Armstrong, M. A. (2007). Documentation of contraception and pregnancy when prescribing potentially teratogenic medications for reproductive-age women. *Annals of Internal Medicine, 147*(6), 370. doi:10.7326/0003-4819-147-6-200709180-00006	Level IV	16% of women in study filled at least 1 category D or X medicine. 48% of women who filled a D and 47% of women who filled an X in 2001 had no contraceptive method dispensed, had not been sterilized, and had no documentation of contraceptive counseling. Women who filled a class D or X prescription were not more likely than women who filled a class A or B prescription to have recently filled a contraceptive prescription or to have previously been sterilized (37.0% vs. 39.4% of prescriptions).	Half of women on D or X medication in 2001 did not have contraception or contraceptive counseling documented in their health record.	Strength- large sample size of 488,175 childbearing age women using chart review. Limitation- limited to what was in medical record, retrospective
Schwarz, E. B., Maselli, J., Norton, M., & Gonzales, R. (2005). Prescription of teratogenic medications in united states ambulatory practices. *The American Journal of Medicine, 118*(11), 1240-1249. doi:10.1016/j.amjmed.2005.02.029	Level IV	Use of a potentially teratogenic, class D or X, medication by a woman of childbearing age is documented on 1 of every 13 visits made to US ambulatory practices. Contraceptive counseling was provided on less than 20% of visits that documented use of a potential teratogen by a woman of childbearing age. Generalists (i.e., internists and family practitioners) provided	Family providers prescribe the largest proportion of teratogenic meds to childbearing age women, yet contraceptive counseling is not regularly included.	Strengths- large sample of 12 681 visits made to 1880 physicians by women of childbearing age (14-44 years) who were not classified as pregnant. Random sampling across the country. Limitations- older study. Case that family practice providers

		ambulatory care to the largest proportion (45%) of women prescribed potentially teratogenic medications		prescribe teratogenic meds and are not providing contraceptive counseling
Mody, S. K., Farala, J. P., Wu, J., Felix, R., & Chambers, C. (2015). Using the electronic medical record to assess contraception usage among women taking category D or X medications. *Birth Defects Research, 103*(10), 887-891. doi: 10.1002/bdra.23419	Level VI	Most commonly prescribed teratogenic meds- alprazolam (27.4%), lisinopril (11.9%), simvastatin (10.0%), minocycline (6.0%), and paroxetine (5.7%). Among the 407 women known to be sexually active with men, 267 women (65.5%) were using contraception.	34.5% of women prescribed teratogenic medication were not on contraception.	Limitation- retrospective chart review. Strength- large sample size of 610 childbearing age women prescribed D or X medication.

Schwarz, E. B., Parisi, S. M., Handler, S. M., Koren, G., Shevchik, G., & Fischer, G. S. (2013). Counseling about medication-induced birth defects with clinical decision support in primary care. *Journal of Women's Health, 22*(10), 817-824. doi:10.1089/jwh.2013.4262	level VI	Primary care providers were instructed on a clinical decision support system to aid in discussing risks and contraception when prescribing teratogenic medication and aids were added to the EMR. 801 patient surveys were analyzed. 26% of survey respondents were prescribed potential teratogens by PCPs . The potential teratogens most commonly prescribed included benzodiazepines (35%), antimicrobials (i.e., doxycycline and fluconazole, 20%), angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers (18%), cardiovascular medications (e.g., beta-blockers, spironolactone, 10%), psychiatric medications (e.g., lithium and some antidepressants, 9%), and statins (7%). 57% of women prescribed potential teratogens reported receiving some form of counseling about the risk of medication-induced birth defects or the benefits of contraception. only 55% of women who	Over 40% of women prescribed teratogenic medication did not get contraceptive counseling or pregnancy risk education. Discrepancy between women's perception and documentation of counseling. women who had been counseled about teratogenic risks or contraception when they were prescribed a potential teratogen were more likely to report using contraception than women who reported no such counseling	Limitation - only 19% completed surveys. If providers give the counseling, patients are more likely to use contraception

		said they had received teratogenic risk counseling or contraceptive counseling had documented evidence of family planning services in their EMR for that visit		
Quinzanos, I., Davis, L., Keniston, A., Nash, A., Yazdany, J., Fransen, R., . . . Zell, J. (2015). Application and feasibility of systemic lupus erythematosus reproductive health care quality indicators at a public urban rheumatology clinic. *Lupus, 24* (2), 203-209. doi:10.1177/0961203314552832	level VI	Sixty-five patients (53%) received potentially teratogenic medications, and 30 (46%) had documented discussions about these medications' potential risk upon their initiation.	High rate of prescribing teratogenic med for lupus but low rate of risk education	Low sample, 137 were childbearing age women and diagnosed with lupus in Denver. May not be generalizable

Goyal, M. K., Hersh, A. L., Badolato, G., Luan, X., Trent, M., Zaoutis, T., . . . Walthall, J. (2015). Underuse of pregnancy testing for women prescribed teratogenic medications in the emergency department. *Academic Emergency Medicine, 22*(2), 192-196. doi:10.1111/acem.12578	level VI	10.1 million estimated visits (7% of visits) were associated with administration or prescription of teratogenic medications. Of these, 22.0% had a pregnancy test.	Low rates of pregnancy testing prior to prescription or admin of teratogenic medication	Limitation- retrospective cross-sectional study, no randomization. provider knowledge of sexual activity, previously documented pregnancy, recent testing, and current contraceptive use cannot be obtained from these data sources which could be why a pregnancy test was not done. Strength- large sample size of 39,859 sampled visits representing an estimated 141.0 million ED visits by reproductive-aged females nationwide
DiPietro Mager, N., Mills, C., & Snelling, A. (2018). Utility of reproductive life plans in identification of potentially teratogenic medication use: A pilot study. *Birth, 45*(1), 50-54. doi:10.1111/birt.12318	level VI	Medication lists were completed for 437 of the 580 reproductive life plans reviewed (75%). Thirty-five women (8%) reported use of a potentially teratogenic medication; most commonly reported agents included blood pressure medications and antidepressants. Only 10 women taking a potentially	Even with doing reproductive life plans, providers still missed the fact that women on teratogenic medication need effective contraception	limitation- retrospective, specific sample makes results less generalizable- women in preconception, prenatal, or interconception services as part of Toledo-Lucas County Healthy Start, self-report. Strength-

		teratogenic medication (29%) reported using some form of contraception, half of which reported use of a less effective method such as condoms.		showed a good way to identify women on teratogenic meds and if they are on contraception
Schwarz, E. B., Parisi, S. M., Handler, S. M., Koren, G., Cohen, E. D., Shevchik, G. J., & Fischer, G. S. (2012). Clinical decision support to promote safe prescribing to women of reproductive age: A cluster-randomized trial. *Journal of General Internal Medicine, 27*(7), 831-838. doi:10.1007/s11606-012-1991-y	Level III	Before CDS implementation 24.2% of visits in which a teratogenic medication was prescribed had documented provision of family planning services. After implementation increased to 26.5%. Not significant. Providers did report improvement on pre and post survey - they more often discussed the risk of medication use during pregnancy, provided preconception counseling, prescribed hormonal birth control, referred for IUD placement. 13% of the time physicians received CDS, they cancelled the prescription that triggered the CDS and prescribed another potentially teratogenic medication	No difference in the simple and multifaceted clinical decision support reminder in the health record. No significant change after CDS implementation in prescribing of teratogenic medication or family planning discussion when prescribing teratogenic meds.	strength- cluster randomized, large sample size 35,110 encounters by 9,972 female patients of childbearing age. Reinforces to change behavior need more than a computer reminder, providers also need to know non-teratogenic alternatives to teratogenic meds and perhaps more information about contraceptive counseling options

