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## **Doctor of Nursing Practice**

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School of Nursing

Decreasing Unintentional Pregnancies for Tennesseans

A doctoral project submitted in partial satisfaction

of the requirements for the degree of

Doctor of Nursing Practice

by

Paula M. Todd

February 2022

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## Abstract

In 2018, 49% of all pregnancies in the United States were unintended, with women with a lower-income status being five times more likely to experience an unplanned pregnancy. Tennessee has a high rate of unintended pregnancies, particularly among the uninsured, low-income, and rural teen populations; some 22% of these unintended pregnancies end in abortion. Oral or transdermal contraceptives that are affordable and accessible for women of childbearing age can reduce unintentional pregnancies. The addressed gap in clinical practice was that contraceptives are not currently available over the counter in Tennessee pharmacies without a prescription, which necessitates a costly medical visit. The purpose of this study was to document the process of nursing advocacy through a legislative initiative to change health policy to allow for over-the-counter contraception to decrease unintentional pregnancies and abortions in Tennessee. This case study used political process theory to describe the process of assembling a coalition and working with state legislators to implement a change in health policy that affects individuals, populations, and society. The case study findings were designed to inform nurses and other health professionals about advocacy and the health policy process, including the political realities of change in a conservative, antiabortion state.

*Keywords:* contraceptives, over-the-counter, pregnancy, abortion

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## Chapter 1: Introduction

Unintended pregnancy can have significant negative consequences for individual women, families, and society (Kost et al., 2018). In 2018, 49% of all pregnancies in the United States were unintended. National rates range from 32%–62% depending on socioeconomic class; women with lower-income status are five times more likely to experience an unplanned pregnancy (Finer & Zolna, 2016). Tennessee has a high rate of unintended pregnancies, particularly among the uninsured, low-income, and rural teen populations (Peipert et al., 2012). Tennessee's unintended pregnancy rate was 49/1000 in women aged 15–44 (Kost et al., 2018). Of these unintended pregnancies, 63% resulted in birth, 22% in abortions, and the remainder resulted in miscarriage (Kost et al., 2018).

Having oral contraceptives that are affordable and accessible for women of childbearing age is associated with a decline in unintentional pregnancies (American College of Obstetricians and Gynecologists, 2015). As a result, over-the-counter options and easily accessible choices empower women of childbearing age to decide which method is best suited for their bodies (American College of Obstetricians and Gynecologists, 2015). This suggests that increased access to contraceptives over the counter without a physician visit and prescription can decrease unplanned pregnancies and abortions in Tennessee. For every 79 to 137 women given free contraception, one abortion can be prevented (Peipert et al., 2012).

Women with no access to maternal health must drive great distances to find a provider. Many women cannot afford to do so, resulting in poor birth outcomes, long-term developmental problems, and missed days from school or work. Having outdated restrictions on contraceptive methods does not help cost or abortion rates and causes poor health outcomes for women and

babies. Helping women access free or affordable family planning contraceptive options is the key.

The unintended pregnancy rate in populations below the federal poverty line is two to three times the national average (Finer & Zolna, 2016). Unintentional pregnancy occurs more among women in poverty (Guttmacher Institute, 2019a). The newborns born to these mothers are born with a predisposition to poor health since most of these mothers smoke, drink, or are less likely to have had prenatal care or follow through with breastfeeding their newborn (Dott et al., 2010). The Affordable Care Act implemented under the Obama administration sought to decrease and eliminate costs for contraceptive methods, thus improving health outcomes for women and children by reducing the unintended pregnancy rates (Fox & Barfield, 2016). The Affordable Care Act allowed children to remain on their parent's insurance until the age of 26; therefore, more were insured and could obtain contraception at no cost.

### **Problem Statement**

Legislation in Tennessee has focused on pro-birth initiatives and strengthening antiabortion laws. Tennessee is a conservative southern U.S. state with many residents that have strong negative feelings about abortion. A review of the Tennessee legislation showed a behind-the-counter oral contraceptive bill was passed in 2016 yet never implemented (TN SB 1677, 2016). No bills have been implemented to prevent unplanned pregnancies to reduce the dilemma of abortion decisions for women. Legislators in Tennessee have historically written and passed bills that deal with the outcomes of unplanned pregnancies, which is problematic for women in lower socioeconomic classes because of a higher rate of unplanned pregnancy in this group (Finer & Zolna, 2016).

Oral contraceptives, vaginal rings, the contraceptive patch, and depo medroxyprogesterone injections are safe to administer without a physician order (American College of Obstetricians and Gynecologists [ACOG], 2019). The ACOG (2019) guidance was intended to inform state legislatures about this approach's safety and needed changes to pharmacy regulations. The American College of Clinical Pharmacy (ACCP) recommends placing oral contraceptives over the counter in retail spaces where a pharmacist is available (as cited in McIntosh et al., 2011). The two guidelines suggested that sales of over-the-counter contraceptives would be where a pharmacist was available to answer questions and have mechanisms in place when needed to cover the costs with Medicaid (ACOG, 2019).

Obtaining reversible contraceptives is a significant problem for childbearing age women because the process is complicated, time-consuming, and not practical. For example, women must see a medical provider in a clinic setting, have a well-woman visit that entails a breast and pelvic exam, and pay for the visit, contraceptive device, or prescription. Surveys of women of childbearing age have shown the capability and desire for this age group to self-educate and decide which reversible method is appropriate for themselves (Grossman et al., 2013). Working with local and state legislators by informing them of the need to increase affordable access to pregnancy prevention measures is necessary to bring about change in Tennessee. Implementing educational strategies, such as an available pharmacist, health department educator, appropriate package inserts, or infomercial options will provide necessary support and information for each woman.

## **Background**

The United States is one of the few industrialized, developed nations that inhibit access to reversible contraceptive methods for women (Peipert et al., 2012). Over 100 countries currently

offer oral contraceptives over the counter (Grossman et al., 2013). The goal of Healthy People 2010 was to have an intentional pregnancy rate reach 70% (Healthy People 2030, 2020). However, the U.S. intentional pregnancy rate, defined as a woman's desire to become pregnant before the pregnancy occurred, was 55% in 2016 (Finer & Zolna, 2016). This is problematic because the National Conference of State Legislatures predicted a 6,000 to 8,000 maternal health provider shortage plus a decrease in obstetric and gynecologic care needs, stating that five million women already live without any access to maternal care (Rivett et al., 2019). Women in Tennessee have one of the highest infant mortality rates within the United States (Johnson, 2019). The maternal death rate has more than doubled in the United States since 1987 (Rivett et al., 2019). The Teen Adolescent Pregnancy Program was created to promote self-worth, knowledge about pregnancy prevention options, and informed sexual decision-making strategies in Tennessee. Yet, teen pregnancies remain a significant problem in the state (Kost et al., 2018). Teens who become pregnant are more likely to drop out of college or high school, never marry, and live in poverty (Tennessee Department of Health, 2018).

The U.S. unintended pregnancy rate is higher than in other industrialized countries (Sedgh et al., 2014). Western Europe has a 40% lower unintended pregnancy rate than the United States. Many of these nations have oral and transdermal contraceptives free or made affordable over the counter. Also, long-acting reversible contraception, such as intrauterine devices (IUDs), injections, and subdermal implants, are free and easily obtainable in these nations (Winner et al., 2012). Russia legalized abortion, made contraceptives available for free, and saw their abortion rates significantly decrease (Guttmacher Institute, 2003).

The United States currently has an abortion rate of 19.6% (Nash & Dreweke, 2019). In countries where abortion is illegal, the rates tend to be higher, even though undocumented. The

health risks to mothers and babies are significant in these countries where abortion is unlawful, leading to increased costs to offset the physical and emotional harm done to the mother and baby during the abortion procedure. The United States has seen a decline in abortion rates in part due to more restrictive laws, the recent closure of clinics due to decreasing funding, and women's ability to self-abort with over-the-counter morning-after pills (Nash & Dreweke, 2019). However, the cost of the morning-after pill cost is currently out of reach for many women, currently \$40 to \$50 at a local pharmacy. Adult women in the United States were surveyed and said \$20 would be the maximum affordable over-the-counter oral contraceptive option and would be able to apply their health savings account funds to this cost (Grossman et al., 2013). This is not within reach for all childbearing-aged women.

Unintentional pregnancies result in increased healthcare costs for states and the nation. The babies and mothers require more healthcare dollars to combat the postpartum depression seen in the mothers of newborns from an untimely pregnancy (Brito et al., 2015). Poor health outcomes are noted in these unintentional pregnancies. Lower birth weights define the poor outcomes for newborns in this group, failure to thrive, early addiction issues, and adverse effects for the mothers seen with postpartum depression (McIntosh et al., 2011).

One barrier to the over-the-counter contraceptive conversation was that Medicaid is not structured to pay for over-the-counter contraceptive medications. A method for retailers to specifically extend a free voucher for contraceptives was never pursued. The cost of oral contraceptives with appropriate, easy-to-understand labeling for the contraceptive products was not created. The current price of oral contraceptives ranges from \$20 to \$100, and implantable rings and IUDs can be upwards of \$900 without insurance (Kosova, 2017). Concern for an increase in transmission of sexually transmitted diseases was raised since women would no

longer be coming to a provider for consultation and advice (Stone, 1993). The concept of transmission of diseases from mother to newborn, known as vertical transmission, from unintended pregnancy was not considered (Stone, 1993). Many teens deferred obtaining oral contraceptives because many clinics require a pelvic and breast exam (Henderson et al., 2010). With the current required pathway, women are only screened for human papillomavirus (HPV) at well-woman visits. These visits do not screen for all sexually transmitted infections, thus negating this argument.

Unintended pregnancy rates and births decrease during times of recession, as noted in 2011 after the 2008 downturn in the United States (Finer & Zolna, 2016). In 2008, the unintended pregnancy rate was 46%, and in 2011, the rate was 39% (Finer & Zolna, 2016). This decline was noted in all demographic groups. The lack of funding to afford having children is one possible driving force that decreases the desire to have children. When the economy began to improve, the desire to have children may have increased and become one factor contributing to an increase in unintentional pregnancies (Finer & Zolna, 2016).

Tennessee remains one of the unhealthiest states in the United States, with its current rank of 42nd (America's Health Rankings, 2019). Women with access to the internet in the United States have access to online contraception options, yet many in Tennessee lack this primary access. The online method requires internet access, a credit card, and the ability to wait on a mail-order shipment. Tennessee nurses advocate for Tennessee to join the other states showing health advances by promoting preventative measures for health benefits for women and children. Research continues to show the benefit of preventing pregnancy until a woman is ready to have children. If providers in Tennessee promoted improved access to safe, affordable

contraception for women, Tennessee would see a decline in unplanned pregnancies, abortion rates, and children born into less-than-optimal situations.

### **Purpose**

The purpose of this case study was to document the process of nursing advocacy through a legislative initiative. This case study describes the process of assembling a coalition and working with state legislators to implement a change in health policy that affects individuals, populations, and society. This case study can inform other nurses and health professionals about advocacy and the health policy process, including the political realities of change in a conservative state.

### **Significance**

This project was significant because a decline in the rate of unintended pregnancies will lead to a decrease in abortions, children in poverty, and an increase in the percentage of newborns and moms' improved health outcomes. This project's data showed that the unintended pregnancy rate would decline when access to contraceptives was made more accessible and a healthcare professional was available for questions. By having reversible contraceptives available for free at county health departments or affordable cost over the counter, more women utilize the appropriate measures to avoid unintended pregnancy. This case study has significance to the U.S. finances associated with unintended pregnancies, including poor prenatal care, undernutrition, higher risk of an opioid use disorder, poor birth outcomes, and high rates of abuse, neglect, and involvement with the justice system. Unintended pregnancy leads to higher school dropout rates, economic strain, and a strain on family relationships (Guttmacher Institute, 2019a).



This case study was significant to nursing as an essential part of nursing leadership in patient advocacy and promoting favorable healthcare policies. This case study can provide insights into this process as it is implemented in the world of politics and political processes. This case study and its results may empower other advanced practice nurses to take similar action.