U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Healthy People 2020. (n. d.). 2020 topics and objectives: Maternal, infant, and child health. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives	n/a	51.0 percent of all pregnancies were intended, as reported in 2002 is baseline. Target 56%	goals of reducing the number of infants born with birth defects, reducing infant mortality, and increasing preconception discussion with childbearing age women . Also goal to increase percent of pregnancies that are intended	Outcomes and QI project are in line with Healthy People 2020 goals
Women's Preventive Services Initiative. (2016). Recommendations for preventive services for women : Final report to the U.S. Department of Health and Human Services, Health Resources & Services Administration. Retrieved from https://www.womenspreventivehealth.org/recommendations/final-report/	Level I	Reviewed the literature about contraception and counseling.	Contraceptive counseling should be included in all childbearing age women exams, preconception discussions should occur in primary care including about teratogenic medication. All forms of contraception should be available and offered. ACA and marketplace insurance must cover	Helps make recommendation that contraceptive counseling is a women's health initiative priority according to ACOG, HRSA, ACP, AAFP, and NPWH

			contraception and counseling without copayments.	
Food and Drug Administration. (2014). Pregnancy and lactation labeling rule. Retrieved from https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf	n/a	Feedback from focus groups and stakeholders that "subsections of prescription drug labeling lacked clarity, often failed to provide meaningful clinical information about drug exposure during pregnancy and lactation and did not address the potential maternal and fetal consequences of discontinuing needed maternal drug therapy during pregnancy." Mental Models Research study in 2009 also confirmed providers rely solely on categories of medications rather than specific clinical information for prescribing	"The final rule creates a consistent format for providing information about the risks and benefits of drug use during pregnancy and lactation and by females and males of reproductive potential." Removes the ABCDX from labeling. " "Females and Males of Reproductive Potential" subsection include relevant information when pregnancy testing or contraception is required or recommended before, during, or after drug therapy".	Education about this new rule can be included in training of providers. The "Risk Summary" and the "Females and Males of Reproductive Potential" are especially important

Lee, J. K., Parisi, S. M., Akers, A. Y., Borrerro, S., & Schwarz, E. B. (2011). The impact of contraceptive counseling in primary care on contraceptive use. *Journal of General Internal Medicine, 26*(7), 731-736. doi:10.1007/s11606-011-1647-3	Level VI	Women who received contraceptive counseling were more likely to be seeing a doctor they considered their PCP. Most women who received counseling (94.0%) reported that all of their questions about birth control had been answered and 92.3% were satisfied with the counseling they received. Women who received a new prescription were significantly more likely to report use of contraception at last intercourse (86.5% vs. 57.9%, p=0.002). women in need of contraceptive counseling who received counseling regarding any method were more likely to use hormonal birth control the last time they had intercourse. even among women who did not receive a new contraceptive prescription, receipt of contraceptive counseling was still associated with a greater likelihood of use of contraception at last intercourse (57.9% vs. 45.9%, p=0.06)- Not statistically significant but clinically it is	"This study of over 700 women in western Pennsylvania found that women who received contraceptive counseling from a primary care provider were significantly more likely than those who did not to subsequently report use of hormonal contraception the last time they had intercourse. These findings provide further support that contraceptive counseling by clinicians improves women's contraceptive use and provide evidence that PCPs can play an important role in promoting	Limitation - only 19% completed surveys and there was difference between who did and did not complete the survey. Women who completed surveys were more likely to be white (91% vs. 81%, p<0.001) and have more than a high school education (78% vs. 71%, p=0.006) which could have affected outcomes

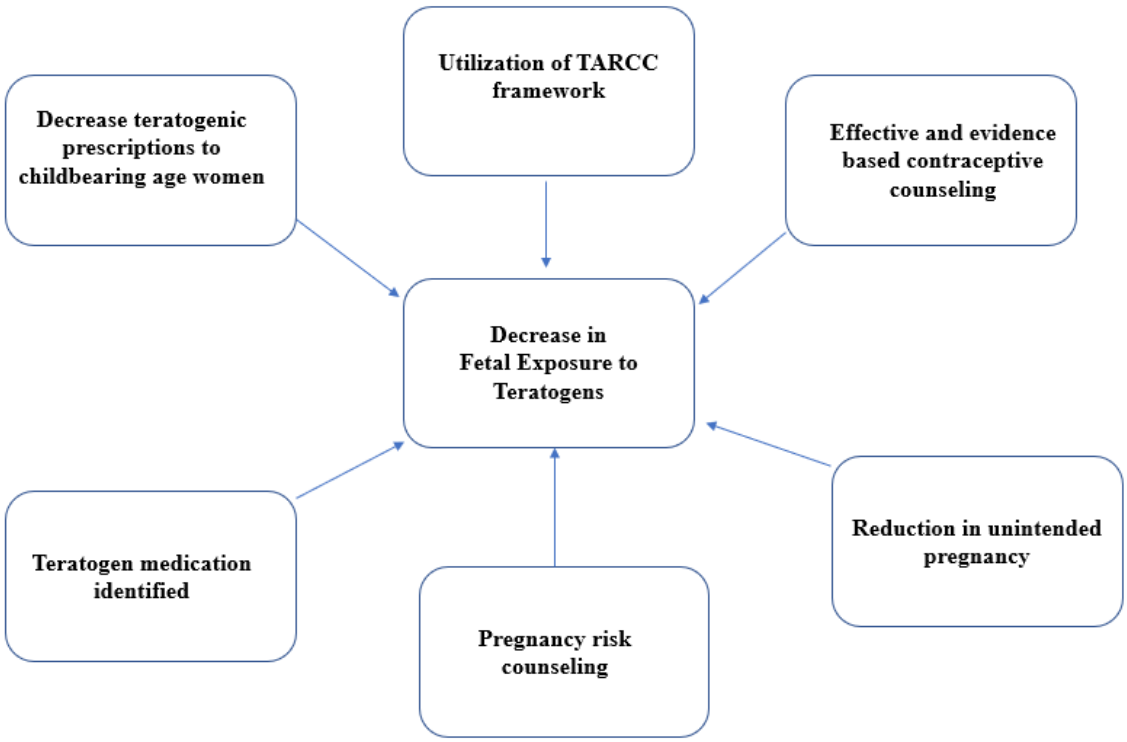
			contraception use."	

Dirksen, R. R., Shulman, B., Teal, S. B., & Huebschmann, A. G. (2014). Contraceptive counseling by general internal medicine faculty and residents. *Journal of Women's Health, 23*(8), 77-713. doi:10.1089/jwh.2013.4567	Level VI	Almost one-fifth of residents and one-third of faculty reported routine contraceptive counseling at prevention-focused visits. . The majority of faculty and residents reported that they perceive inadequate time (75.3%) and inadequate knowledge (74.0%) as reasons for not performing contraceptive counseling. More than 95% of all providers reported that it was important to be able to discuss various forms of contraception, including their effectiveness and potential adverse effects. 2 factors that increased the likelihood of providing contraceptive counseling included , reported high self-efficacy for contraceptive counseling (vs. low self-efficacy) and reported adequate knowledge regarding contraceptive methods	Provider education and high self-efficacy can improve chances that counseling is done. The majority of resident and faculty providers felt that they would provide contraceptive counseling more often if they had more knowledge regarding contraceptive methods. Of resident participants, 70.0% agreed that they would have preferred more training in contraceptive methods and counseling as part of their internal medicine residency. Of faculty participants, 72.7% agreed that they would like more CME regarding contraceptive	Limitation: Provider survey, moderate response rate (Of 95 outpatient internal medicine faculty members contacted, 66 (69.5%) responded; of 146 internal medicine residents contacted, 80 (54.8%) responded). Provides evidence that making providers more aware and more confident in their ability to provide counseling can increase the chances it is done

			methods and counseling.	