### **Nature of the Project**

This project was a qualitative descriptive case study. Case study designs are important because the researcher can compile large volumes of research data from many other researchers (Yin, 2009). Multiple researchers looking at similar data yields less bias when interpreting the data (Yin, 2009). The case study approach is best suited for answering how and why questions of a problem. Unplanned pregnancies and abortion rates remain a significant issue for Tennessee. This descriptive case study approach examined interventions from other states and countries and the effects on women's health and, ultimately, the community's health.

### **Question Guiding the Inquiry**

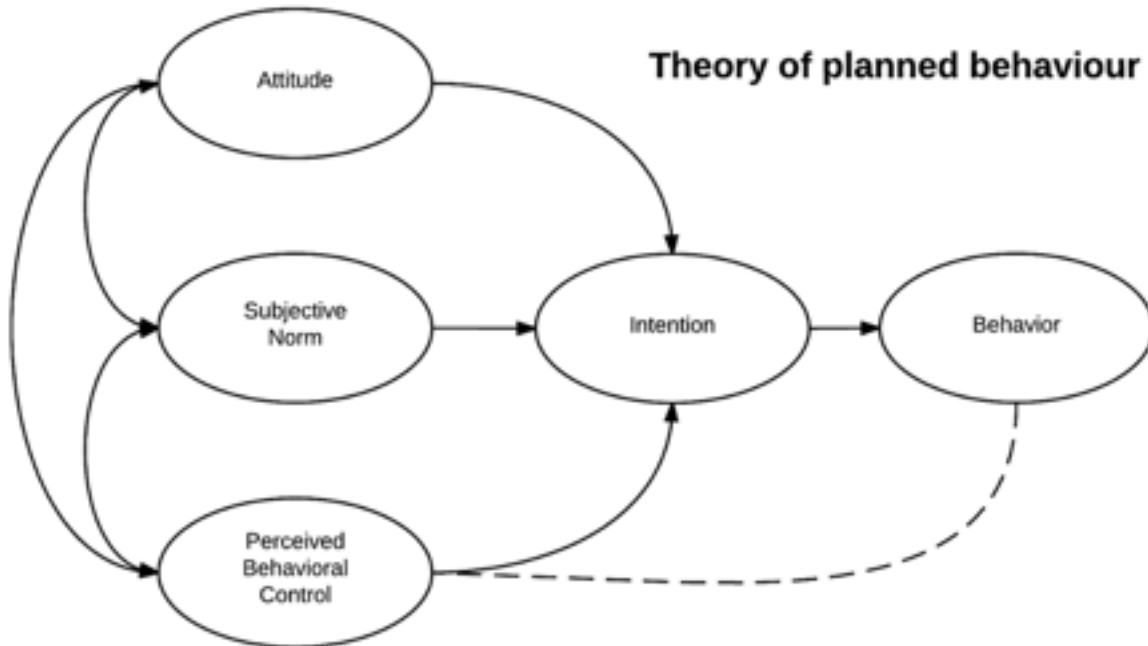
PICOT:

- P: The high rate of unintentional pregnancies and abortion in Tennessee and lack of over-the-counter contraception.
- I: Persuasion of legislators to pass legislation for affordable over-the-counter oral contraceptives for Tennessee.
- C: Tennessee unintentional pregnancy rates and abortion rates compared to rates in states and countries where oral contraceptives are available over the counter.
- O: Affordable over-the-counter oral contraceptives: an advance toward accelerating a decline in abortion rates and unplanned pregnancies in Tennessee.

- T: 12 months.

### **Conceptual Framework**

Two concepts guided the project: the rationale for over-the-counter contraception and the empowerment for women's self-efficacy and the health policy process. Icek Ajzen introduced the theory of planned behavior that linked one's beliefs and behavior (see Figure 1; Ajzen, 1985). The theory of planned behavior extends Ajzen's prior work with Martin Fishbein on the theory of reasoned action, which explains one's actions based on the relationship between their beliefs and attitudes. For example, if a person believes a behavior to be positive and viewed as positive by those around them, they have a higher motivation to do the action (Ajzen & Fishbein, 1980). The theory of planned behavior refines the idea by stating that a person is more likely to enact a specific behavior if they feel they will be successful in implementing this new behavior (Ajzen, 1985).

**Figure 1***Ajzen's Theory of Planned Behavior*

*Note.* From *Theory of Planned Behavior* [Diagram], by R. Orzanna, 2015, August 11, Wikimedia Commons ([https://commons.wikimedia.org/wiki/File:Theory\\_of\\_planned\\_behavior.png](https://commons.wikimedia.org/wiki/File:Theory_of_planned_behavior.png)).

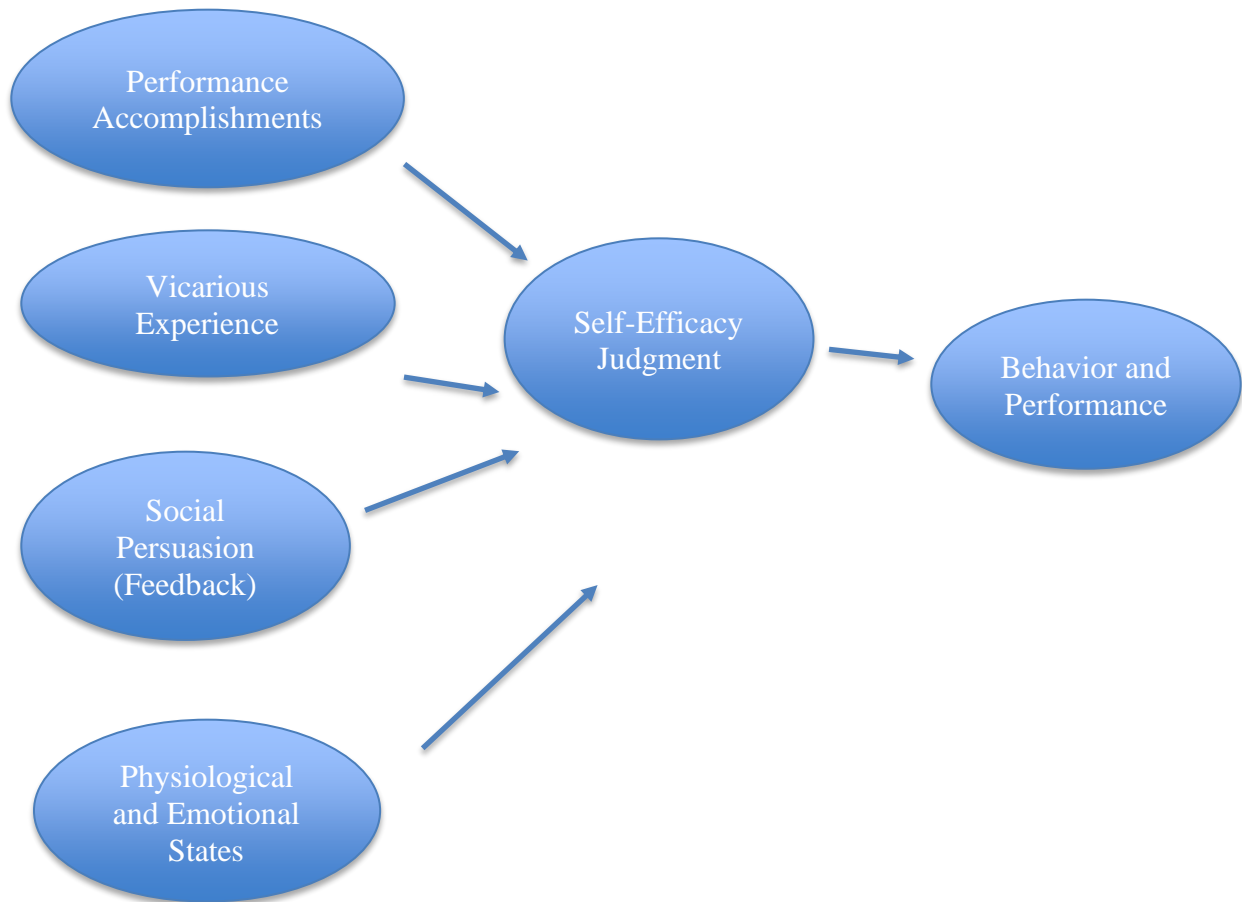
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The resulting feeling of strong control links to the self-efficacy theory proposed by Bandura (1977). Bandura stated that self-efficacy is the most important predictor of behavioral change, delineating two components: self-efficacy is the person's belief or confidence to successfully implement the change, and outcome expectancy is the belief that the implemented change will be successful and lead to a positive difference. This is important because a person's behavior is strongly influenced by their belief in their ability to implement the change successfully (Bandura et al., 1980).

Bandura's (1977) self-efficacy theory was relevant to the problem of interest in seeking an abortion alternative for Tennessee. By educating and empowering the women of Tennessee to self-direct their oral contraceptive needs, the patients will feel an increase in control of their health and more confidence in caring for themselves. The theory of planned behavior is relevant to the over-the-counter oral contraceptive discussion. By increasing ease of access to oral contraceptives for Tennessee women, the feeling of privilege to care for oneself will result in oral contraceptive use and a decline in abortion rates. Bandura's (1977) self-efficacy theory explains that when a person believes their actions will positively change their health and well-being, they will persevere to make a change that will make a difference in their lives (see Figure 2).

**Figure 2**

*The Flow of Ideas According to Bandura's Self-Efficacy Theory*



*Note.* Adapted from *Psychology of Learning for Instruction* (3rd ed., p. 318), by M. Driscoll, 2004, Allyn & Bacon. Copyright 2004 by Allyn & Bacon.

### ***Health Policy Process Theory***

Nurses are frontline healthcare providers and see the direct impact of healthcare policy on patient health outcomes (Arabi et al., 2014). Nurses are in a unique position to advocate for patients and work with policymakers to develop legislation beneficial for the patient's health (Arabi et al., 2014). Nurses are given the task of implementing healthcare policy change and must be involved in developing these healthcare policies. The nursing profession can influence

patients' positive health changes while working with policymakers to write effective legislation for improved patient outcomes (Arabi et al., 2014).

### ***Political Policy Process Theory***

The political process has been implemented successfully to bring awareness to a social issue to bring about needed change (Caren, 2007). When the existing delivery method is no longer sufficient to meet a population's needs, the process or system must be analyzed. A change is proposed in political settings to improve the availability of resources. By utilizing respected leaders within a group, motivated members within a community and political leaders, collaboration allows for developing an effective delivery method to bring about needed change.

### **Scope and Limitations**

This case study was delimited to one conservative southern state and covered only two legislative cycles. The intent was to illustrate the process so that others could learn from this experience.

### **Chapter Summary**

The high rate of unplanned pregnancies and abortions in Tennessee was linked to the lack of access to contraceptives and healthcare. The purpose of this case study was to detail the problems of an unplanned pregnancy and describe the process of assembling an alliance of medical providers to accomplish the needed policy change. The policy changes will impact low-income women through policies that promote ready access to care. This project was an in-depth look into real-world scenarios, specifically obstacles that the women of Tennessee are facing to access contraceptive needs. This case study contributes to the nursing profession by impacting healthcare outcomes by increasing access to contraception and its effect on unplanned pregnancies and abortions. This case study elaborated on the political realities of advocacy and

policy. The legislative change can improve access to reproductive care for underserved women with many barriers to care, including travel, losing work hours, and finances. An extensive review of the literature will be presented in Chapter 2.

## Chapter 2: Literature Review

This chapter provides a review of the literature that will guide the development of a policy briefing paper to utilize with legislators on this project to improve oral contraceptive access and reduce unplanned pregnancy in Tennessee.

### Literature Search Methods

The literature search for this project included PubMed, PubMed Advanced Search, and the Cochrane Library. Search terms used were *oral contraceptives, over-the-counter, pregnancy, reducing abortion, teen pregnancy, unplanned, legislation, randomized controlled trials, and access to contraception*. Articles included Tennessee teen pregnancy data and women over 18 who reported unplanned or untimely pregnancies. Data concerning access to oral contraceptives, access to healthcare providers, and access to telemedicine or online healthcare options were included. Unplanned pregnancy and abortion rates with and without over-the-counter contraception access were key terms for the legislative search. The search also included professional position papers and foundation reports.