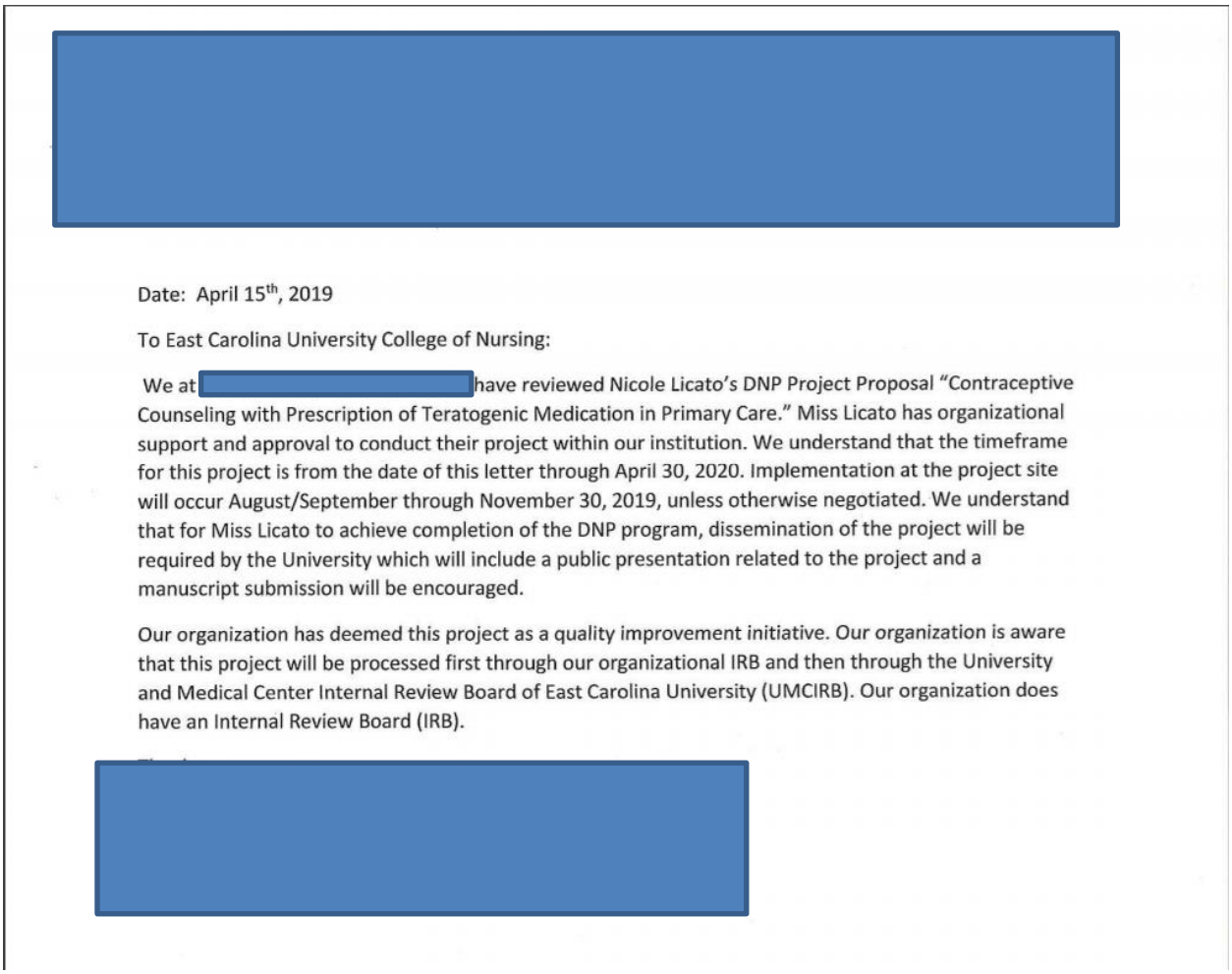
Appendix C

DNP Project Concept Map



Appendix D

Clinic Site Letters of Approval



[redacted]

Date: April 15th, 2019

To East Carolina University College of Nursing:

We at [redacted] have reviewed Nicole Licato's DNP Project Proposal "Contraceptive Counseling with Prescription of Teratogenic Medication in Primary Care." Miss Licato has organizational support and approval to conduct their project within our institution. We understand that the timeframe for this project is from the date of this letter through April 30, 2020. Implementation at the project site will occur August/September through November 30, 2019, unless otherwise negotiated. We understand that for Miss Licato to achieve completion of the DNP program, dissemination of the project will be required by the University which will include a public presentation related to the project and a manuscript submission will be encouraged.

Our organization has deemed this project as a quality improvement initiative. Our organization is aware that this project will be processed first through our organizational IRB and then through the University and Medical Center Internal Review Board of East Carolina University (UMCIRB). Our organization does have an Internal Review Board (IRB).

[redacted]

[redacted]

July 9, 2019

To East Carolina University College of Nursing:

We at [redacted] have reviewed Nicole Licato's DNP Project Proposal "Teratogenic Medication Safety in Primary Care." Miss Licato has organizational support and approval to conduct their project within our institution. We understand that the timeframe for this project is from the date of this letter through April 30, 2020. Implementation at the project site will occur August/September through November 30, 2019, unless otherwise negotiated. We understand that for Miss Licato to achieve completion of the DNP program, dissemination of the project will be required by the University which will include a public presentation related to the project and a manuscript submission will be encouraged.

Our organization has deemed this project as a quality improvement initiative. Our organization is aware that this project will be processed first through our organizational IRB and then through the University and Medical Center Internal Review Board of East Carolina University (UMCIRB). Our organization does have an Internal Review Board (IRB).

Thank you

[redacted]

Appendix E

DNP Project Budget

Line Item	Quantity	Unit Cost	Total
Educational Seminar			
Food			
Case of Bottled Water	2	$2.99	$5.98
Soda	6	$2.00	$12.00
Set of Napkins	2	$1.00	$2.00
Set of Plates	2	$1.00	$2.00
Set of Cups	2	$1.00	$2.00
Food	2	$50.00	$100.00
Materials			
Packet of Handouts	20	$3.00	$60.00
Box of Pens	2	$5.00	$10.00
Folders	20	$2.00	$40.00
Copies Education Survey	40	$0.04	$1.60
Supplies			
Copies of Mid Project Survey	20	$0.04	$0.80
Copies of Post Implementation Survey	40	$0.04	$1.60
TARCC Baby Computer Slider	15	$3.00	$45.00
Snacks Throughout Project	1	$50.00	$50.00
Total			**$332.98**

Appendix F

Site IRB Approval Form

[redacted]

[redacted]NSTITUTIONAL REVIEW BOARD DECLARATION OF ACTIVITY NOT MEETING THE DEFINITION OF RESEARCH

The [redacted]IRB has determined that the following activity does not meet the definition of research as described in 45 CFR 46.102(d), 21 CFR 50.3(c) and 21 CFR 56.10(c) and satisfies the Privacy Rule as described in 45 CFR 164.514.

Protocol ID: Pro00103319
Reference ID: 327763
Protocol Title: Teratogenic Medication Safety in Primary Care
Principal Investigator: [redacted]

This IRB declaration is in effect from August 09, 2019 and does not expire. However, please be advised that any change to the proposed research will require re-review by the IRB.

[redacted]

Appendix G

East Carolina University IRB Approval

Click "download PDF" to save a copy of this page for your records.
Note: The IRB Office does not maintain copies of your responses.

Below is a summary of your responses

Download PDF

Quality Improvement/Program Evaluation Self-Certification Tool

Purpose:
Projects that do not meet the federal definition of human research pursuant to 45 CFR 46 do not require IRB review. This tool was developed to assist in the determination of when a project falls outside of the IRB's purview.

Instructions:
Please complete the requested project information, as this document may be used for documentation that IRB review is not required. Select the appropriate answers to each question in the order they appear below. Additional questions may appear based on your answers. If you do not receive a STOP HERE message, the form may be printed as certification that the project is "not research", and does not require IRB review. The IRB will not review your responses as part of the self-certification process.

Name of Project Leader:

Nicole Licato

Project Title:

Teratogenic Medication Safety in Primary Care

Brief description of Project/Goals:

The population of focus for the DNP project will be 15 primary care providers located at two [redacted] Primary Care offices. The providers will attend an education session about the importance of contraceptive and pregnancy risk counseling for childbearing age patients on teratogenic medications. They will be introduced to a framework developed by Shroff, McNeil, and Borrero (2017) called

TARCC, which providers can use when they prescribe medication. The purpose of the project is to increase primary care provider knowledge of the TARCC framework. The long term outcomes are to reduce the number of teratogenic prescriptions for childbearing age women and increase contraceptive use for patients who receive teratogenic prescriptions. Overall, the goal is to reduce unintended fetal exposure to teratogenic medication. Provider surveys will be used to evaluate outcomes after the education session, mid-implementation, and at the end of the project. Baseline and outcomes data reports will be extracted by a third party. The DNP student will have no connection to the health record.

Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

- ○ Yes
- ● No

Has the project received funding (e.g. federal, industry) to be conducted as a human subject research study?

- ○ Yes
- ● No

Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

- ○ Yes
- ● No

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?

- ○ Yes
- ● No

Will the results of the project be published, presented or disseminated outside of the institution or program conducting it?