The search focused on research from 2015 to 2021; however, older historical sources were necessary to show the ongoing issue of unintentional pregnancies and abortion rates in Tennessee. As the newest state statistics were released, the data were added to the continuing statistical data research. Articles were included if the researched population reported unplanned or untimely pregnancy data. Abortion statistics for Tennessee and the United States were included. Policies and position statements on best practices were examined. Articles included Tennessee teen pregnancy data and research concerning access to oral contraceptives, access to healthcare providers, and access to telemedicine or online healthcare options.



Opinion pieces from the American College of Gynecology, the American Academy of Family Physicians, and the American Pharmacists Association were included because they showed their support for over-the-counter contraception access. Sixty-five articles were selected for this paper. For legislative audiences, 25 resources were utilized in the white paper due to their implications in the legislative change process.

### **Incidence of Unplanned Pregnancy and Consequence**

The United States has one of the highest unplanned pregnancy rates of all developed countries (Guttmacher Institute, 2019a). The unplanned pregnancy rate is 45% higher for women of color than White, non-Hispanic women. The rates are 58% in Hispanic women and 79% in Black women (ACOG, 2019). In the United States, 42% of unplanned pregnancies end in abortion (Guttmacher Institute, 2019a, 2019b). Seventy-three percent of the associated costs of women with unplanned births are publicly funded (Sonfield & Kost, 2015). Lack of access to healthcare and lack of access to oral contraceptives have proven critical components of this continuing statistic (Guttmacher Institute, 2019a).

At the time of the study, the unintentional pregnancy rate in Tennessee was 48%, the 10th-highest teen pregnancy rate in the United States (Tennessee Department of Health, 2018; United States Department of Health and Human Services, 2019). This is problematic because family planning centers can only meet the needs of 26% of the women in Tennessee (Kost et al., 2018). While the sexual activity rates in teens have declined in recent years, the unplanned pregnancy rate has remained constant (Abma & Martinez, 2017). For example, unintentional pregnancies, specifically among women under the age of 20, resulted in limited educational and employment opportunities for these women (Guttmacher Institute, 2019a). Unintended

pregnancies result in poorer maternal and child health outcomes leading to increased medical costs and long-term financial strain for teen mothers (Yazdkhasti et al., 2015).

From a healthcare provider and delivery perspective, unintended pregnancy is an immediate classification parameter for a high-risk pregnancy (Yazdkhasti et al., 2015). When a pregnancy is unintended, these women are at a greater risk for depression, suicide, poor nutrition, and unstable family relationships. These women are often in social circumstances that prevent access to proper maternal-fetal care, lack of financial resources for sufficient insurance coverage, or an immigration status precluding them from preventative healthcare. The infants of these women are more likely to experience low gestational weight due to a lack of prenatal care obtained by these mothers. At the macro level, a community's public health has a tremendous impact on the economic growth of its nation.

Regarding the Triple Aim Initiatives, the Institute for Healthcare Improvement laid out the framework for a three-armed plan to improve patient and population health while simultaneously decreasing per capita costs (Institute for Healthcare Improvement [IHI], 2020).

Improving the patient experience of care, including quality and satisfaction, occurs by empowering the patient to self-direct which method of contraception is best for their menstruation needs, contraception needs, and prevention of transmission of infection to a newborn. Improving the health of populations occurs by increasing access to contraception for more women, minorities, and the uninsured. Women using oral contraceptives will also decrease their chances of ovarian cancer (American Cancer Society, 2018). Reducing the per capita cost of healthcare comes when pregnancies are prevented, women can manage their own monthly cycle needs, and patients are not forced to decide between working or college and changing their life course to have a child (IHI, 2020).

From July 2018 to July 2019 in the United States, 119 million unintended pregnancies were prevented, 21 million unsafe abortions were prevented, and 134,000 maternal deaths were averted (Kost et al., 2018). Approximately half of all U.S. births are paid for through Medicaid (Sonfield & Kost, 2015). Of the unplanned births, public insurance paid for 68% of the 1.5 million births. A publicly funded birth cost was \$12,700 for the pre- and postpartum time. To include the first 60 months of life, the cost of an unplanned pregnancy increases to \$20,716. Per 2010 data, the cost to the United States was \$21 billion (Centers for Disease Control and Prevention, 2017).

### **Barriers to Women's Health Contraceptive Services**

Conducting a literature review of the history of birth control legislation in the United States revealed that a critical barrier to over-the-counter contraception was physician resistance to a change in pharmacy laws. Physician income is derived from mandatory physical examination before obtaining a prescription for contraceptives. Access to care is reduced for low-income and marginalized populations and women of color (Yazdkhasti et al., 2015). Access to family planning requires women to take off work or school, arrange for childcare, locate a provider to perform a gynecologic exam, provide a prescription for contraception, and then purchase costly medication totaling a cost of \$50–\$800 annually (Planned Parenthood, 2020). Low-income and teen populations have difficulties overcoming these arduous barriers to service (Planned Parenthood, 2020).

Women have higher insurance premiums than men, primarily due to contraceptive needs (Arons et al., 2012). Women pay about 68% more out-of-pocket care than men due to contraception needs (Guttmacher Institute, 2020a). The Affordable Care Act (ACA) had a mandate to require insurance to cover contraception for women (Health Resources and Services

Administration, n.d.). The U.S. Supreme Court overturned this legislation in the middle of the 2020 pandemic, leading to a higher economic burden for lower-income women (Totenberg, 2020).

Access to care is also limited by the provider shortage in the United States (Hughes, 2019). The marginalized populations feel the physician shortage the most (Heiser, 2019). Today's need is to increase the number of primary care providers by 95,900 to serve the races and socioeconomic classes equally (Heiser, 2019). Rural, underserved, and southern states will experience the shortages more immediately, yet the provider shortage will be felt across the nation (Health Resources and Services Administration, 2020).

All 95 counties in Tennessee either fall within a partially medically underserved area (MUA) or are an area designated as a medically underserved population (MUP; Health Resources and Services Administration, 2019). Tennessee's need for providers is outpacing the supply, lending itself to an increase in the number falling into the underserved population category (Hughes, 2019). Maternal health and obstetric care in rural communities and counties with higher Black, Latino, and lower-income women are lacking (Centers for Medicare and Medicaid Services, n.d.). With approximately one-half of the counties in the United States lacking obstetric care, women must drive hours to seek maternal healthcare (March of Dimes, 2018). Women living in poorer communities must seek care at the nearest hospital, which often does not have an obstetrician on staff for higher risk pregnancies, thus leaving the local family practice physicians to provide this care (March of Dimes, 2018).

### **Professional Policy Statements**

The National Association of Nurse Practitioners in Women's Health (NPWH) published their position paper supporting increased access to oral contraceptives by placing them over the

counter (Nurse Practitioners in Women's Health [NPWH], 2019). This position aligns with a 2012 ACOG position paper reaffirmed in 2019 (Isley & Allen, 2019). In addition to increased access, the over-the-counter availability of oral contraceptives has shown an increase in women's consistent use, leading to a decrease in unplanned pregnancy rates (Isley & Allen, 2019). Women have demonstrated their ability to correctly self-assess which contraceptive suits their needs (Isley & Allen, 2019). The CHOICE study revealed a woman's ability to assess and report her contraindications to a hormonal contraceptive more accurately versus a healthcare provider's assessment (Isley & Allen, 2019). For example, the rate of venous thrombosis is higher in a pregnant and postpartum woman than in a nonpregnant woman using oral contraception (Isley & Allen, 2019). The prevalence of contraindications to oral contraceptives is low in women of reproductive age. Women who obtained oral contraceptives over the counter had the same rate of getting pap smears compared to women who received a prescription from a doctor (Isley & Allen, 2019). The rate of women who desired screenings for cervical cancer and sexually transmitted infections and sought care was consistent. The women who did not obtain the screenings reported a lack of access to care, unable to find a provider who offered these services, and the cost of seeking reproductive care (Isley & Allen, 2019).

Higher-income countries require prescriptions more often than other developed countries where contraceptives are over the counter or free (Grossman et al., 2013). All states allow the over-the-counter purchase of the morning-after pill, prevention medications, and many pain relievers with far more severe side effects than oral hormonal contraceptives (Delphi Behavioral Health Group, n.d.). The oral contraceptive manufacturers have met the safety criteria for the over-the-counter status of a medication (McIntosh et al., 2011). The self-assessment for contraindication tool combined with the lower strength of hormonal contraceptives demonstrated

the safety and efficacy of over-the-counter status feasibility of oral contraceptives (McIntosh et al., 2011). The manufacturer's labeling allows accurate self-assessment and demonstration of benefits outweighing the risks, and low risk for misuse and abuse meets the criteria for the over-the-counter status of oral contraceptives (McIntosh et al., 2011).

### **Literature on Over-the-Counter Access to Contraceptives**

Current and historical research findings showed a decline in unintentional pregnancy rates and abortion rates when oral contraceptives were available over the counter (Sedgh et al., 2014). Numerous studies from other developed countries showed a significant decrease in abortion rates once oral contraceptives were placed over the counter (Guttmacher Institute, 2019b). In developed countries worldwide, unplanned pregnancies and teen pregnancy rates declined significantly once access to oral contraceptives was made more convenient, over the counter, and at an affordable cost or free.

Oregon allows oral contraceptives to be written and dispensed by pharmacists after the woman completes a self-assessment questionnaire at the pharmacy window (Oregon Board of Pharmacy, 2016). The change of Oregon's legislation replaced the physician barrier with a pharmacist barrier (Carroll, 2018). While legislation made contraception available behind the counter via pharmacists, women must request the medication with a pharmacist and hope the drug is affordable and in stock. While several states in the United States, such as Oregon, California, Hawaii, and Maryland, have placed oral contraceptives behind the counter, the numerous barriers, including cost, accessibility, and possible embarrassment, deter women from seeking help (Gleason, 2019). The compiled data show the benefits and successes of offering lower-cost, discreet home delivery options and personalized telemedicine options through sites such as heydoctor.org and GoodRx.com (Carroll, 2018).

## Historical Legislative Actions

Recent Tennessee Legislation includes the recently passed heartbeat bill HB2263 and SB2196 (Tennessee General Assembly, 2022a). These bills intend to prevent abortion when a heartbeat is heard via a required ultrasound (Tennessee General Assembly, 2022a). A change in legislation allowing women to access low-dose, oral contraceptives over the counter would work synergistically with the mentioned bill by decreasing untimely pregnancies, thus reducing the number of abortions in Tennessee. A change in legislation would address the actual problem of unplanned pregnancy instead of addressing its symptoms.

There is no Tennessee legislation blocking over-the-counter access to oral contraceptives. Yet, no legislation was implemented to enhance access to contraception (Tennessee General Assembly, 2022b). House Joint Resolution 0527 excludes emergency contraception from the list of paid prescription medications on the TennCare Medicaid list (Tennessee Gen. Assemb. H. J. Res. 0527, n.d.-c). The Tennessee General Assembly passed an adult store taxation bill, House Bill 3081, which allows sexual promotion stores in the state and receives taxes off these sexual promotion items (Tennessee General Assembly, 2012). The Tennessee General Assembly passed legislation, House Bill 3621, calling for abstinence education in schools, including the distribution of condoms (Tennessee General Assembly, n.d.-a). Tennessee has enacted a refusal law that allows pharmacists to refuse to dispense emergency contraception and contraceptives if a practice goes against their religious beliefs (National Conference of State Legislatures, 2018).

The bills passed by the Tennessee legislature within the last 10 years include the Heartbeat Bill, HB0077/SB1236, which allows Tennessee to have authority over each pregnancy once the cardiac activity of the fetus at six weeks can be determined (Tennessee General Assembly, 2021). The outcome aims to prevent an abortion, not an unplanned pregnancy

(Tennessee General Assembly, 2021). This bill puts a woman legally at risk who miscarries and could warrant an investigation into the cause of her miscarriage (Rodriquez, 2019). This Heartbeat Bill puts family practice physicians and obstetricians at legal risk in the event of a patient's miscarriage (Rodriquez, 2019). An investigation can be launched into the miscarriage cause, possibly ending in a homicide charge and life in prison for the medical provider (Rodriquez, 2019).

The Tennessee Board of Pharmacy amended its practice guidelines, Rule 1140-15, in 2017, by authorizing pharmacists to dispense hormonal contraceptives (Tennessee Pharmacists Association, n.d.). The shortage of pharmacists, lack of access to pharmacies, and continued provider barriers have not helped women in underserved or marginalized populations.

### **Suggested Legislative Language**

Several bills at the state and federal levels were written to increase access to contraception for women in the United States. Ayanna Pressley (Pressley, 2019) carried the Affordability is Access Act of Massachusetts. Representative Love carried the Over-the-Counter Contraceptives Act of 2016 at the federal level, in the House, House Bill HR 5138 (Over-the-Counter Contraceptives Act, 2016). Also, in the Senate at the national level, Joni Ernst carried Senate Bill 930, known as the Allowing Greater Access to Safe Contraception Act (Allowing Greater Access to Safe Contraception Act, 2019). Nationally, the proposed legislation HR 3296, known as the Affordability is Access Act, would move contraceptives to over-the-counter status (Pressley, 2019). With Tennessee having 15.2% of its women living in poverty, 41.7% female-headed households living in poverty, and 13.2% of reproductive age women uninsured, a change in current, antiquated ineffective legislation is a must (National Women's Law Center, n.d.).



## **Findings**

In countries where oral contraceptives are available over the counter, unplanned pregnancies and abortion rates are significantly lower (Peipert et al., 2012). The majority of the research in the United States linked unplanned pregnancies to the lack of access to oral contraceptives and healthcare options (Dehlendorf et al., 2010). Tennesseans have fewer healthcare options due to geographical location, healthcare provider shortages, and lower socioeconomic levels (Health Resources and Services Administration, 2020). The literature consistently showed women's economic and social benefits to determine when they have children and its effect on their education and career. The literature showed that women of all ages could safely and appropriately select the contraceptive pill right for them.

## **Search Limitations**

Research specific to Tennessee was minimally available. Since there are only three Planned Parenthood clinics in Tennessee and access to care is not available for all women, some Tennesseans may seek care in neighboring states for their family planning needs or use online telemedicine routes (Weigel et al., 2019). Counties in Tennessee are responsible for the reporting of abortions and pregnancies. There is a lack of extensive data on how over-the-counter contraceptives lower pregnancy and abortion from the states in the United States.

## **Conclusion**

The literature review findings showed a statistically significant decline in unplanned pregnancies and abortion rates in countries where affordable oral contraceptives are available over the counter or covered by a countries' universal healthcare plan.

## **Chapter Summary**

The data continues to show that improving access to oral contraceptives will lead to a decline in unplanned pregnancies. A decrease in unintentional pregnancies will reduce abortion rates (Peipert et al., 2012). Research demonstrates the benefit of improved access to healthcare options for women of childbearing age. This paper adds to the body of knowledge, showing that access to affordable over-the-counter contraceptives will lead to a decline in unintentional pregnancies and abortion rates.

### **Chapter 3: Research Method**

This qualitative case study focused on the role of nursing leaders in advocating for health policy improvements for women in Tennessee with decreased access to oral contraception and unplanned pregnancies and abortion. The process started with exploring disenfranchised women's inability to obtain preventative care leading to an unplanned pregnancy was critical for this study. The development of the project and case study used the political process theory.

#### **Purpose**

The purpose of this case study was to document the process of nursing advocacy through a legislative initiative. This case study described the process of assembling a coalition and working with state legislators to implement a change in health policy that affects individuals, populations, and society. This case study was designed to inform other nurses and health professionals about advocacy and the health policy process, including the political realities of a conservative state's government.

#### **Project Design**

This case study project explored the process and experience with nursing involvement in the health policy change process with the Tennessee legislature and the political realities of advocacy and policy. The case study described the problem, the purpose, the systematic approach to a policy change, a detailed process of change and its political implications, and an analysis of the efforts and recommendations. A literature review provided information to show the benefits of over-the-counter oral contraceptives and statistical benefits for preventing pregnancies that might end in abortion. This literature review was the basis for developing a white paper, a technique used in persuasion. The study design allowed for a large volume of data on the current policy's effect on low-income women and those with minimal access to healthcare

and medications. Data triangulation was used during the process to enhance the validity of the conclusions or recommendations in alignment with Yin's (2009) case study analysis techniques.

Given the enormous volume of research available, a combination of an extensive systematic review and compilation of the data was the most logical approach to show the proven methods other states and countries have. The study's design will show how policy change impacts low-income women and women with decreased access to care. The case study project will inform others about the future practice of policy change.

The current goal of improving access to comprehensive healthcare detailed in the Health People 2030 guidelines was the underpinning for this case study report. Timely access to healthcare is essential for women concerning family planning needs. Access to affordable contraceptive prescription drugs in an efficient manner is detailed within the Access to Health Services objective in the Healthy People 2030 goals (United States Department of Health and Human Services, 2016). Also, the availability of affordable preventative medications for women for family planning purposes is included in the Healthy People 2030 goals. Healthy People 2030 had within its objectives to decrease unintentional pregnancy rates.

By implementing Yin's (2009) case study methods, the four data analysis principles were utilized to categorize the data. Yin's first principle stated that data analysis must result from relevant evidence. The literature must show the real-world experience of studied subjects, thus making the evidence applicable to this study. Secondly, Yin stated that all the available data must be included even if research conflicts with another study. This study was designed to have as much general information and demonstrated agreement between the numerous research articles. Yin's (2009) third case study analysis guideline was that all critical elements within the case study must be addressed. This study included as much relevant information as possible

within the given timeframe for the case study project. Finally, Yin (2009) stated that the researcher must apply prior experiences and existing knowledge base to the current research problem. Therefore, the case study design allowed me as the researcher to draw from 20 years of primary healthcare experience serving the medically underserved, including Tennessee's lower socioeconomic class. Yin's (2009) case study approach facilitated analyzing this real-world phenomenon without manipulating the variables, thus yielding clear evidence for needed change. The concept of research triangulation was applied by incorporating my experience as the researcher, political leaders, medical, nursing, pharmaceutical providers in Tennessee, and the medically underserved women in Tennessee within the case study framework.

The potential for researcher bias was carefully considered. Input on the case study research and applications were sought from trusted advisors and were incorporated. Personal experience with the medically underserved of Tennessee influenced the research perspective yet was supported by trusted advisors.

### **Steps in This Case Study Process**

The problem under study was decreased access to essential healthcare services and medications and the impact on unplanned pregnancies and the abortion rate. The intervention included identification and advocacy with key leaders to obtain their stance on the introduction of legislation. Creating a map for each legislative district was vital to identifying medically underserved communities and the legislators that would need to be involved in policy change. Profiling the legislators by historical voting patterns and previous political stances was helpful to determine which leaders would best advocate for change in Tennessee legislation. Also, there was a need to identify each legislator's voting alliances, including personal inclination, weighing the strength of their support, and developing specific approaches to neutralizing the opposition to

realize the need for change in legislation. It was necessary to obtain suitable sponsors interested in the target population in Tennessee and to work closely with the sponsors on the legislative approach.

A white paper was developed to inform legislators and community leaders about the issue's importance (see Appendix A). The benefits of the white paper format included an allowance for examining a large volume of existing research, analysis, and compilation of all the findings. Data analysis allowed for observation of patterns and keywords that yielded concrete evidence to support the case study project format.

Key recommendations were detailed for the medical, nursing, pharmacy community, and community leaders in my area to change healthcare outcomes. Partnering with local physicians, pharmacists, nurse practitioner association leaders, and policy advisors was key to advocating for needed change. Research to determine the elements of the legislative language changes revealed samples of other states' legislation. The compiling of legislative bills from six states within the United States showed potential language for Tennessee's legislative change (see Appendix B).

### **Methodology Appropriateness**

This case study approach was appropriate for describing the impact of nursing efforts to advocate for underserved populations. The Doctor of Nursing Practice (DNP) involvement in the health policy process is consistent with the American Association of Colleges of Nursing DNP Essentials V, VI, and VII (American Association of Colleges of Nursing, 2006). The case study started by focusing on available data that will change healthcare outcomes by increasing access to contraception and its potential effect on the rate of unplanned pregnancies and abortions. The project's sustainability will come when healthcare policies are changed to improve healthcare access and medications. The recommendations will be detailed in Chapter 5. My hope is that this

case study bridges a gap between existing data and current medical practice restricted by state legislation.

### **Feasibility and Timeline**

The informal meetings with local and state legislators began in November 2020 and continued through 2021. This case study describes the actions and outcomes throughout spring and summer 2021. Given the conservative nature of the Tennessee legislature, the results of the 2020 elections in November, and the overriding health issues dealing with the COVID-19 virus, it is expected that this process will take at least two and perhaps three legislative cycles. The initiative will first focus on approaching those legislators most likely to lead and influence others.

### **Institutional Review Board Approval and Process**

This project was a descriptive case study. There was no patient contact or identifying data collected at any time. No descriptive details from the coalition interviews were included. The institutional review board (IRB) proposal was submitted to Abilene Christian University's Institutional Review Board.

### **Target Population and Interprofessional Collaboration**

The target population for this case study was women in Tennessee with family contraceptive planning needs. The social dynamics within the medically underserved women in communities of Tennessee were analyzed. While women with family planning needs in Tennessee were the primary focus, healthcare providers, local legislators, and community leaders were included in the case study process to demonstrate how interprofessional collaboration improves the population's health through healthcare policy change.

**Study Results**

The case study format allowed for analysis of a large volume of descriptive data that detailed needed intervention for a real-life problem of unplanned pregnancies. This case study was congruent with Yin's (2009) case study design. It allowed for the inference of a solution based on the triangulation of a large volume of research and data, thus increasing its reliability and validity (Yin, 2009).

**Chapter Summary**

The evidence-based practice supports the need to improve healthcare delivery for family planning needs for the women in Tennessee. The benefits and impediments were explored during the implementation of this case study project. The project can inform the other nurse leaders regarding the process of advocacy through a legislative change in health policy.



## **Chapter 4: Results**

### **Intended Outcomes**

This qualitative case study project explored the process and experience with nursing involvement in the realities of advocacy and politics in attempts at health policy change process with the very conservative Tennessee legislature. This case study described the problem, the purpose, the systematic approach to a policy change, a detailed process of change and its political implications, and an analysis of the efforts and recommendations. Chapters 2 and 3 described the scope of the problem and the literature supporting the need for this specific policy change. This chapter describes the approach to the process of change and the initial efforts.

The desired outcome is a legislative initiative to change the health policy to allow for over-the-counter contraception to decrease unintentional pregnancies and abortions in Tennessee. The underlying problem is the lack of access to essential healthcare services and medications and the impact on unplanned pregnancies and abortion rates. The intervention included identification and advocacy with key leaders to obtain their stance on the introduction of legislation and to ascertain their active support in a formal action coalition.

### **The Process**

#### ***Stakeholder Identification***

Using the concept of policy change, the first step in the planning process involved identifying key stakeholders and their likely support or opposition to the legislation. The overall purpose was to identify key stakeholders interested in forming a multidisciplinary action committee. After IRB approval (see Appendix C), I interviewed the key stakeholders, including primary care medical providers, current legislators, and full-time pharmacists. Participants communicated frequently via email, phone calls, and safe in-person meetings. Each interview

began with the same questions. Second or follow-up interview questions were based on initial meeting responses to further develop or build on the first meeting. This committee's volunteers were asked to participate in a consensus development of a white paper that can be modified with statistics from each legislative district.