- ○ Yes
- ● No

Based on your responses, the project appears to constitute QI and/or Program Evaluation and IRB review is not required because, in accordance with federal regulations, your project

does not constitute research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI and/or Program Evaluation findings. Finally, if the project changes in any way that might affect the intent or design, please complete this self-certification again to ensure that IRB review is still not required. Click the button below to view a printable version of this form to save with your files, as it serves as documentation that IRB review is not required for this project. 7/17/2019

Appendix H

DNP Project Data Collection Tools

Teratogenic Medication Safety in Primary Care
Preliminary Data Collection Tool

1. Circle your role in the clinic: MD, NP, PA

2. Years of primary care experience:

3. Circle how competent you feel in your ability to use the TARCC framework:

   1 Not at all competent
   2 A little competent
   3 Somewhat competent
   4 Very competent
   5 Extremely competent

4. Circle how competent you feel in your ability to provide effective contraceptive counseling:

   1 Not at all competent
   2 A little competent
   3 Somewhat competent
   4 Very competent
   5 Extremely competent

5. What does each letter of the TARCC framework stand for?

   T

   A

R

C

C

6. What would make prescribing lisinopril to a 41-year-old female safe? Select all that apply:

    - Switch it to a calcium channel blocker or beta blocker
    - Switch it to an angiotensin-converting enzyme inhibitor
    - Switch it to an angiotensin-receptor blocker
    - Ensure she is on contraception
    - Discuss pregnancy risk with the patient
    - Nothing, this is a safe medication for this patient

7. How likely are you to use the TARCC framework over the next month?

    1 Not likely
    2 Slightly likely
    3 Somewhat likely
    4 Very likely
    5 Extremely likely

Thank you for attending the session!

Teratogenic Medication Safety in Primary Care
Mid-Implementation Data Collection Tool

1. Estimate how many times you have used the TARCC framework since the education session:

   0-3
   4-6
   7-9
   10 or more

2. How likely are you to use the TARCC framework in the next 1 month?

   1 Not likely
   2 Slightly likely
   3 Somewhat likely
   4 Very likely
   5 Extremely likely

3. What does each letter of the TARCC framework stand for?

   T

   A

   R

   C

   C

4. Circle how competent you feel in your ability to use the TARCC framework:

   1 Not at all competent
   2 A little competent
   3 Somewhat competent

4 Very competent

5 Extremely competent

5. What recommendations do you have to increase your use of the TARCC framework?

Teratogenic Medication Safety in Primary Care
Final Data Collection Tool

1. Circle how competent you feel in your ability to use the TARCC framework:

1 Not at all competent

2 A little competent

3 Somewhat competent

4 Very competent

5 Extremely competent

2. Circle how many times you have used the TARCC framework since the education session:

0-3
4-6
7-9
10 or more

3. What are the barriers to using the TARCC framework?

4. How helpful do you feel the TARCC framework has been in improving the quality of your care?

1 Not at all helpful

2 A little helpful

3 Somewhat helpful

4 Very helpful

5 Extremely helpful

5. How helpful do you feel it would be to have the TARCC framework be an automatic reminder in Epic if you prescribe a teratogenic medication?

1 Not at all helpful

2 A little helpful

3 Somewhat helpful

4 Very helpful

5 Extremely helpful

6. How important is it that the education session and TARCC framework be shared with other primary care sites in the network?

1 Not at all important

2 A little important

3 Somewhat important

4 Very important

5 Extremely important

7. How likely are you to use the TARCC framework over the next month?

1 Not likely

2 Slightly likely

3 Somewhat likely

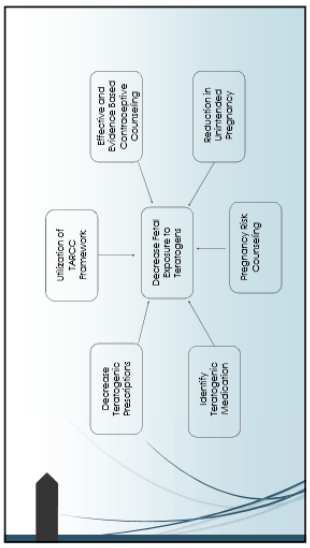
4 Very likely

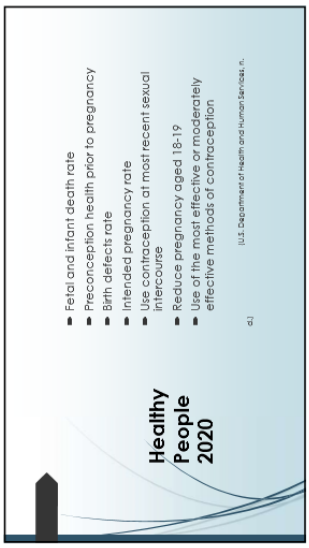
5 Extremely likely

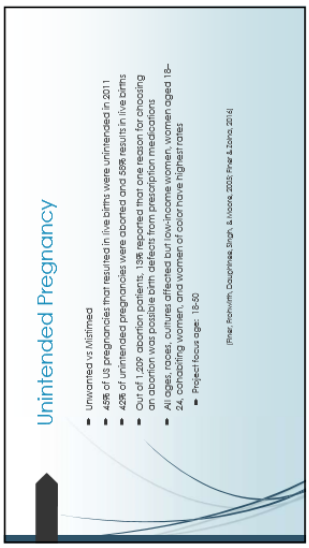
Thank you very much for your participation in the DNP Project!

Appendix I

Site A Education Session PowerPoint Slides







Policy and Health Care Implications

- ACOG, ACP, AAFP, ASRM, NPWH call for contraceptive counseling and preconception planning at all health promotion visits for childbearing age women
- Tightening abortion policies
- Cost savings by preventing 1 abortion: $450 - $5000
- Cost savings by preventing 1 birth defect- hospital cost of one child with a birth defect is $78,000
- Ethical and evidence-based practice

(ACOG & ASRM, 2019; Jarman & Jones, 2014; NBDPN, 2010; Parker et al., 2010; Women's Preventive Services Initiative, 2016)

Current Practices in the Literature

- National Health and Nutrition Examination Survey 1999 to 2006
  - 47% of childbearing age non-pregnant women: at least 1 medication in the past 30 days
  - >50%: more than two prescriptions
  - 5 of top 10: caution advised or contraindicated
- In most studies, < **50%** received pregnancy risk/contraceptive counseling with a teratogen
- **benzodiazepines**, **ACE inhibitors**, **ARB**, **anticonvulsants**, certain antibiotics, **statins**, lithium, isotretinoin, paroxetine, and **warfarin**

(DiPietro Mager et al., 2018; Mody et al., 2015; Schivas et al., 2008; Shroff et al., 2017; Tinker, Broussard, Frey, & Gilboa, 2015)

[redacted]

- 2,219 childbearing age women seen
- 2,591 provider encounters
- 42,631 active medications
- 30% of women were on at least 1 teratogenic class
- 217 new teratogenic medications prescribed
- 44% reported they were sexually and on a form of birth control
- **56% could be at risk**

Barriers

- What have you experienced?
- Barriers: lack of (1) time, (2) knowledge of alternative medications, and (3) confidence in contraceptive and pregnancy risk counseling
- Counseling was done but not documented
- Inaccurate input for sexual activity and birth control use
- Remembering!
- No EHR Flag

(Dirksen et al., 2014; Shroff et al., 2017)

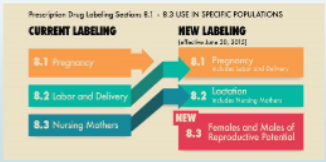
TARCC Framework

Shroff, McNeil, & Borrero (2017)

T- is it teratogenic?
A- is there a safer alternative?
R- if not, discuss pregnancy risk
C- discuss contraceptive counseling
C- chart counseling or change in medication was done

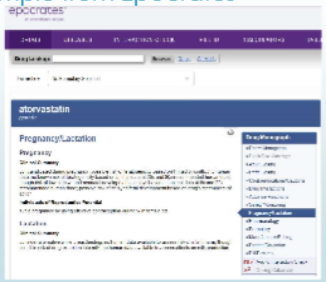
Teratogen

- How do you determine the safety of medication?
- 2015: FDA Pregnancy and Lactation Labeling Final Rule
- More risks and benefits, shared-decision making, no cut and dry categories
- New prescriptions and medication reconciliation

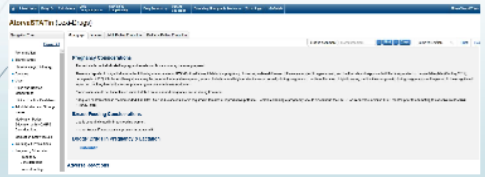


From https://www.fda.gov/drugs/labeling/pregnancy-and-lactation-labeling-drugs-final-rule