The early process of identifying key stakeholders targeted local providers, pharmacists, professional associations, and citizen advocacy groups. Local county-level stakeholders were healthcare providers in private practice, pharmacists in an independent or chain pharmacy, and local legislators. The participants' demographics included White male and female healthcare providers, Asian healthcare providers, and White and African American legislative personnel. The providers and pharmacists fully supported the over-the-counter measure. They cited research from the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians (2007) with backing to reinforce the safety of this proposed measure. Providers referenced the Patient Protection and Affordable Care Act of 2010 to support the over-the-counter contraceptive measure. The participants referred me to other colleagues in nearby larger cities who would likely advocate for expanding medication access.

Data collection involved analysis of existing research on access to contraceptive care and medications, interviews with the key informants, and observations of existing healthcare delivery and access in middle Tennessee. Those interviewed were chosen based on longstanding relationships serving alongside one another in the communities of Tennessee. During each interview, detailed descriptions were recorded of the medical provider or legislator's ideology regarding increasing access to contraceptive care for women in Tennessee. Debriefing occurred after each interview, and answers were categorized based on prioritization of increasing access to

contraceptive care, voting patterns and upcoming legislative docket agendas, and whether the legislator was willing to discuss changes for the state of Tennessee.

### ***Organizational Support***

Key leaders from the state Association of Pharmacists were contacted as they successfully backed behind-the-counter legislation four years earlier. The legislator stated that the Tennessee Pharmacy Association supported the legislation. Still, the measure was never implemented due to no one spearheading the educating of the Tennessee pharmacists plus the lack of encouragement to partner with a local physician that would create the standing order allowing for the dispensing of these contraceptive medications. Supporters of the behind-the-counter 2016 Tennessee legislation were contacted and expressed support of over-the-counter access.

The Tennessee Medical Association (TMA) has historically opposed over-the-counter legislation. The TMA has opposed over-the-counter contraceptive access stating that women need a medical doctor to guide the decision-making process, even though the American Medical Association supports over-the-counter access (ACOG, 2019). The TMA passed resolutions in 2015 to increase access to care (Resolution 7-13) plus the resolution to decrease healthcare disparities (Resolution 10-15; Tennessee Medical Association [TMA], 2019). Providers admitted privately that the primary concern was the loss of revenue for women's health visits. The Tennessee Nurses Association (TNA) was contacted in June 2021 to obtain its position on over-the-counter contraception. Their response is currently pending. Planned Parenthood Action Fund (2014) supports measures to increase access to some birth control methods by making them available over the counter.

## Development of a White Paper

The final action coalition consisted of two primary care physicians, two nurse practitioners, two legislators, and two pharmacists. The term white paper was used to refer to an official government report, indicating that the document is informative in nature. This genre is used to argue a specific position or propose a solution to a problem addressing the targeted audience (Purdue Online Writing Lab, n.d.). The benefits of the white paper included an allowance for examining a large volume of existing research, analysis, and compilation of the findings. The key message was the prevention of unwanted pregnancies, which are likely to result in abortion. The initial white paper included these key points:

1. Abortion is directly related to unplanned pregnancies.
2. One of the contributors to unplanned pregnancies in Tennessee is the lack of provider access.
3. The proposed solution is to adopt the ACOG position that over-the-counter contraceptives are safe and effective for the prevention of pregnancy.
4. A decrease in abortion rates parallels the reduction in unplanned pregnancies in other countries that offer over-the-counter contraceptives.
5. Support is being sought for legislative bill number xx to allow pharmacists to dispense contraception over the counter after education and appropriate screening of women to purchase.

A white paper was developed with the committee members to inform legislators and community leaders about the issue's importance. Partnering with local physicians, pharmacists, nurse practitioner association leaders, and policy advisors was key to advocating for needed change. The white paper included a PowerPoint presentation showing Tennessee's growing

underserved population, decreased access to primary medical care, and the ongoing data on unplanned pregnancy and abortion rates (see Appendix A). The message to legislators and lobbyists included key recommendations for the medical, nursing, and pharmacy community leaders in my area to change healthcare outcomes.

To test the concepts to be included in the white paper, legislators were contacted who are known to be advocates for the prevention of abortion in this historically antiabortion state. Therefore, the key message was the prevention of unwanted pregnancies that are likely to result in abortion. Five legislators were interviewed. Initially, two legislators were very supportive and believed the proposed legislation was an excellent idea. The legislators suggested names of multiple Democratic and Republican legislators to gain support and begin momentum for the proposed bill. The legislators who were hesitant to support the legislation stated they believed the bill was a good idea but knew they had constituents who would not support it. All agreed upon improving access to care. All agreed upon improving access to medications. All agreed that the plan would decrease unplanned pregnancies and abortions.

### **Planning the Legislative Approach**

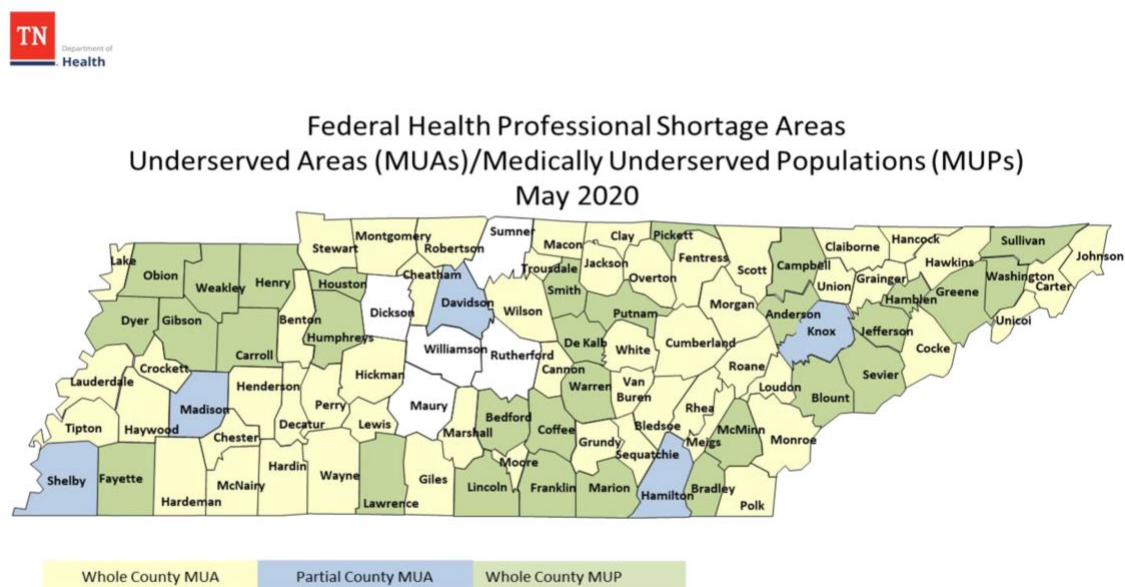
The fundamental concept of representative democracy is that each legislator is expected to vote for issues that have significance in their community. Therefore, it is vital to add targeted local data to any white paper to show that the presenter has taken the time to understand the local issues and why the legislator should be motivated to listen to points included in the white paper. A data map was developed.

The data shows the shortage of primary care providers, particularly in rural areas, which point to a need for additional resources and healthcare options at a low cost (see Figure 3; Health Resources and Services Administration, 2020). West Tennessee is ranked with Health

Professional Shortage Area (HPSA) score ranging from 19–24. Middle Tennessee HPSA ranges up to 17–20 (Health Resources and Services Administration, 2020). East Tennessee HPSA ranges up to 17–21 (Health Resources and Services Administration, 2020). The counties with the highest HPSA scores included Davidson (19), Hardeman (21), Lake (22), Rutherford (17), Shelby (24), and Williamson (21; Health Resources and Services Administration, 2020).

### Figure 3

*Medically Underserved Areas and Medically Underserved Populations, May 2020*



Data Source: Health Resources and Services Administration, U.S. Department of Health and Human Services, 2019

Note: Partial county shortage designations are comprised of the select urban census tracts which met eligibility criteria

*Note.* From *Health Resources and Services Administration, U.S. Department of Health and Human Services, 2019.* (<https://www.tn.gov/health/health-program-areas/division-of-health-disparities-elimination-/rural-health/federal-shortage-areas.html>).

Creating a map for each legislative district was vital to identifying medically underserved communities and the legislators that would need to be involved in legislative change. Identifying

the underinsured counties, provider-to-patient ratios, and unwanted pregnancies were completed (see Figure 4).

#### Figure 4

##### *Federal Health Professional Shortage Areas, May 2020*



*Note.* From *Health Resources and Services Administration, U.S. Department of Health and Human Services, 2019.* (<https://www.tn.gov/health/health-program-areas/division-of-health-disparities-elimination-/rural-health/federal-shortage-areas.html>).

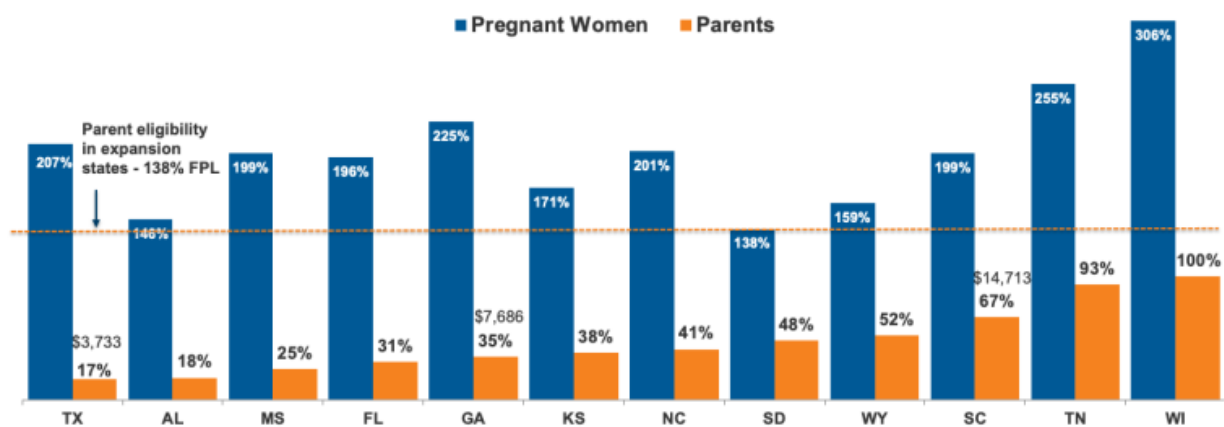
I used two methods to triangulate the data. Through direct observation and work experience, I had firsthand knowledge of this healthcare delivery and access issue within my patient population in middle Tennessee. I searched archival records to find external data to validate my observations, which demonstrated this longitudinal issue of decreased healthcare and prescription medication access. Since access has remained an issue in Tennessee, unplanned pregnancy and abortion rates have not shown a statistically significant decline over time.

## Legislative Profiling

Profiling the legislators by historical voting patterns and previous political stances was helpful to determine which leaders would best advocate for change in Tennessee legislation (see Appendix D). One starting point was knowing which legislators sponsored the 2016 Tennessee legislation in support of behind-the-counter legislation was a starting point. Another was identifying which organizations, substantial party donors, and individuals that opposed increasing access to contraceptives were key. I also obtained a map of voting patterns showing that legislators in larger cities leaned more democratically and smaller cities leaned more conservatively on women's issues of abortion, access to contraceptive medications, and covering the costs of contraceptive medications (see Figures 5, 6, and 7).

**Figure 5**

*Medicaid Eligibility and Restrictions for Parents Versus Pregnant Women*

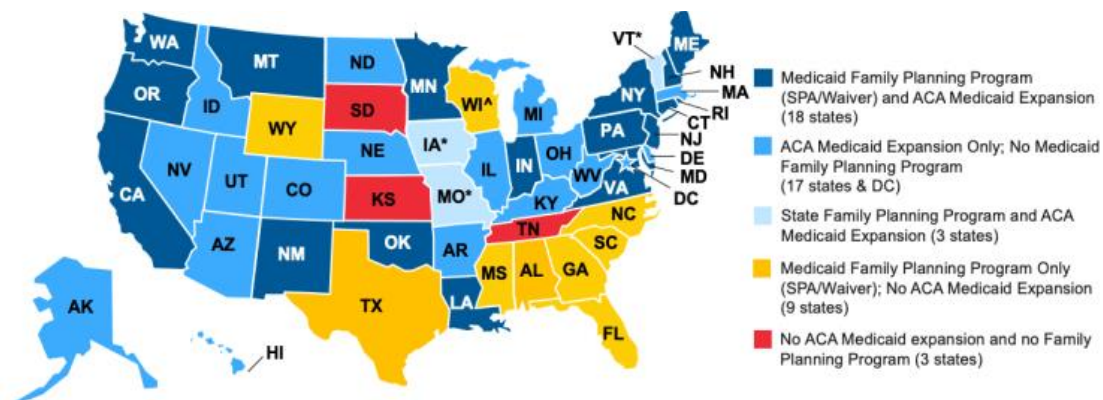


*Note.* From *Status of State Medicaid Expansion Decisions: Interactive Map*, by Kaiser Family Foundation, 2021, August 10 (<https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>). Reprinted with permission from Kaiser Family Foundation.



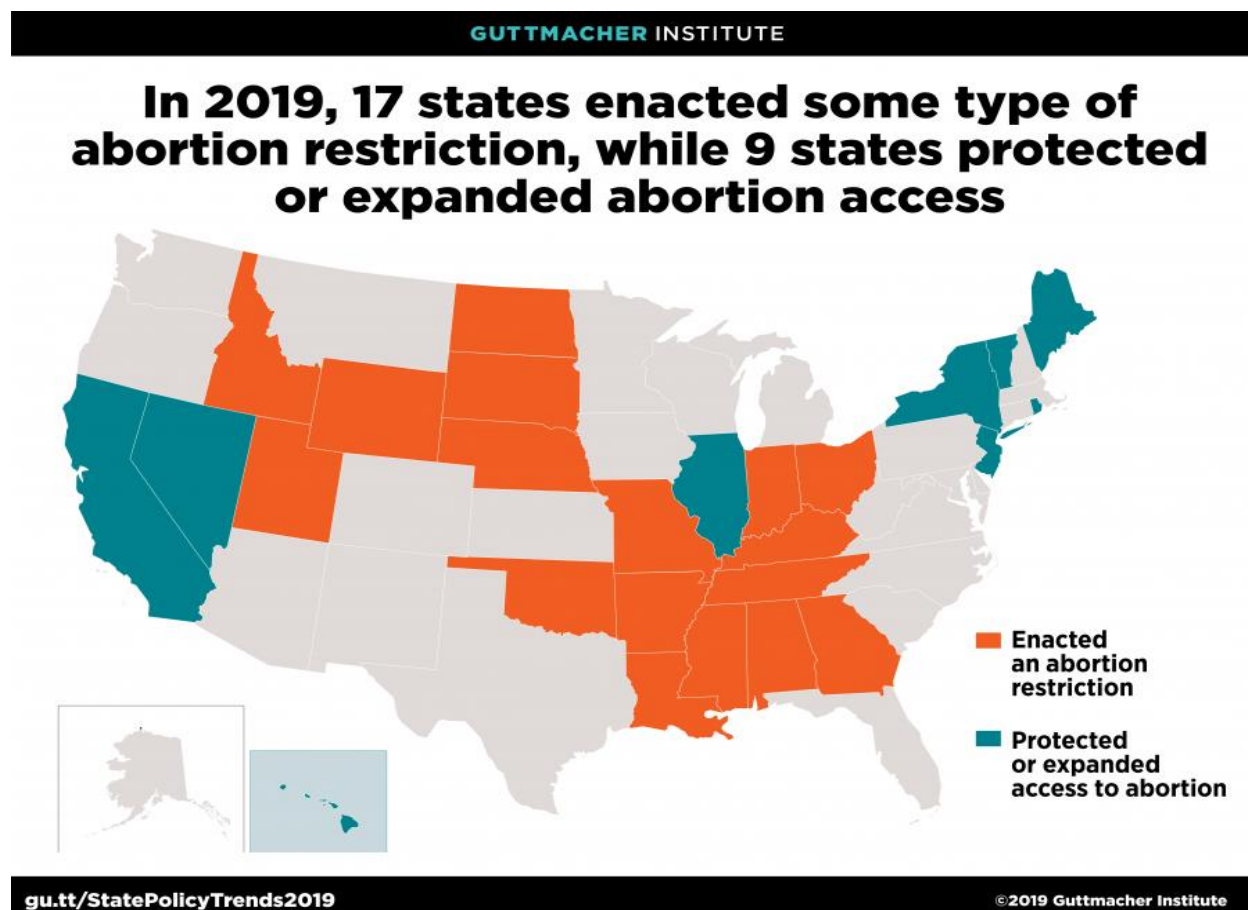
**Figure 6**

*State Decisions on Medicaid Expansion, December 2020*



*Note.* From *Expanding Postpartum Medicaid Coverage*, by U. Ranji, I. Gomez, and A.

Salganicoff, 2021, March 9, Kaiser Family Foundation (<https://www.kff.org/womens-health-policy/issue-brief/expanding-postpartum-medicaid-coverage/>). Reprinted with permission from the Kaiser Family Foundation.

**Figure 7***Legislation Affecting Access to Abortion*

*Note.* From *The U.S. Abortion Rate Continues to Drop: Once Again, State Abortion Restrictions Are Not the Main Driver*, by Guttmacher Institute, 2019b, September 18

(<https://www.guttmacher.org/gpr/2019/09/us-abortion-rate-continues-drop-once-again-state-abortion-restrictions-are-not-main>). Copyright 2019 by Guttmacher Institute.

At the time of this project, the Tennessee Health and Welfare Committee comprised one Democrat and eight Republicans (Tennessee General Assembly, n.d.-b). This is the legislative committee to which the proposed bill would be directed for initial review. Historically this committee in Tennessee has not focused on expanding access to healthcare or contraceptive medications (Tennessee General Assembly, n.d.-b). Expansion of healthcare access legislation

votes has been cast down party lines, but at the same time, working in the guidelines of a collaborative physician agreement, increasing contraceptive availability by allowing pharmacists to dispense received support from Republicans and Democrats.

Also, there was a need to identify each legislator's voting alliances, including personal inclination, weighing the strength of their support, and developing specific approaches to neutralizing the opposition to realize the need for change in legislation. It was necessary to obtain suitable sponsors interested in the target population in Tennessee and to work closely with the sponsors on the legislative approach.

### **Sample Legislation**

It was essential to introduce legislation models used in other states so that the key legislative sponsors could develop a similar bill for submission in the next legislative session. Research to determine the elements of legislative language changes revealed samples of other states' legislation. The National Conference of State Legislatures (NCSL) had three, which seemed applicable to and replicable for Tennessee (see Appendix B).

- NCSL H.R. 5138-Over-the-Counter Contraceptives Act of 2016.
- NCSL S. 930-116th Congress: Allowing Greater Access to Safe and Effective Contraception.
- Act (2019–2020). In addition to the two already passed, NCSL H.R. 3296, the Affordability is Access Act (Congresswoman Pressley's bill), has been written for the state of Massachusetts.

### **Limitations to Implementation of the Plan**

The COVID-19 pandemic put this healthcare legislative change low on priorities for the 2019 and 2020 legislative sessions. The legislative focus shifted to improving access to care via

telemedicine and emergency authorization of the Full Practice Authority Act. The key team members for improving access to contraceptives will resume the lobbying efforts in the fall of 2021 when vaccine immunity is more widespread. Key variables in this project included access to providers and legislators depending on pandemic Centers for Disease Control (CDC) guidelines, work requirements for each medical participant, and timing of the session for state legislators. The new rise in the Delta variant in the highly unvaccinated state of Tennessee may preclude lobbying efforts for the 2022 session. It is essential to time the introduction to avoid conflict with an emergency health agenda.

### **Findings**

Expansion of access to contraception remains low on the list of legislative issues in this conservative southern state. Key informants and key research documents corroborate the proposed need to expand access to contraceptive healthcare. Expansion of access to contraceptive care was high on the list of most of the surveyed primary care providers in rural areas. One provider had not thought about the expansion of access to contraceptive care simply because their practice does minimal obstetric or gynecologic services for their predominantly older population. Younger providers, pharmacists, and female providers were interested in seeing access to contraceptive care be made easier for the community. Providers and pharmacists were interested in learning how to increase access to contraceptive care through over-the-counter legislative change and affordable online options.

### **Chapter Summary**

The purpose of the study was to document the process of nursing advocacy through a legislative initiative to change healthcare policy. The case study method detailed by Yin (2009) was appropriate for describing the effects of social determinants on real-world, contemporary

scenarios. The proposed legislative changes were well-received by providers and pharmacists but met with resistance from conservative legislators. This information was used to plan a specific approach to these legislators to neutralize the opposition to the proposed legislation. There is now a coalition named the Advocacy Action Committee that will coordinate the lobbying efforts toward the spring 2022 legislative session.

## **Chapter 5: Discussion, Conclusions, and Recommendations**

The purpose of this case study was to document the process of nursing advocacy through a legislative initiative to change health policy in Tennessee. The project served to demonstrate the steps of the process before the actual introduction of new legislation. The process included outreach to stakeholders to identify the potential for alliances and to form a coordinated action committee. The second step was drafting a white paper and validating the key points with selected legislators. The third step was the process of legislative mapping, which informs the strategic approaches of lobbying and building support before the introduction of legislation. This education included specific statistics by legislative district and copies of similar legislation obtained from the State Council of Legislators.

### **Implication and Analysis**

The formation of this project followed the political process theory, which recommends obtaining broad support for a proposed change in health legislation before reaching out to individual legislators (Meyer, 2004). The wider coalition support is likely to gain the attention of elected officials than the personal approach, as this indicates that more than one voter sees the issue as significant. This group needs to agree and support a white paper used in the lobbying of selected representatives.

### **Purpose of Mapping and Targeting**

To identify potential supporters to sign onto the bill before its being introduced in the legislative session is needed by targeting members of the committee likely to be assigned this bill for discussion and advancement, and then prioritizing the efforts of the action committee to be first directed toward the potential supporters, then those who may be persuaded, and to neutralize the argument of the opponents. This comprehensive approach is similar to political campaign

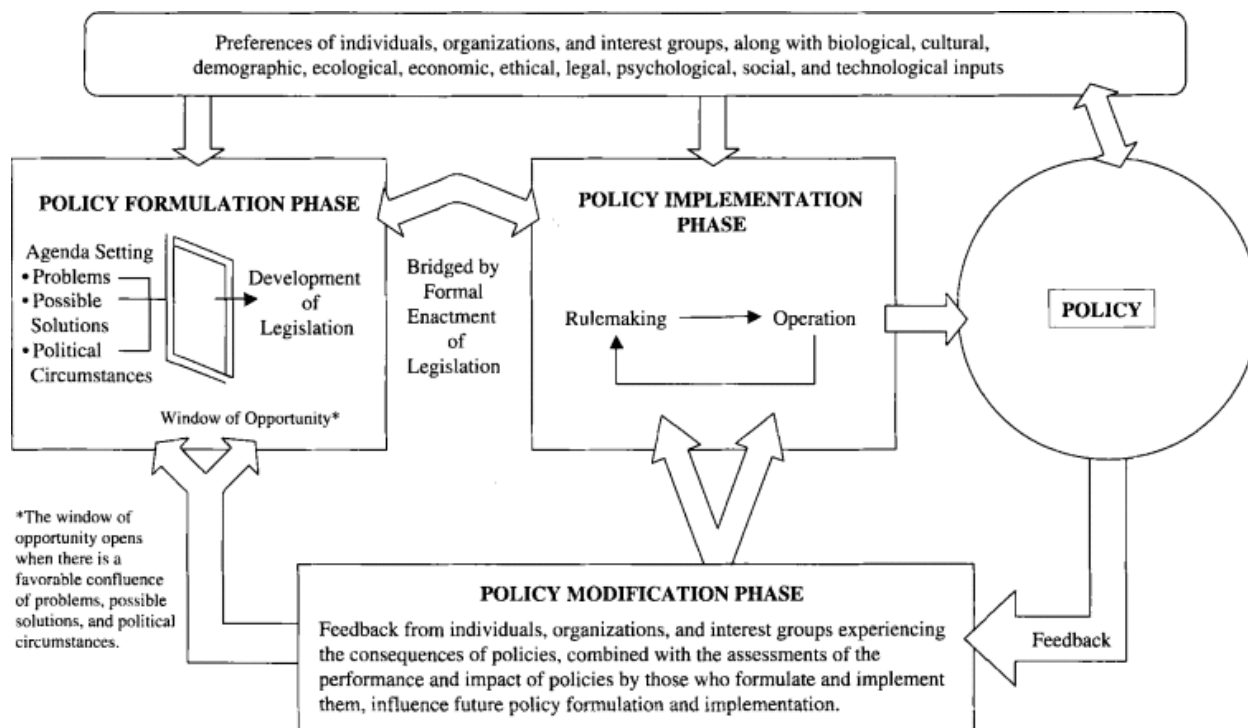
strategies of creating the message, assembling a team to share the message, and targeting various audiences.