Example from Epocrates



Example from Epic Lexi Comp



Alternatives

Teratogen	Safer Alternatives
Statins	Not many, maybe Omega-3 fatty acids
Angiotensin Converting Enzyme Inhibitors (Lisinopril) Angiotensin Receptor Blocker (Losartan)	Labetalol Methyldopa Nifedipine, Other CCB with caution Hydrochlorothiazide
Benzodiazepines	Some SSRIs (Celexa, Prozac, Zoloft) – still some risk with serotonin syndrome in newborn No paroxetine
Anticonvulsants (valproic acid, phenytoin,	None are without risk Lamotrigine (Lamictal) Levetiracetam (Keppra)

Risk

- Emphasize importance of not becoming pregnant while on medication
- Reproductive life planning
- Use the "Reproductive Potential" section of the FDA rule
- Risk to fetus or newborn
- Weighing risks/benefits of medication

Contraception

- Quality Family Planning- CDC and Family Planning National Training Center
- Sexual activity
- Current and previous birth control practices
- Clarifying Misconceptions- future fertility, reversability, side effects
- Discussing each option based on her preference
- Shared-decision making
- Safety in prescribing: CDC Medical Eligibility Criteria Wheel and Chart

Chart

Teratogenalternative
A safer alternative medication has been chosen for this patient to avoid exposure to a potentially teratogenic medication

Teratogencounseling
The patient was adequately counseled on the risks of pregnancy while taking [blank for medication name]. Contraceptive counseling was performed to reduce the risk of pregnancy while on the medication. The patient verbalized understanding.

Also remember to accurately capture **current sexual activity and birth control methods** in the social history

Outcomes

- Use of TARCC
- Percentage of sexually active childbearing age (18-50) women using contraception while on a teratogenic medication
  - Goal: Increase by 10%
- Percentage of childbearing age women on a teratogenic medication
  - Decrease by 5%
- # newly prescribed teratogens

Going Forward

- Post session survey
- Informal feedback over the next few months
- Mid-Implementation survey and reminders
- Survey at the end of the project
- Sustainability- EHR and other DPC sites

Thank you!

References

American College of Obstetricians and Gynecologists & American Society for Reproductive Medicine. (2019). Prepregnancy counseling. Fertility and Sterility, 111(1), 32-42. doi:10.1016/j.fertnstert.2018.12.003

Center for Disease Control and Prevention. (2016). United States Medical Eligibly Criteria. Retrieved from https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html

DiFletto Magee, N., Mills, C., & Snelling, A. (2018). Utility of reproductive life plans in identification of potentially teratogenic medication use: A pilot study. Birth, 45(1), 50-54. doi:10.1111/birt.12318

Dirksen, R. R., Shulman, B., Teal, S. B., & Huebschmann, A. G. (2014). Contraceptive counseling by general internal medicine faculty and residents. Journal of Women's Health, 23(8), 717-713. doi:10.1089/jwh.2013.4567

Family Planning National Training Center. (2019). Putting the QFP into practice series toolkit. Retrieved from https://www.fpntc.org/resources/putting-qfp-practice-series-toolkit

Finer, L. B., & Zolna, M. R. (2016). Declines in unintended pregnancy in the United States, 2008–2011. The New England Journal of Medicine, 374(9), 843-852. doi:10.1056/NEJMsa1506575

Finer, L. B., Frohwirth, L. F., Dauphinee, L. A., Singh, S., & Moore, A. M. (2005). Reasons U.S. women have abortions: Quantitative and qualitative perspectives. Perspectives on Sexual and Reproductive Health, 37(3), 110–118. Retrieved from https://www.guttmacher.org/sites/default/files/article_files/3711005.pdf

Food and Drug Administration. (2014). Pregnancy and Lactation Labelling (Drugs) Final Rule. Retrieved from https://www.fda.gov/drugs/labeling/pregnancy-and-lactation-labeling-drugs-final-rule

Jerman, J., & Jones, R. K. (2014). Secondary measures of access to abortion services in the United States, 2011 and 2012: Gestational age limits, cost, and harassment. Women's Health Issues, 24(4), 419-424. doi:10.1016/j.whi.2014.05.002

Mody, S. K., Farala, J. P., Wu, J., Felix, R., & Chambers, C. (2015). Using the obstetric medical record to assess contraception usage among women taking category D or X medications. Birth Defects Research, 103(10), 887-891. doi: 10.1002/bdra.23419

National Birth Defects Prevention Network. (2015). Birth defects state profile- North Carolina. Retrieved from https://www.nbdpn.org/docs/NC_BDprofile_2015_20160901.pdf

Parker, S. E., Mai, C. T., Canfield, M. A., Rickard, R., Wang, Y., Meyer, R. E., ... Correa, A. (2010). Updated national birth prevalence estimates for selected birth defects in the United States, 2004-2006. Birth Defects Research. Part A, Clinical and Molecular Teratology, 88(12), 1008-1016. doi:10.1002/bdra.20735

Schwarz, E. B., Maselli, J., Norton, M., & Gonzales, R. (2005). Prescription of teratogenic medications in united states ambulatory practices. The American Journal of Medicine, 118(11), 1260-1269. doi:10.1016/j.amjmed.2005.03.029

Shroff, S., McNeil, M., & Barrera, S. (2017). An innovative framework to improve teratogenic medication risk counseling. Journal of Midwifery & Women's Health, 62(3), 353-357. doi:10.1111/jmwh.12606

Tinker, S. C., Broussard, C. S., Frey, M. T., & Gilboa, S. M. (2018). Prevalence of prescription medication use among non-pregnant women of childbearing age and pregnant women in the united states (NHANES, 1999–2006). Maternal and Child Health Journal, 19(8), 1097-1106. doi:10.1007/s10995-014-1611-z

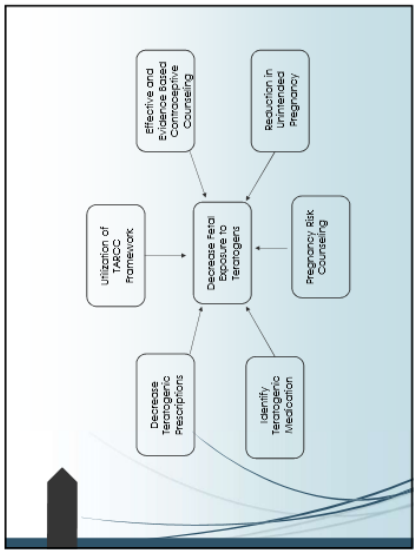
Up To Date

U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Healthy People 2020. (n. d.). 2020 topics and objectives: Maternal, infant, and child health. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives

Women's Preventive Services Initiative. (2016). Recommendations for preventive services for women : Final report to the U.S. Department of Health and Human Services, Health Resources & Services Administration. Retrieved from https://www.womenspreventivehealth.org/recommendations/final-report/

Appendix J

Site B Education Session PowerPoint Slides



Current Practices in the Literature
National Health and Nutrition Examination Survey 1999 to 2006
47% of childbearing age non-pregnant women: at least 1 medication in the past 30 days
>50%: more than two prescriptions
5 of top 10: caution advised or contraindicated
In most studies, < 50% received pregnancy risk/contraceptive counseling with a teratogen
benzodiazepines, ACE Inhibitors, ARB, anticonvulsants, certain antibiotics, statins, lithium, isotretinoin, paroxetine, and warfarin

Barriers
What have you experienced?
Barriers: lack of (1) time, (2) knowledge of alternative medications, and (3) confidence in contraceptive and pregnancy risk counseling
Counseling was done but not documented
Inaccurate input for sexual activity and birth control use
Remembering!
No EHR Flag
(Dirksen et al., 2014; Shroff et al., 2017)

Policy and Health Care Implications
ACOG, ACP, AAFP, ASRM, NPWH call for contraceptive counseling and preconception planning at all health promotion visits for childbearing age women
Tightening abortion policies
Cost savings by preventing 1 abortion: $450 - $5000
Cost savings by preventing 1 birth defect- hospital cost of one child with a birth defect is $78,000
Ethical and evidence-based practice

842 childbearing age women seen
960 provider encounters
25,937 active medications
47% of women were on at least 1 teratogenic class
84 new teratogenic medications prescribed
49% reported they were sexually and on a form of birth control
51% could be at risk

TARCC Framework

Shroff, McNeil, & Borrero (2017)

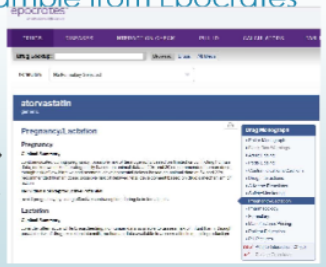
T- is it teratogenic?
A- is there a safer alternative?
R- if not, discuss pregnancy risk
C- discuss contraceptive counseling
C- chart counseling or change in medication was done

Teratogen

- How do you determine the safety of medication?
- 2015: FDA Pregnancy and Lactation Labeling Final Rule
- More risks and benefits, shared-decision making, no cut and dry categories
- New prescriptions and medication reconciliation

From https://www.fda.gov/drugs/labeling/pregnancy-and-lactation-labeling-drugs-final-rule

Example from Epocrates



Example from Epic Lexi Comp

Alternatives

Teratogen	Safer Alternatives
Statins	Not many, maybe Omega-3 fatty acids
Angiotensin Converting Enzyme inhibitors (Lisinopril) Angiotensin Receptor Blocker (Losartan)	Labetalol Methyldopa Nifedipine, Other CCB with caution Hydrochlorothiazide
Benzodiazepines	Some SSRIs (Celexa, Prozac, Zoloft) – still some risk with serotonin syndrome in newborn No paroxetine
Anticonvulsants (valproic acid, phenytoin, phenobarbital, carbamazepine, topiramate)	None are without risk Lamotrigine (Lamictal) Levetiracetam (Keppra)
Warfarin	Heparin 2nd line- fondaparinux, argatroban, danaparoid

Risk

- Emphasize importance of not becoming pregnant while on medication
- What is her current pregnancy risk?
  - Sexual Activity
  - Birth Control
  - Vasectomy
- Reproductive life planning
- Use the "Reproductive Potential" section of the FDA rule
- Risk to fetus or newborn
- Weighing risks/benefits of medication

Contraception

- Quality Family Planning- CDC and Family Planning National Training Center
- Current and previous birth control practices
- Clarifying Misconceptions- future fertility, reversibility, side effects
- Discussing each option based on her preference
  - BC Method Options Chart and Packet
- Shared-decision making
- Safety in prescribing: CDC Medical Eligibility Criteria Wheel and Chart

Chart

.teratogenalternative

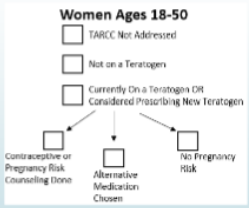
A safer alternative medication has been chosen for this patient to avoid exposure to a potentially teratogenic medication

.teratogencounseling

The patient was adequately counseled on the risks of pregnancy while taking [blank for medication name]. Contraceptive counseling was performed to reduce the risk of pregnancy while on the medication. The patient verbalized understanding.

Also remember to accurately capture **current sexual activity and birth control methods** in the social history

- Pre Work
- In the patient room
- Reminder and Objective Measurement
- Weekly Collection



Outcomes

- Use of TARCC
- Percentage of sexually active childbearing age (18-50) women using contraception while on a teratogenic medication
  - Goal: Increase by 10%
- Percentage of childbearing age women on a teratogenic medication
  - Decrease by 5%
- # newly prescribed teratogens

Going Forward

- Post session survey
- Informal feedback over the next few months
- Mid-Implementation survey and reminders
- Survey at the end of the project
- Sustainability- EHR and other DPC sites

Thank you!

References

American College of Obstetricians and Gynecologists & American Society for Reproductive Medicine. (2019). Preconception counseling. *Fertility and Sterility, 111*(1), 53-62. doi:10.1016/j.fertnstert.2018.12.005

Center for Disease Control and Prevention. (2016). United States Medical Eligibly Criteria. Retrieved from https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html

DiPietro Mager, N., Mills, C., & Snelling, A. (2018). Utility of reproductive life plans in identification of potentially teratogenic medication use: A pilot study. *BMC, 63*(1), 50-56. doi:10.1111/jpm.12518

Dineen, R. E., Shulman, S., Taal, S. S., & Hussashmann, A. G. (2014). Contraceptive counseling by general internal medicine faculty and residents. *Journal of Women's Health, 23*(8), 717-713. doi:10.1089/jwh.2013.4547

Family Planning National Training Center. (2019). Putting the QFP into practice series toolkit. Retrieved from https://www.fpntc.org/resources/putting-qfp-practice-series-toolkit

Finer, L. B., & Zolna, M. R. (2016). Declines in unintended pregnancy in the United States, 2008–2011. *The New England Journal of Medicine, 374*(9), 843-852. doi:10.1056/NEJMsa1506575

Finer, L. B., Frohwirth, L. F., Dauphinee, L. A., Singh, S., & Moore, A. M. (2005). Reasons U.S. women have abortions: Quantitative and qualitative perspectives. *Perspectives on Sexual and Reproductive Health, 37*(3), 110–118. Retrieved from https://www.guttmacher.org/sites/default/files/article_files/3711005.pdf

Food and Drug Administration. (2014). Pregnancy and Lactation Labeling (Drugs) Final Rule. Retrieved from https://www.fda.gov/drugs/labeling/pregnancy-and-lactation-labeling-drugs-final-rule

Jerman, J., & Jones, R. K. (2014). Secondary measures of access to abortion services in the United States, 2011 and 2012: Gestational age limits, cost, and harassment. *Women's Health Issues, 24*(4), 419-424. doi:10.1016/j.whi.2014.05.002

Appendix K

TARCC Reminder Card

Teratogenic medication?

Alternative that is safer?

Risk to pregnancy discussion

Contraceptive counseling discussion

Charting with dot phrases

.teratogenalternative

.teratogencounseling

Shroff, McNeil, & Borrero (2017)

Appendix L

Site A Plan Do Study Act One

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: Implement a 1-hour provider education session about the TARCC framework, including background information about the problem of teratogenic medication in primary care.
    a. **Prediction**: Providers will be able to use the TARCC framework in practice after the education session and be able to answer knowledge uptake questions correctly on the preliminary data collection tool.
    b. **Who, what, where, when**: Seven primary care providers in a primary care practice will participate in the 1-hour education session on August 22, 2019. Providers will receive a toolkit with session materials, including tools to teach contraceptive counseling.
    c. **Plan to collect data**: Each provider will complete a preliminary data collection tool immediately after the education session. The tool contains perceived competency questions and knowledge uptake questions about TARCC usage.
2. **Do**: The education session was cut short to 25-30 minutes. Six providers attended the entire session, and one provider attended for the last 10 minutes. The session was more of a discussion in which providers applied the framework to their practice. Due to the shortened session, the preliminary data collection tool was not collected immediately after the meeting but rather the week after. Ultimately, seven data collection tools were collected and completed.

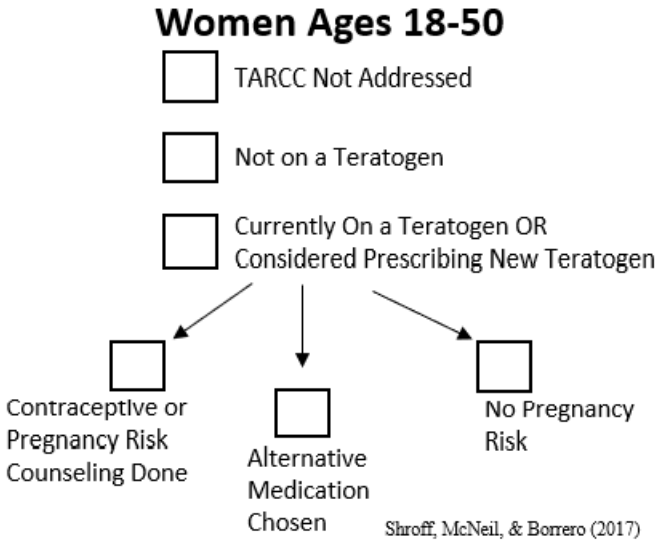
3. **Study**: The average rating for competency in using the TARCC framework was 3.6 on 5-point scale. Only 43% rated themselves as “Very or Extremely Competent” in using TARCC. The average rating for competency in performing effective contraceptive counseling was 4.1 on 5-point scale. 86% rated themselves as “Very or Extremely Competent” in contraceptive counseling. 71% got the TARCC acronym correct, and 71% got the case scenario right. 71% stated they were “Very or Extremely Likely” to use the TARCC framework in the next month with an average rating of 3.6 on a 5-point scale.

   Less than half feel competent using the TARCC framework, and less than 80% were correct on the knowledge uptake survey. During informal conversations, providers stated it was hard to remember to use TARCC and that they needed better reminders. Also, at this time, it is not possible to track the exact number of times providers use TARCC in practice.