### **Implication for Nurse Leaders**

The role of nurse leaders is to advocate for the underrepresented members of society. Women's reproductive rights are under attack from conservative groups. The same groups oppose abortion but have yet to address the root causes of unplanned pregnancy, including low-cost access to contraception. Naming this bill as antiabortion puts a more positive spin on advocating for preventing a public health problem and societal dilemma. Nurse leaders must understand the policy process to participate in the pivotal steps of changing legislation.

The political process model used in health policy change via the legislative process included ideas from Ferguson (2001; see Figure 8) and Ratzan (2003; see Figure 9).

Figure 8

*Health Policymaking Flowchart*

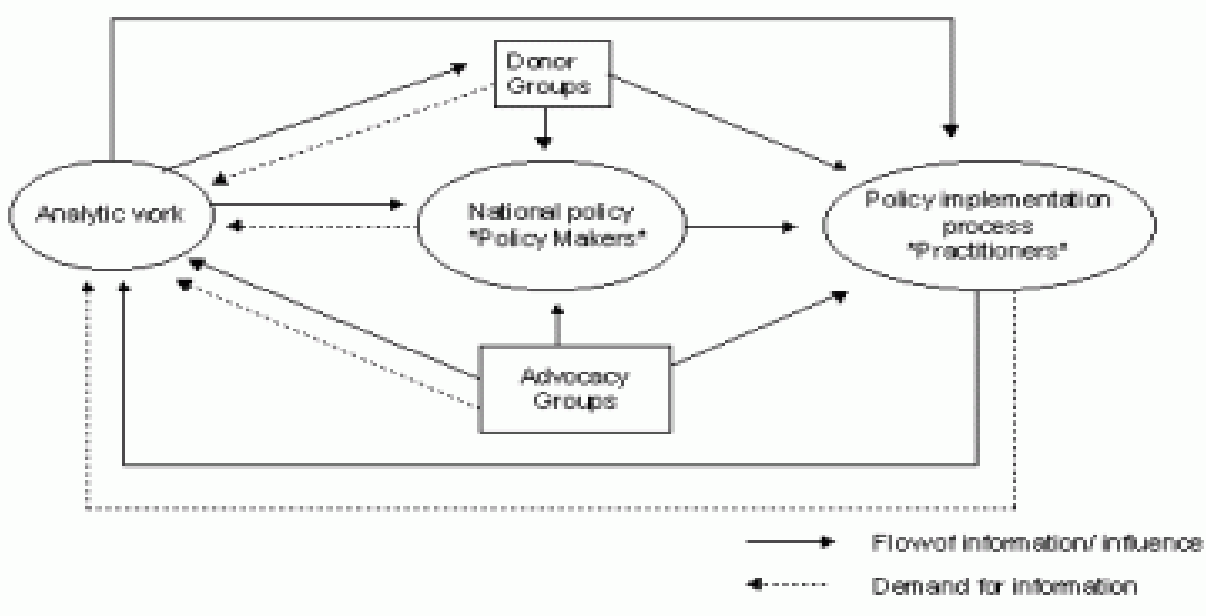
Note. From "An Activist Looks at Nursing's Role in Health Policy Development, by S.

Ferguson, 2001, September 1, *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, 30(5),

545–551 ([https://www.joggn.org/article/S0884-2175\(15\)33920-4/fulltext](https://www.joggn.org/article/S0884-2175(15)33920-4/fulltext)). Copyright 2001 by

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**Figure 9***The Role of Analysis in Policy Formation*

*Note.* From *Policy Formation: The Role of Analysis*, by S. C. Ratzan, 2003, November 4, Communication Initiative Network (<https://www.comminit.com/content/policy-formation-role-analysis>). Copyright 2003 by the Communication Initiative Network.

**Significance of the Findings**

Healthy People 2030 included improving access to healthcare providers for all people (United States Department of Health and Human Services, 2016). With one in four lacking access to primary healthcare and one in five lacking health insurance, Americans are missing out on basic preventative testing and medications, thus leading to an unhealthy nation. This case study demonstrated that when access to essential preventive medications was improved, the rate of unplanned pregnancy declined, and the rate of abortion decreased.

The Triple Aim Initiatives included a redesigned model for the delivery of healthcare services and population health management. In turn, a decrease in the cost of healthcare would be seen, and overall population health would improve. This project is in line with these national

guidelines to improve the overall health of the Tennessee population while decreasing the per capita cost of healthcare.

Collaboration with healthcare professionals, legislators, and nursing organizations is within the foundation of these initiatives to improve population health.

### **Evidence-Based Practice Findings and Relationship to DNP Essentials**

- DNP Essential V: Healthcare Policy for Advocacy in Healthcare. This research applies to the DNP Essential V by demonstrating the process of advocating for healthcare policy change through professional, data-driven communication.
- DNP Essential VI: Interprofessional Collaboration of Improving Patient and Population Health Outcomes. This research applies to the DNP Essential VI by showing the benefits of interprofessional collaboration to improve the delivery of healthcare and improve the health of the community and greater population. This case study shows the effects of psychosocial factors involved in a population's health.
- DNP Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health. This case study research applies to the DNP Essential VII through the demonstration of the value of DNP education in a comprehensive assessment of a population's needs and leading the way for other nurses to implement the process in their community.

### **Recommendations for Future Research and Clinical Practice**

There is a need for politically savvy nursing leaders to promote the health of underserved women in a system where women's rights are being systematically attacked, particularly around the ability of women to choose abortion. A vast majority of the American population is uneasy about abortion; however, there has been little advocacy in recent years for increased access to

preventative education and the availability of affordable contraception. This was the primary reason for titling this project as Prevention of Abortion instead of Reproductive Freedom. It is hoped that this messaging will appeal to both the antiabortion legislators and those who truly wish to improve women's health in Tennessee.

Suggested changes for nursing practice include incorporating healthcare policy awareness into nursing programs and nursing workspaces and how to work with legislators for policy change. The realistic process of policy change, without the involvement of politics, is difficult.

### **Next Steps for the Action Committee**

- Create a legislative lobbying plan with specific assignments of persons to approach the various members.
- Identify legislators to introduce this new legislation and work with their staff to draft the legislation for introduction spring 2022 session.
- Activate the plan with regular communications and coordination of efforts.
- Evaluate efforts and revise strategy for 2023, if necessary.

### **Final Summary**

The overall goal for this case study was to describe the process of nursing advocacy through a legislative initiative to change health policy. Due to the COVID pandemic, the planned introduction earlier into legislative sessions has been pushed back to the spring of 2022. Given the competing demands for legislation from all sectors, this process is expected to take two to three years. This case study provided detail on specific strategies that can be used for similar advocacy approaches.

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## **Appendix A: White Paper**

### **Decreasing Unintentional Pregnancies for Tennesseans**

#### **Executive Summary**

In 2018, 49% of all pregnancies in the United States were unintended. Women with lower-income status are five times more likely to experience an unplanned pregnancy. Tennessee has a high rate of unintended pregnancies, particularly among the uninsured, low-income, and rural teen populations. Twenty-two percent of these unintended pregnancies end in abortion. Oral contraceptives that are affordable and accessible for women of childbearing age can lead to a decline in unintentional pregnancies. The gap in clinical practice is that oral contraceptives are not currently available over the counter in pharmacies without a prescription, which necessitates a costly medical visit.

#### **Background**

The United States is one of the few industrialized, developed nations that inhibit access to reversible contraceptive methods for women (Peipert et al., 2012). Over 100 countries currently offer oral contraceptives over the counter (Grossman et al., 2013). The goal of Healthy People 2010 was to have an intentional pregnancy rate reach 70% (Healthy People 2030, 2020). However, the United States' intentional pregnancy rate, defined as a woman's desire to become pregnant before the pregnancy occurred, was 55% in 2016 (Finer & Zolna, 2016). This is problematic because the National Conference of State Legislatures predicted a 6,000 to 8,000 maternal health provider shortage plus a decrease in obstetric and gynecologic care needs, stating that 5 million women live without any access to maternal care (Johnson, 2019). Women in Tennessee have one of the highest infant mortality rates within the United States (Bellazaire & Skinner, 2019). The maternal death rate has more than doubled in the United States since 1987

(Johnson, 2019). In Tennessee, the Teen Adolescent Pregnancy Program was created to promote self-worth, knowledge about pregnancy prevention options, and informed sexual decision-making strategies, yet teen pregnancies remain a significant problem in the state (Kost et al., 2018). Teens who become pregnant are more likely to drop out of college or high school, never marry, and live in poverty (Tennessee Department of Health, 2018).

The United States' unintended pregnancy rate is higher than in other industrialized countries (Sedgh et al., 2014). Western Europe has a 40% lower unintended pregnancy rate than the United States (Sedgh et al., 2014). Many of these nations have oral contraceptives free or made affordable over the counter. Also, long-acting reversible contraception, such as intrauterine devices (IUDs), injections, and subdermal implants, are free and easily obtainable in these nations (Winner et al., 2012). Russia legalized abortion, made contraceptives available for free, and saw their abortion rates significantly decrease (Guttmacher Institute, 2003).

Currently, the United States has an abortion rate of 19.6% (World Population Review, 2020). In countries where abortion is illegal, the rates tend to be higher, even though undocumented. The health risks to mothers and babies are significant in these countries where abortion is illegal, leading to increased costs to offset the physical and emotional harm done to the mother and baby during the abortion procedure (World Population Review, 2020). The United States has seen a decline in abortion rates in part due to more restrictive laws, the recent closure of clinics due to decreasing funding, and women's ability to self-abort with over-the-counter morning-after pills (Guttmacher Institute, 2020b). However, the cost of the morning-after pill cost is currently out of reach for many women, currently \$40–\$50 at a local pharmacy. Adult women in the United States were surveyed and said \$20 would be the maximum affordable over-the-counter oral contraceptive option and would be able to apply their health



savings account funds to this cost (Grossman et al., 2013). This is not within reach for all childbearing-aged women.

Unintentional pregnancies result in increased healthcare costs for states and the nation. The babies and mothers require more healthcare dollars to combat the postpartum depression seen in the mothers of newborns from an untimely pregnancy (Brito et al., 2015). Poor health outcomes are noted in these unintentional pregnancies. Lower birth weights define the poor outcomes for newborns in this group, failure to thrive, early addiction issues, and adverse outcomes for the mothers seen with postpartum depression (McIntosh et al., 2011).

Unintended pregnancy can have significant negative consequences for individual women, families, and society. Tennessee has a high rate of unintended pregnancies, particularly among uninsured women, low-income, and rural teen communities. In 2018, 56% of all pregnancies were unintended (Guttmacher Institute, 2019a). Tennessee's unintended rate was 49/1000 in women aged 15–44 (Power to Decide, 2020). Nationally rates range from 32%–62% (Finer & Zolna, 2016). Sixty-three percent of unintended pregnancies in Tennessee resulted in birth and 22% in abortions, with the remainder resulting in miscarriage (Guttmacher Institute, 2019a). Women with lower-income status are five times more likely to experience an unplanned pregnancy (Finer & Zolna, 2016).