4. **Act:** Providers stated they needed more readily available reminders about the TARCC framework to make it more likely to use in practice. Providers will be given TARCC reminder laminated cards to put on their computers to aid in reminding them what the acronym stands for and to use it in practice when prescribing medication. Also, plan to repeat the TARCC, meaning knowledge uptake question on the mid-implementation tool to compare to preliminary data collection.

Appendix M

TARCC Checklist



Shroff, McNeil, & Borrero (2017)

Appendix N

Site A Plan Do Study Act Two

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: Providers stated they needed more readily available reminders about the TARCC framework to make it more likely to use in practice. Providers will be given TARCC reminder laminated cards to put on their computers to aid in reminding them what the acronym stands for and to use it in practice when prescribing medication.
    a. **Prediction**: Providers will be more likely to use the TARCC in practice and will be able to reiterate the TARCC acronym correctly.
    b. **Who, what, where, when**: Seven primary care providers in a primary care practice will be given a laminated card with the TARCC acronym spelled out along with the two dot phrases they can use to chart its use in the electronic health record. The card will be given out along with snacks during provider lunch breaks.
    c. **Plan to collect data**: Informal discussions with providers will determine if this aided in using the TARCC framework and in understanding what the framework means.
2. **Do**: Six providers were given a baggie with snacks that were attached to the TARCC reminder card and Velcro stick pad. One provider is out on leave for six weeks. It was suggested to put the card on their computers on the bottom left corner since that is where they enter medications into the medical record. During discussions with providers, they stated it would be helpful to have a more systematic way to use the TARCC framework

to make it a more ingrained process in their care. One provider voiced a concern that she sees many patients over 65 years in which this is not applicable.

3. **Study**: After one week of using the reminder cards, one provider stated she had used the framework three times and was appreciative of the information. Another provider stated she used it two to three times last week but had a hard time remembering to use it more consistently. The site champion said it would be good to have reminders in the rooms with patients so they can use the framework when they are actively looking at patient medications. Another provider wanted a reminder to use while doing pre-work in the morning so she could identify which patients would benefit from TARCC usage. It would also be helpful to have a way to objectively track the number of times TARCC is used.
4. **Act:** A checklist with the TARCC decision tree will be created on small bright colored sheets and placed in exam rooms. Copies of the checklist will also be given to providers to use at their desks during pre-work. The checklist will also include women aged 18-50, so providers know for whom the acronym applies. Providers can check off the appropriate box ideally for all women they see aged 18-50. The providers will then place the checklists in designated boxes for collection by the DNP student each week. The number of checklists collected will be compared to the number of women seen in clinic every one to two weeks who are 18-50 years old. This denominator will be collected by the Health Center Administrator and given to the student in a de-identified report. This will aid in tracking TARCC usage while also increasing provider reminders to use the TARCC framework in the exam room with patients.

Appendix O

Site A Plan Do Study Act Three

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: A checklist with the TARCC decision tree will be created on small bright colored sheets and placed in exam rooms. Copies of the checklist will also be given to providers to use at their desks during pre-work. The checklist will also include women aged 18-50, so providers know for whom the acronym applies. Providers can check off the appropriate box ideally for all women they see aged 18-50. The providers will then place the checklists in designated boxes for collection by the DNP student each week.
    a. **Prediction**: The checklist will aid in tracking TARCC usage while also increasing provider reminders to use the TARCC framework in the exam room with patients.
    b. **Who, what, where, when**: Checklists will be given to all primary care providers working at the site and drop boxes will be placed at all provider desks. The checklists will be started on Monday, September 23, 2019 and the first data pull will be on Monday September 30, 2019.
    c. **Plan to collect data**: The number of checklists collected will be compared to the number of women aged 18 to 50 who were seen in the clinic every week. This denominator will be collected by the Health Center Administrator and given to the student in a de-identified report each Monday for the week before. The DNP student will empty the boxes 1-2 times weekly to keep a count of the forms. Informal feedback from providers will also be used to determine the success of the PDSA.

2. **Do**: On Monday, September 23, 2019, six providers were given checklists. The seventh provider is still out on leave. Five of the providers wanted their checklists placed in their exam rooms near the computer and pen holder. One provider wanted hers in her pocket to use wherever she is. The last provider wanted them at her desk to use during pre-work each morning. Each provider has a dropbox at their desk or in their office. A total of 300 copies of the checklists were placed throughout the clinic. The DNP student met with each provider for a few minutes to discuss the checklist and answer questions.
3. **Study**: A total of 41 checklists were completed for patients in the first week of its use. Providers stated that the checklist made it much easier for them to remember to use the framework. A total of 178 women aged 18 to 50 were seen in the clinic the week of September 23rd. Therefore 23 % of women aged 18-50 received the screening.
4. **Act:** To further increase the use of the TARCC checklist, a weekly Monday morning email will go out, highlighting one teratogenic medication class or article. The email will go to all providers, and the site champion will highlight it at huddle. This will begin Monday October 7th. I also plan to put balloons on the checklist drop boxes and provide more snacks to providers to remind them to use the checklists. This will be done with the mid-implementation survey the week of 10/14.

Appendix P

Site A Plan Do Study Act Four

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: To further increase the use of the TARCC checklist, a weekly Monday morning email will go out, highlighting one teratogenic medication class or article. The email will go to all providers, and the site champion will highlight it at the huddle. This will begin Monday, October 7th. I also plan to put balloons on the checklist drop boxes and provide more snacks to providers to remind them to use the checklists. This will be done with the mid-implementation survey the week of 10/14.
    a. **Prediction**: The weekly email will give providers a weekly reminder about using the checklist and feedback on progress. It will also increase provider knowledge of teratogenic medication to use in practice.
    b. **Who, what, where, when**: Weekly email will go out to seven primary care providers and the Health Center Administrator. The email will include the previous week's rate of TARCC usage and highlight one class of teratogenic medication. Emails start Monday, October 7th. The seven providers will also be given a mid-implementation survey the week of 10/14.
    c. **Plan to collect data**: Continue to collect the percentage of women aged 18-50 who receive TARCC screening each week. We will also be collecting data on the mid-implementation survey.
2. **Do**: On Monday, October 7th, the first email went to all providers, which highlighted 23% TARCC usage and ACE inhibitors. The following week an email was sent that reported a drop in TARCC usage to 13% and highlighted statins. The third email was sent on 10/21,

highlighting a slight increase in TARCC usage (14%) and highlighted benzos. The mid implementation survey was completed 10/16 and 10/17. Two providers completed the surveys the week of 10/21 because they were out of the office the end of the week before. Six providers completed the mid implementation survey compared to seven on the preliminary survey because one provider has been out on sabbatical since the education session and has just gotten back. Snacks and small balloons were attached to the drop boxes to further remind providers about using the survey.

3. **Study**: There was a decrease in the percentage of women receiving a TARCC screening in week 2 (13%) compared to week 1 (23%). This may be because the first week, it was new, and there was a big push to complete the checklists. The weekly provider emails started on 10/7, and that week we saw 14% of women receive the TARCC checklist. Therefore, it is possible that the emails are helping increase provider awareness. The site champion felt the emails were helpful, and we agree they should be continued. One provider stated he is having trouble remembering to use the framework and would like his CMA involved.

Based on the mid-implementation surveys, 50% of providers reported they are very or extremely comfortable using TARCC compared to 43% on the preliminary survey. Also, 83% wrote the TARCC acronym correctly vs. 71% on the preliminary. I have had a couple of informal discussions with providers about how the TARCC framework helped them have a good discussion with a patient and altered their plan of care. 83% of providers reported they had used the TARCC framework seven or more times since the education session, and 40% reported they had used it ten or more times. The average likelihood that providers will use TARCC in the next month increased to 4.0

from 3.6. However, only 67% of providers stated they are very or extremely likely to use it over the next month compared to 71% in the preliminary survey. Overall there has been an improvement in TARCC usage since the preliminary survey. Providers want to see this incorporated into the medical record and have CMAs help in administering the TARCC framework.

4. **Act:** We plan to pilot the use of a CMA to help a provider remember to use the framework. She will attach a checklist to every face sheet for a woman aged 18-50. This will prompt the provider to fill out the checklist during the visit. If this is successful for the provider, other providers will be offered the same option. Providers can then talk to their CMAs about the process, and the DNP student will support the new plan. Also, we will share Site B's idea of placing the TARCC checklist and acronym in Epic as part of the well-woman exam template. Last, we will continue the weekly provider emails and start a countdown to project completion.

Appendix Q

Site A Plan Do Study Act Five

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: We plan to pilot the use of a CMA to help a provider remember to use the framework. She will attach a checklist to every face sheet for a woman aged 18-50. This will prompt the provider to fill out the checklist during the visit. If this is successful for the provider, other providers will be offered the same option. Providers can then talk to their CMAs about the process, and the DNP student will support the new plan. Also, we will share Site B's idea of placing the TARCC checklist and acronym in Epic as part of the well-woman exam template. Last, we will continue the weekly provider emails and start a countdown to project completion.
    a. **Prediction**: This will increase the provider's ability to use TARCC with all of his female patients aged 18 to 50.
    b. **Who, what, where, when**: One provider will try this with his one CMA. Discussed with provider and CMA week of 10/14.
    c. **Plan to collect data**: Plan to continue collecting weekly TARCC checklist usage data.
2. **Do**: Discussed with provider and CMA the checklist process on 10/16. Gave checklists to CMA and provider.
3. **Study**: Provider gave feedback that his CMA has not had time to help him. She is busy doing her other tasks and is already struggling to do those. He has started looking at his patient load each morning and trying to complete one checklist for every female aged 18-50. He did notice that he only has one or two patients in that category each day. The week

of 10/14, we had the highest percentage of TARCC checklists used at 29%. This is likely related to the midterm survey and reminding providers about the checklist. The week of 10/21 usage was back down to 16%, and the week of 10/28 down to 12%. The week of 10/28 there were several providers out of the office, and they were short CMAs. This could be related to the decline. The final semester survey is happening the week of 11/12. The highest ratings on the survey were placing a reminder in Epic and sharing TARCC with other primary care offices. 83% stated they are very or extremely competent in using TARCC compared to 43% at the beginning of the project. 4.17 rating for likelihood of using TARCC in the next month compared to 3.6 at the beginning of the project.

4. **Act:** Based on survey results, the DNP student will contact Lisa Nadler regarding encounter specialist templates and adding TARCC. Also, the student will continue to work on the decision tree/BPA for Epic. At this point, it is clear a systematic reminder in Epic is needed to promote use of TARCC. Also, this project will be shared with the practice medical directors at a meeting in Spring 2020.

Appendix R

Site B Plan Do Study Act One

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: Implement a 1-hour provider education session about the TARCC framework, including background information about the problem of teratogenic medication in primary care. Include TARCC reminder card in provider toolkit.
    a. **Prediction**: Providers will be able to use the TARCC framework in practice after the education session and be able to answer knowledge uptake questions correctly on the preliminary data collection tool.
    b. **Who, what, where, when**: Seven primary care providers in a primary care practice will participate in the 1-hour education session on September 24, 2019. Providers will receive a toolkit with session materials, including tools to teach contraceptive counseling and a TARCC reminder card.
    c. **Plan to collect data**: Each provider will complete a preliminary data collection tool immediately after the education session. The tool contains perceived competency questions and knowledge uptake questions about TARCC usage.
2. **Do**: The education session was attended in full by seven primary care providers on September 24, 2019. The session was 50 minutes in total. All seven providers completed the preliminary data collection tool immediately after the education session.
3. **Study**: The average rating for competency in using the TARCC framework was 3.4 on a 5-point scale. Only 57% rated themselves as “Very or Extremely Competent” in using TARCC. The average rating for competency in performing effective contraceptive counseling was 3.9 on 5-point scale. 86% rated themselves as “Very or Extremely

Competent" in contraceptive counseling. 100% got the TARCC acronym correct, and 86% got the case scenario right. 57% stated they were "Very or Extremely Likely" to use the TARCC framework in the next month with an average rating of 3.7 on a 5-point scale. Based on this data, improvement is needed to increase the likelihood that providers will use the framework and their comfort in using it.

4. **Act:** The site champion suggested that providers create a phrase with the TARCC framework to put into the female physical exam template in Epic. This will increase the likelihood that providers will remember to use the framework during well-woman exams. The site champion stated that these visits are more likely to allow for time to discuss medications and birth control. Also, birth control can only be prescribed or refilled if a woman has had a physical within the past year. This suggestion will go out to providers in an email on Thursday and will be discussed at huddle by the site champion on Monday morning.

Appendix S

Site B Plan Do Study Act Two

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: The site champion suggested that providers create a phrase with the TARCC framework to put into the female physical exam template in Epic. This will increase the likelihood that providers will remember to use the framework during well-woman exams. The site champion stated that these visits are more likely to allow for time to discuss medications and birth control. Also, birth control can only be prescribed or refilled if a woman has had a physical within the past year. This suggestion will go out to providers in an email on Thursday and will be discussed at huddle by the site champion on Monday morning.
    a. **Prediction**: Providers will incorporate TARCC into their well-women templates and become more competent in using the TARCC framework.
    b. **Who, what, where, when**: Email will be sent to all seven providers with site champion's idea and a screenshot of how she incorporated it into her template.
    c. **Plan to collect data**: Mid implementation survey to be administered week of 10/14 to all seven providers.
2. **Do**: Email was sent to providers on October 3rd with a follow-up email with the screenshot on Oct 15th. Mid implementation surveys were handed out on 10/15. Surveys were collected and returned by site champion on 10/18 except for one provider who was out on vacation for the week. The final survey was collected on 10/21.
3. **Study**: Providers reported a slightly higher rating of TARCC competency from preliminary to midterm (3.4 to 3.7). However, only 57% of providers reported they were

very or extremely competent at using TARCC, which is the same percentage from the preliminary survey. The providers had an average of 3.0 for the likelihood of using the TARCC framework in the next month, which is lower than the 3.7 average on the preliminary survey. After a discussion with the site champion, it is likely that with competing demands, staff turnover, and lack of computerized reminders, providers are unlikely to use TARCC.

4. **Act:** To promote reminders about TARCC and increase provider awareness, the DNP student will send the providers a weekly email highlighting a teratogenic class. Also, the student will reach out to the pharmacist, who is in the clinic once per week. He works with patients with chronic diseases and often makes recommendations for medications for hypertension, cholesterol, and diabetes. Therefore, several classes of teratogenic medications are often recommended to providers. The DNP student will reach out to him to see what strategies he uses to ensure safe teratogen prescribing and offer the TARCC framework to him as well.

Appendix T

Site B Plan Do Study Act Three

Objective: Increase provider knowledge and use of the TARCC framework in a primary care practice.

1. **Plan**: To promote reminders about TARCC and increase provider awareness, the DNP student will send the providers a weekly email highlighting a teratogenic class. Also, the student will reach out to the pharmacist, who is in the clinic once per week. He works with patients with chronic diseases and often makes recommendations for medications for hypertension, cholesterol, and diabetes. Therefore, several classes of teratogenic medications are often recommended to providers. The DNP student will reach out to him to see what strategies he uses to ensure safe teratogen prescribing and offer the TARCC framework to him as well.
    a. **Prediction**: Weekly provider emails will remind them to use TARCC in their practice. Ideas from the pharmacist will be used to improve outcomes in the project, as well.
    b. **Who, what, where, when**: Meeting with pharmacist set for 11/1. Weekly emails to providers started on 10/20.
    c. **Plan to collect data**: Meeting with site champion for feedback. Final data collection tool planned for 11/19.
2. **Do**: Met with the pharmacist on 11/1. Started weekly emails every Monday to providers on 10/20. Final data collection tool administered 11/19.
3. **Study**: Based on site champion and provider feedback a reminder must be placed in Epic. Site champion also stated that LMP and contraceptive use are not routinely documented at all female provider visits. The highest ratings on the final data collection tool were

placing a reminder in Epic and sharing TARCC with other primary care offices (4.3 and 4.5 on 5-point scale, respectively). 83% stated they are very or extremely competent in using TARCC compared to 57% at the beginning of the project. 4.0 rating for the likelihood of using TARCC in the next month compared to 3.7 at the beginning of the project.

4. **Act:** Plan to work on developing a best practice advisory for Epic that flows into a decision tree with TARCC elements. Plan to work on developing triggers, questions, and prompts to give to providers for feedback over the next few months. After the project plan to pitch the idea to [redacted] for possible inclusion in Epic. Also, the site champion has started reminding CMAs during huddle and using a whiteboard to ensure LMP and contraception are documented at each female visit regardless of chief complaint. LMP is now being done more often at female visits. Providers report looking at LMP more and documenting more (E. Stern, personal communication, November 20, 2019).