The community I serve has two clinics. Access to care is difficult for women in this Tennessee county. Many hourly wage earners live in the county and cannot take off work to seek care and cannot afford expensive medications. The unplanned pregnancy rate has declined to about 49% for Tennessee, yet abortion rates have stayed consistent in the state (Power to Decide, 2020).

With the United States Supreme Court amending the Affordable Care Act coverage for birth control, women in the United States with particular insurances cannot obtain their needed birth control (Totenberg, 2020). Racial disparities are more pronounced now. Black women, minorities, and women of color are seeing the most significant financial hit (Totenberg, 2020). Women must pay out of pocket to obtain medication to help with the menstrual cycle, family planning, and prevent vertical transmission of an infection to an infant. A woman's employer now decides whether or not they will have contraception made available for their employees (Totenberg, 2020). Racial disparities will become more pronounced due to these groups' inability to take off work to seek medical care or have the financial means to pay for a prescription.

### **Problem**

Legislation in Tennessee has focused on pro-birth initiatives and strengthening antiabortion laws. No bills have been implemented to prevent unplanned pregnancies to reduce the dilemma of abortion decisions for women. Legislators in Tennessee have historically written and passed bills that deal with the outcomes of unplanned pregnancies, which is problematic for women in lower socioeconomic classes because of a higher rate of unplanned pregnancy in this group (Finer & Zolna, 2016).

Recent Tennessee legislation includes the recently passed heartbeat bill HB2263 and SB2196 (Tennessee General Assembly, 2022a). This bill intends to prevent abortion from when a heartbeat is heard via a required ultrasound (Tennessee General Assembly, 2022a). A change in legislation that would allow women to access low-dose, oral contraceptives over the counter would work synergistically with the bill previously mentioned by decreasing untimely

pregnancies, thus reducing the number of abortions in Tennessee. A change in legislation would address the actual problem of unplanned pregnancy instead of addressing its symptoms.

Oral contraceptives, vaginal rings, the contraceptive patch, and depo medroxyprogesterone injections are safe to administer without a physician order (American College of Obstetricians and Gynecologists [ACOG], 2019). The American College of Obstetricians and Gynecologists' guidance was intended to inform state legislatures about this approach's safety and needed changes to pharmacy regulations (ACOG, 2019). The American College of Clinical Pharmacy (ACCP) recommends placing oral contraceptives over the counter in retail spaces where a pharmacist is available (McIntosh et al., 2011). The two guidelines suggested that sales of over-the-counter contraceptives would be where a pharmacist was available to answer questions and have mechanisms in place when needed to cover the costs with Medicaid (ACOG, 2019).

Obtaining reversible contraceptives is a significant problem for childbearing age women because the process is complicated, time-consuming, and not practical. For example, women have to see a medical provider in a clinic setting, have a well-woman visit that entails a breast and pelvic exam, and pay for the visit, contraceptive device, or prescription. Surveys of women of childbearing age have shown the capability and desire for this age group to self-educate and decide which reversible method is appropriate for themselves (Grossman et al., 2013).

### **Solution**

Reversible contraceptives that are affordable and accessible for women of childbearing age can lead to a decline in unintentional pregnancies. Over-the-counter options, including easily accessible choices, will empower childbearing age women of the community to decide which method is best suited for their bodies. Increased access to safe, over-the-counter contraception

without a physician visit and required prescription has the potential to decrease unplanned pregnancies and abortions. Implementing educational strategies, such as an available pharmacist, health department educator, appropriate package inserts, or infomercial options will provide necessary support and information for each woman.

Regarding the Triple Aim Initiatives, the Institute for Healthcare Improvement laid out the framework for a three-armed plan to improve patient and population health while simultaneously decreasing per capita costs (Institute for Healthcare Improvement [IHI], 2020).

Improving the patient experience of care, including quality and satisfaction, occurs by empowering the patient to self-direct which method of contraception is best for their menstruation needs, contraception needs, and prevention of transmission of infection to a newborn. Improving the health of populations occurs by increasing access to contraception for more women, minorities, and the uninsured. Women using oral contraceptives will decrease their chances of ovarian cancer (American Cancer Society, 2018). Reducing the per capita cost of healthcare comes when pregnancies are prevented, women can manage their own monthly cycle needs, and patients are not forced to decide between working or college and changing their life course to have a child (IHI, 2020).

From July 2018 to July 2019, 119 million unintended pregnancies were prevented, 21 million unsafe abortions were prevented, and 134,000 maternal deaths were averted (Kost et al., 2018). Approximately half of all U.S. births are paid for through Medicaid (Sonfield & Kost, 2015). Of the unplanned births, public insurance paid for 68% of the 1.5 million births (Sonfield & Kost, 2015). The cost of a publicly funded delivery was \$12,700 for pre- and postpartum time (Sonfield & Kost, 2015). To include the first 60 months of life, the cost of an unplanned

pregnancy increases to \$20,716 (Sonfield & Kost, 2015). Per 2010 data, the cost to the United States was \$21 billion (Sonfield & Kost, 2015).

### **Recommendations**

The National Association of Nurse Practitioners in Women's Health (NPWH) published their position paper supporting increased access to oral contraceptives by placing them over the counter (Nurse Practitioners in Women's Health, 2019). This position aligns with the American College of Obstetricians and Gynecologists (ACOG) position paper published earlier in 2012 and reaffirmed in 2019 (Isley & Allen, 2019). In addition to increased access, the over-the-counter availability of oral contraceptives has shown an increase in women's consistent use, leading to a decrease in unplanned pregnancy rates (Isley & Allen, 2019). Women have demonstrated their ability to correctly self-assess which contraceptive is right for their needs (Isley & Allen, 2019). The CHOICE study revealed a woman's ability to assess and report her contraindications to a hormonal contraceptive more accurately versus a healthcare provider's assessment (Isley & Allen, 2019). The rate of venous thrombosis is higher in pregnant and postpartum women than in nonpregnant women using oral contraception (Isley & Allen, 2019). The prevalence of contraindications to oral contraceptives is low in women of reproductive age (Isley & Allen, 2019). Women who obtained oral contraceptives over the counter had the same rate of getting pap smears compared to women who received a prescription from a doctor (Isley & Allen, 2019). The rate of women who desired screenings for cervical cancer and sexually transmitted infections and sought care was consistent (Isley & Allen, 2019). The women who did not obtain the screenings reported a lack of access to care, unable to find a provider who offered these services, and the cost of seeking reproductive care (Isley & Allen, 2019).

Coordinating legislation is needed to coincide with the medical experts' recommendations and pharmaceutical companies to offer affordable over-the-counter oral contraceptives to accelerate a decline in abortion rates and unplanned pregnancies in Tennessee

### **Conclusion**

In countries where oral contraceptives are available over the counter, unplanned pregnancies and abortion rates are significantly lower (Peipert et al., 2012). The majority of the research in the United States linked unplanned pregnancies to the lack of access to oral contraceptives and healthcare options (Dehlendorf et al., 2010). Tennesseans have fewer healthcare options due to geographical location, healthcare provider shortages, and lower socioeconomic levels (Health Resources and Services Administration, 2020). The literature consistently showed women's economic and social benefits to determine when they have children and its effect on their education and career. The literature showed that women of all ages could safely and appropriately select the oral contraceptive pill right for them.

The literature review findings showed a statistically significant decline in unplanned pregnancies and abortion rates in countries where contraceptives are available over the counter or covered by a country's universal healthcare plan.

## **Appendix B: National Conference of State Legislatures: Access to Contraception**

### **HR 2701: Youth Access to Sexual Health Services Act of 2019 (North Carolina)**

This bill authorizes the Department of Health and Human Services to award grants to support the access of marginalized youth to sexual health services such as sexual health education and contraception. Marginalized youth are disadvantaged individuals under the age of 26. Grants may be awarded to state or local health or education agencies, public schools, nonprofit organizations, hospitals, Indian tribes, and tribal organizations.

Grants may be used to (a) provide sexual health information to marginalized youth, (b) promote effective communication regarding sexual health among marginalized youth, (c) promote and support opportunities for school-age parents, and (d) train individuals who work with marginalized youth to promote sexual health and the development of safe and supportive environments.

Grants may not be used to provide access to health services that (a) are medically unsound; (b) withhold sexual health-promoting or lifesaving information; (c) promote gender stereotypes; or (d) are insensitive or unresponsive to the needs of young people, including youth with varying gender identities and sexual orientations, sexually active youth, pregnant or parenting youth, and survivors of sexual abuse or assault.

Unobligated funds for abstinence education are transferred and made available for these grants.

### **S930: Allowing Greater Access to Safe and Effective Contraception Act (Iowa)**

This bill permits health savings accounts, medical savings accounts, and employer reimbursements for medications to be used for over-the-counter drugs. The bill also removes the

limit on employee contributions to flexible spending accounts offered under specified health plans established pursuant to a pretax salary reduction agreement with an employer (i.e., cafeteria plans).

Further, the bill requires the Food and Drug Administration to give priority review, at no cost, to applications for modifications to already-approved contraceptive drugs that are intended for routine use and available over the counter. Such drugs, however, must require a prescription for individuals under the age of 18.

**HR 5138: Over-The-Counter Contraceptives Act of 2016 (UT/VA/WY/AZ/CO/IL)**

This bill requires the Food and Drug Administration (FDA) to prioritize review of supplemental drug applications (applications to modify the approved use of a drug) for contraceptive drugs intended for routine use that would be available to individuals aged 18 and older without a prescription. The FDA must waive user fees for such supplemental drug applications. Any drug that is eligible for this priority review must be a prescription drug for individuals under age 18.

This bill repeals provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 to allow health savings accounts and health flexible spending accounts (HFSAs) to be used to pay for medicine without a prescription and to remove the limit on salary reduction contributions to an HFSA under a cafeteria plan, effective as if the provisions had never been enacted.

**HR 3296/S1847: Affordability is Access Act 2019 (Massachusetts)**

This bill establishes several requirements relating to health-insurance coverage of, and access to, over-the-counter contraceptives.



Specifically, the bill requires the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury to specify that private health insurance plans must cover over-the-counter contraceptives that are approved by the Food and Drug Administration (FDA), even without a prescription. Under current law, private health insurance plans (with some exceptions) must cover FDA-approved prescription contraceptives without cost-sharing requirements.

The bill also prohibits retailers from interfering with an individual's access to oral contraceptives that are meant for routine, daily use and are FDA-approved for use without a prescription.

#### **HR 421: Allowing Greater Access to Safe and Effective Contraception Act (Utah)**

This bill requires the Food and Drug Administration (FDA) to prioritize review of supplemental drug applications (applications to modify the approved use of a drug) for contraceptive drugs intended for routine use that would be available to individuals aged 18 and older without a prescription. The FDA must waive user fees for such supplemental drug applications. Any drug that is eligible for this priority review must be a prescription drug for individuals under age 18.

This bill repeals provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 to allow health savings accounts and health flexible spending accounts (HFSAs) to be used to pay for medicine without a prescription and to remove the limit on salary reduction contributions to an HFSA under a cafeteria plan, effective as if the provisions had never been enacted.

## Appendix C: IRB Approval

### ABILENE CHRISTIAN UNIVERSITY

*Educating Students for Christian Service and Leadership Throughout the World*

Office of Research and Sponsored Programs  
320 Hardin Administration Building, ACU Box 29103, Abilene, Texas 79699-9103  
325-674-2885



December 8, 2020

Paula M. Todd  
Abilene Christian University

DeaPaula,

On behalf of the Institutional Review Board, I am pleased to inform you that your project titled "Decreasing Unintentional Pregnancies for Tennesseans",

(IRB# 20-205 ) is exempt from review under Federal Policy for the Protection of Human Subjects as:

- Non-research, and  
 Non-human research

Based on:

Activity does not involve a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)].

If at any time the details of this project change, please resubmit to the IRB so the committee can determine whether or not the exempt status is still applicable.

I wish you well with your work.

Sincerely,

*Megan Roth*

Megan Roth, Ph.D.  
Director of Research and Sponsored Programs